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OUR PATENT SYSTEM AND HEALTH CARE INFORMATION TECHNOLOGY: VALUABLE INCENTIVE OR IMPEDIMENT TO INNOVATION?

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INTRODUCTION

Patentable inventions have often been transformative, but the pace of such innovation has changed exponentially in the last thirty years. The patent law still seeks to reward ingenuity and nowhere should this maxim be truer than in the area of health information technology. But the pace and scope of changes in that arena have made rewarding that ingenuity with a patent increasingly difficult. The courts have struggled to apply patent laws to technology that is new and novel to a fault. This Article seeks to address how it is possible to continue to reward ingenuity in a field where progress will save not just money but lives.

PART I. HEALTH INFORMATION TECHNOLOGY

The U.S. health care system is in dire straits due to issues such as "increasing demand, spiraling costs, inconsistent and poor quality of care, and inefficient, poorly coordinated care systems."[1] In 2000, the World Health Organization "ranked the U.S. health care system 37th out of 191 and identified our poor use of information technology as among the primary reasons for this 'dismal' ranking."[2] More recently, the Commonwealth

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1. PAUL SHEKELLE ET AL., COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY, EVIDENCE REPORT/TECHNOLOGY ASSESSMENT, NO. 132, at 1 (2006), *available at* http://healthit.ahrq.gov/sites/default/files/docs/page/hitsys.pdf.

2. Sharona Hoffman & Andy Podgurski, *Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 HARVARD J.L. & TECH. 103, 104–

Fund ranked our overall health care system last compared to ten other first-world countries, particularly in terms of access, efficiency, and equity.[3] These rankings are even more troubling considering our health care system is the most expensive in the world.[4] In 2011, our health expenditures per capita were $8,508.[5] This year alone, our government is projected to spend somewhere between $3.1 and $3.8 trillion on health care.[6] Projections for 2015 are even larger.[7] Furthermore, the U.S. Census Bureau has estimated that by 2050 there will be approximately 88.5 million Americans over the age of sixty-five, half a million of which will be centenarians.[8] This means improved health care services will be crucial to effectively manage and treat our aging population. Needless to say, health care in the United States is in desperate need of reform.

Health information technology ("HIT") is increasingly viewed as critical to dramatically transforming the health care industry by improving the overall efficiency and quality of the health delivery system,[9] which in turn can help "save lives, cut costs, and expand access to care."[10] Specifically, it can be used "to harness real-time information from a variety of data sources to respond to the needs of patients and providers in a timely manner, improve quality, reduce costs, identify and track disease outbreaks, and manage large patient populations."[11] The importance of incentivizing HIT innovation is widely recognized and hard to overstate.

So what exactly *is* HIT? It can be generally defined as "the application of information processing involving both computer hardware

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105 (2008) (citing Editorial, *World's Best Medical Care?*, N.Y. TIMES, Aug. 12, 2007, at WK9).

3. The other ten countries were Australia, Canada, France, Germany, Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United Kingdom. KAREN DAVIS ET AL., THE COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: HOW THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 12 (2014), *available at* http://www.commonwealthfund.org/~/media/files/publications/fund-report/2014/jun/1755_davis_mirror_mirror_2014.pdf.

4. *Id*. at 7.

5. *Id*. at 11.

6. Dan Munro, *Annual U.S. Healthcare Spending Hits $3.8 Trillion*, FORBES (Feb. 2, 2014, 11:03 PM), http://www.forbes.com/sites/danmunro/2014/02/02/annual-u-s-healthcare-spending-hits-3-8-trillion/.

7. *Id*.

8. Richard Sisk, *Census: A Half Million Centenarians by 2050*, MOUTH OF THE POTOMAC (Apr. 25, 2011, 4:54 PM), http://www.nydailynews.com/blogs/dc/census-million-centenarians-2050-blog-entry-1.1660177.

9. Basit Chaudhry et al., *Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care*, 144 ANNALS OF INTERNAL MED. 742, 742 (2006), *available at* http://annals.org/article.aspx?articleid=723406.

10. Frank Pasquale, *Grand Bargains for Big Data: The Emerging Law of Health Information*, 72 MD. L. REV. 682, 683 (2013).

11. EHEALTH INITIATIVE & MCKESSON, THE STATE OF HEALTH ANALYTICS IN 2013: IMPROVING QUALITY & LOWERING COSTS 2 (2013), *available at* http://www.ehidc.org/resource-center/white-papers-and-briefs/view_document/24-white-paper-the-state-of-health-analytics-in-2013-data-and-analytics.

and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making."[12] "[It] is often considered a silent partner in healthcare—not seen by patients, but a critical part of the system."[13] In a similar vein, the U.S. National Library of Medicine defines health informatics as "the interdisciplinary study of the design, development, adoption, and application of IT-based innovations in healthcare services delivery, management and planning."[14] It is a collection of tools and mechanisms by which someone can use sophisticated algorithms to search, filter, and process relevant medical information. Simply put, health informatics is the science (or, the how and the why) behind health care IT.[15] The Office of the National Coordinator for Health Information Technology ("ONC") further explained that these technologies "enable the secure collection and exchange of vast amounts of health data about individuals."[16] This vast amount of data is generally referred to as "big data."[17] The technological ability to securely collect, store, exchange, analyze, and convert this into valuable, useable information in a tolerable time is what makes HIT innovations so critical to the future of our health care system.

In 2011, U.S. health care data[18] alone reached 150 exabytes.[19] To put this figure into perspective, one exabyte is equal to

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12. TOMMY G. THOMPSON & DAVID J. BRAILER, THE DECADE OF HEALTH INFORMATION TECHNOLOGY: DELIVERING CONSUMER-CENTRIC AND INFORMATION-RICH HEALTH CARE, FRAMEWORK FOR STRATEGIC ACTION 38 (2004), *available at* http://www.providersedge.com/ehdocs/ehr_articles/the_decade_of_hit-delivering_customer-centric_and_info-rich_hc.pdf.

13. Eric Venn-Watson, *The Evolution of Health IT*, HEALTHCARE IT NEWS (Sept. 16, 2014), http://www.healthcareitnews.com/blog/evolution-health-it.

14. *Health Informatics*, U.S. NAT'L LIBRARY OF MED., http://www.nlm.nih.gov/hsrinfo/informatics.html (last visited Feb. 8, 2015).

15. "For example, health IT professionals should be able to resolve infrastructure problems with a network connection, whereas trained public health informaticians should be able to support public health decisions by facilitating the availability of timely, relevant, and high-quality information." Thomas G. Savel & Seth Foldy, *The Role of Public Health Informatics in Enhancing Public Health Surveillance*, *in* CDC'S VISION FOR PUBLIC HEALTH SURVEILLANCE IN THE 21ST CENTURY, 61 MORBIDITY AND MORTALITY WEEKLY REPORT 20 (2012), *available at* http://www.cdc.gov/mmwr/pdf/other/su6103.pdf.

16. DEP'T OF HEALTH AND HUMAN SERVS., OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY: FEDERAL HEALTH INFORMATION TECHNOLOGY STRATEGIC PLAN 2011–2015 4 (2011), *available at* http://www.healthit.gov/sites/default/files/utility/final-federal-health-it-strategic-plan-0911.pdf.

17. *Big Data: What and Why It Matters*, SAS, http://www.sas.com/en_us/insights/big-data/what-is-big-data.html (last visited Mar. 30, 2015).

18. "HIT includes a variety of integrated data sources, including patient Electronic Medical Records [("EMRs")], Decision Support Systems, and Computerized Physician Order Entry for medications." RAND Corporation, *Health Information Technology: Can HIT Lower Costs and Improve Quality?*, RB-9136-HLTH 1, 1 (2005), *available at* http://www.rand.org/content/dam/rand/pubs/research_briefs/2005/RAND_RB9136.pdf.

1,000,000,000,000,000,000, or 10^{18} bytes.[20] "Five exabytes is equivalent in size to the information contained in half a million new libraries the size of the Library of Congress print collection."[21] According to the same source, "five exabytes is twenty-five times all the printed information in the world."[22] One hundred fifty exabytes is also fifteen times larger than the estimated total storage capacity of all of Google's data centers combined.[23] It is predicted that if the growth of information continues at this rate, health care data will soon reach zettabyte (10^{21} bytes) scale and even yottabytes (10^{24} bytes) not long after.[24] "Unfortunately, not enough of this deluge of [structured and unstructured] data sets has been systematically collected and stored, and therefore this valuable information has not been aggregated, analyzed, or made available in a format to be readily accessed to improve healthcare."[25]

Why is mining this mother lode of raw, untapped medical data such a big deal? Simply put, it matters because the meaningful utilization of this data "has the power to fundamentally change health care in this country."[26] Leveraging the knowledge gained from innovative HIT informatics "can dramatically improve safety, research, quality, and cost efficiency, all of which are critical factors necessary to facilitate health care reform."[27] HIT analytics "can be applied to better hospital operations, track outcomes for clinical and surgical procedures, including length of stay, readmission rates, infection rates, mortality, and comorbidity prevention," and "to benchmark effectiveness-to-cost models."[28] The continued adoption of HIT innovations enhances physicians' ability "to identify, monitor, and coordinate care for their patients, particularly those with chronic conditions."[29]

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19. INST. FOR HEALTH TECH. INFO., TRANSFORMING HEALTH CARE THROUGH BIG DATA 5 (2013), *available at* http://c4fd63cb482ce6861463-bc6183f1c18e748a49b87a25911a0555.r93.cf2.rackcdn.com/iHT2_BigData_2013.pdf.

20. PETER LYMAN & HAL R. VARIAN, HOW MUCH INFORMATION 3 (2003), *available at* http://groups.ischool.berkeley.edu/archive/how-much-info-2003/printable_report.pdf.

21. *Id*.

22. *Id*.

23. WHAT IF?, http://what-if.xkcd.com/63/ (last visited Jan. 8, 2015).

24. FED. BIG DATA COMM'N, TECH AM. FOUND., DEMYSTIFYING BIG DATA: A PRACTICAL GUIDE TO TRANSFORMING THE BUSINESS OF GOVERNMENT 9 (n.d.), *available at* http://www.techamerica.org/Docs/fileManager.cfm?f=techamerica-bigdatareport-final.pdf.

25. *Top 10 Innovations for 2012: #8 Harnessing Big Data to Improve Healthcare*, CLEVELAND CLINIC, http://summit.clevelandclinic.org/Top-10-Innovations/Top-10-for-2012/Top-10-Articles/8-Harnessing-Big-Data-to-Improve-Healthcare.aspx (last visited Jan. 8, 2015).

26. Alex Ruoff, *Claims Administration: HHS Aims to Leverage Health Data to Spur Innovation in Private, Public Sector*, 23 BNA'S MEDICARE REP. 1399, 1410 (2012) (quoting Bryan Sivak, Chief Technology Director at HHS).

27. CLEVELAND CLINIC, *supra* note 25.

28. *Id*.

29. DAVIS, *supra* note 3, at 8.

HIT also has a close relationship with the health industry's overall costs. As one scholar stated, "there can be little doubt that a good part of the hundreds of billions of dollars wasted in American health care annually is due to information failures."[30] Indeed, the McKinsey Global Institute "calculates that the U.S. health care system could save $300 billion annually if the industry unleashed the full economic potential of data and analytics, a significant portion of which could reduce national health expenditures" by almost eight percent.[31]

To better understand the magnitude of potential benefits derived from HIT innovation, it is helpful to examine the tangible impact it has already made. For example, innovations in healthcare informatics have led to breakthroughs in Parkinson's disease and cancer research. Intel and the Michael J. Fox Foundation for Parkinson's Research are collaborating on a research initiative that "utilizes a big data analytics platform which detects patterns collected from wearable technologies used to monitor symptoms" and "can create a new paradigm for measurement of Parkinson's disease."[32] This coupling of data science and wearable computing provides invaluable information for a disease that is notoriously difficult to monitor due to its variability.[33] With respect to cancer, one company uses "advanced imaging registration algorithms" to "align[] the unstructured imaging and treatment data" which creates "a clinical knowledge repository on every patient treated," and "deliver[s] analytics to assist providers with medical decisions."[34] Furthermore, population-based analytics can then be applied to this base "to help oncologists understand how they are treating their patients for outcomes research and reporting."[35]

Furthermore, there is evidence of the beneficial impact of HIT innovation on a local level. Vanderbilt Medical Center ("VUMC") has begun to "embed[] analytics in clinical workflow" and already "achieved demonstrable results."[36] A 2012 Sage Growth Partners Industry Report stated that:

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30. Frank Pasquale, *Grand Bargains for Big Data: The Emerging Law of Health Information*, 72 MD. L. REV. 682, 718 (2013).

31. DON MCDANIEL & DAN D'ORAZIO, THE CHANGING ROLE OF ANALYTICS FOR HEALTH CARE PROVIDERS, SAGE GROWTH PARTNERS INDUSTRY REPORT (2012) [hereinafter SAGE WHITE PAPER], *available at* http://sage-growth.com/wp-content/uploads/2014/12/CHANGING-ROLE-OF-ANALYTICS-FOR-HC-PROVIDERS-FEB-2012.pdf; *see also* RAND Corporation, *supra* note 21, at 1–2..

32. Gabriel Perna, *Parkinson's Research Initiative to Use Analytics, Wearables*, HEALTHCARE INFORMATICS (Aug. 15, 2014), http://www.healthcare-informatics.com/news-item/parkinsons-research-initiative-use-analytics-wearables.

33. *Id*.

34. Jennifer Dennard, *HIT Innovation is in the Eye of the Beholder*, MEDCITY NEWS (Oct. 25, 2013, 5:09 PM), http://medcitynews.com/2013/10/competition-heats-innovation-award/.

35. *Id*.

36. SAGE WHITE PAPER, *supra* note 31, at 4.

> [VUMC] has deployed analytics to gauge expected versus observed clinical outcomes. Their efforts to decrease Ventilated Acquired Pneumonia (VAP), with cases numbering upward of 300,000 cases per year in the United States, provide tangible proof of their success in engaging analytics to improve health status. Their clinical team established eight measures that help alleviate VAP []. They implemented evidence-based order sets and then created real-time dashboards for the points of care that inform the nursing staff on compliance with the eight measures. When they analyzed their data, they discovered that compliance on the measures was up significantly, but health status had not improved commensurately with the level of effort and improved compliance. Consequently, they conducted a subset analysis that showed that compliance with all eight of measures provided the tipping point to avoiding VAP. They began a new indicator for nurses that provided real-time data on full compliance with all eight measures. When implemented, they noted a radical drop in VAP. [Director of Information Technology Integration at VUMC,] Dr. [Ed] Shultz noted that 'people are now comparing us to best of breed, where we were just average in the past. It is really an analytics victory in the ability to see patterns that would have been invisible without the data warehouse to see that retrospective analysis and real-time reporting.'[37]

Vanderbilt is just one of a growing number of health care organizations that are seeing the advantages of HIT analytics. The Ohio State University's Wexner Medical Center uses data algorithms "to identify patients in need of intervention and personalize care for those individuals in order to reduce initial hospitalization as well as readmissions."[38] Similarly, the Wyoming Department of Health, by using a program called WYhealth, which mines Medicaid data and utilizes a population health platform, was able to reduce patient emergency room visits by twenty percent and improve its thirty-day hospital readmission rate in just one year.[39] The Louisiana State University Health Care Services Division and the Tobacco Control Initiative were even able to use a health informatics system to

37. *Id.*

38. Neil Versel, *Analytics Gives Patient Care, Safety a Lift*, HEALTH CARE IT NEWS, Aug. 4, 2014, at 18, *available at* http://www.pageturnpro.com/HIMSS-Media/59913-Healthcare-IT-News-August-2014/index.html#19.

39. Rajiv Leventhal, *Data Analytics Reduced Readmissions, ER Visits in Wyoming*, HEALTHCARE INFORMATICS (Aug. 13, 2014), http://www.healthcare-informatics.com/news-item/data-analytics-reduced-readmissions-er-visits-wyoming.

assess the effect of a federal cigarette tax increase on the readiness to quit smoking among low-income smokers in the state.[40] The University of Pittsburgh Medical Center ("UPMC") "has put $105 million toward a massive data analytics program, which is employed to analyze the success of a patient-centered medical home pilot. UPMC found that those with medical homes had substantially better health outcomes after six months in the program, and the medical home reduced health expenditures by $15 million in the first year."[41] Its School of Health Sciences is in the process of building an electrocardiogram database that researchers can analyze in order to further refine cardiopulmonary resuscitation interventions and thus save more lives.[42]

Recently, Mayo Clinic researchers founded Ambient Clinical Analytics, a venture that "aims to bring data assimilation, communication and analytics to the bedside."[43] One of the platform's tools "is a clinical EMR [electronic medical records] technology that combats information overload by using analytics to filter relevant patient data and support best-care practices for ICUs and ORs."[44] Other "scientifically-validated tools" include the patented Septic Shock Sniffer and patent-pending Ventilator-Induced Lung Injury Sniffer, which provide smart alerts to address various hospital dangers.[45]

In addition, according to the results of a two-year study done by Aetna Innovation Labs and a data analytics firm, big data analytics were able to predict the future risk of metabolic syndrome on both an individual and population level.[46] The individualized reports predicted not only which of the patients was at a high risk of having metabolic syndrome and developing it within the next year, but also which specific factors would be the cause of it.[47] This type of report allows a patient and their doctor to take personalized steps to mitigate this risk.[48] It is particularly useful technology since metabolic syndrome can lead to conditions such as chronic heart

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40. Tung-Sung Tseng et al., *Using a Health Informatics System to Assess Effect of a Federal Cigarette Tax Increase on Readiness to Quit Among Low-Income Smokers, Louisiana, 2009*, 11 PREVENTING CHRONIC DISEASE 1, 1 (2014), *available at* http://www.cdc.gov/pcd/issues/2014/pdf/13_0203.pdf.

41. Versel, *supra* note 38, at 18.

42. Gabriel Perna, *Pitt Researchers to Create ECG-Based Database for Real-Time CPR Decision Making*, HEALTHCARE INFORMATICS (June 25, 2014), http://www.healthcare-informatics.com/news-item/pitt-researchers-create-ecg-based-database-real-time-cpr-decision-making.

43. Mike Miliard, *Mayo Clinic Launches Bedside Analytics*, HEALTHCARE IT NEWS (March 20, 2014), http://www.healthcareitnews.com/news/mayo-clinic-launches-bedside-analytics.

44. *Id*.

45. *Id*.

46. Rajiv Leventhal, *How Aetna is Using Big Data to Give Patients Personalized Care*, HEALTHCARE INFORMATICS 2 (Aug. 7, 2014), http://www.healthcare-informatics.com/article/how-aetna-using-big-data-give-patients-personalized-care.

47. *Id*.

48. *Id*.

disease, stroke, and diabetes; three things which, combined, "account for nearly twenty percent of all healthcare costs in the U.S." and affects one-third of American adults.[49] "The analytical models used also helped identify individual variable impact on risk associated with adherence to prescribed medication," an issue that costs this country $300 billion annually.[50]

HIT informatics even helps combat healthcare fraud. Data analysis is being used by Medicare and Medicaid to help "identify[] improper claims before they are paid and [to] detect[] other patterns of fraud and abuse."[51] This is notable considering that the Federal Bureau of Investigation "estimates that fraudulent billings to public and private health care programs are 3–10 percent of total health spending, or $75–$250 billion."[52] Additionally, these anti-fraud programs help "prevent the harm to patients who are fraudulently exposed to radiation, invasive surgeries, and medications they do not need, or suffer the lasting consequences of receiving a fraudulent diagnosis."[53]

There can be little dispute as to the value, both actual and potential, of HIT informatics. Indeed, an exhaustive study found that ninety-two percent of recent articles on HIT "reached conclusions that were positive overall."[54] The Cleveland Clinic even identified "Harnessing Big Data to Improve Healthcare" as one of the top ten most important medical innovations of 2012.[55] Given its significance, it only seems logical to incentivize groundbreaking health care advances in dynamic big data technology.

PART II. BUSINESS METHOD PATENTS & THE § 101 KICKBACK

In view of the foregoing section, HIT informatics might logically be seen as a category of innovations that our patent system was created to promote. However, these technologies typically have several characteristics that arguably cloud their consideration for patent eligibility. HIT informatics are rarely tethered to a specific device, system, or network, but rather are intended for distributed operation across an array of

49. *Id*. at 1.

50. *Id*. at 1–2.

51. Lewis Morris, *Combating Fraud in Health Care: An Essential Component of Any Cost Containment Strategy*, 28 HEALTH AFFAIRS 1351, 1353 (2009), *available at* http://content.healthaffairs.org/content/28/5/1351.full.html.

52. *Id*. at 1351.

53. *Fighting Health Care Fraud and Abuse*, AM. HEALTH INS. PLANS (Jan. 4, 2015, 2:38 PM), http://www.ahip.org/Issues/Fighting-Health-Care-Fraud-and-Abuse.aspx.

54. Melinda B. Buntin et al., *The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results*, 30 HEALTH AFFAIRS 464, 464 (2011).

55. CLEVELAND CLINIC, *supra* note 25.

hardware.[56] HIT informatics, at least in the context used most frequently here, are not directly transformative. The relevant technologies more often constitute decision support or status indications for healthcare entities, rather than providing actual control over a device or system, for example in the form of tangible inputs.[57] It may further be persuasively argued that HIT informatics, even while implemented by definition in tangible hardware of some form, do not themselves define an improved version of the hardware, but rather provide an improved result upon execution.

This section will focus on the difficulties which have arisen in the patent law with respect to the aforementioned characteristics, and why they may be relevant to patent protection for future innovations in HIT.

A. Principles of Patent Subject Matter Eligibility

Article I, Section 8, Clause 8 of the United States Constitution empowers the U.S. Congress, in pertinent form, "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[58] This power conferred to Congress is otherwise open with respect to implementation, except that the Clause arguably embodies a mandate that any patent system must effectively "promote," rather than impede, innovation for the betterment of society.[59]

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56. *See, e.g.*, Rakesh Agrawal, et al., *Enabling the 21st Century Health Care Information Technology Revolution*, 50 COMMUNICATIONS OF THE ACM 36 (2007) (discussing an "agnostic" HIT solution "to establish a nationwide system of electronic health records that provides caregivers with all relevant information about every patient; encourage the sharing of medical knowledge through computer-assisted clinical decision support; facilitate computerized order entry among providers for tests, medicine, and procedures; and ensure secure, private, interoperable exchange of health information"); *see also Technical Infrastructure*, N.Y. STATE DEP'T OF HEALTH, https://www.health.ny.gov/technology/technical_infrastructure.htm (last updated Jan. 2009) ("Interoperability is essential to realizing the expected benefit from health IT and vastly improving the availability and use of health information to improve patient care. Perpetuating siloed information systems that do not interconnect will significantly impede the adoption and effective use of health IT tools, including electronic health records. Interoperability enables patient health information to be exchanged in real time among disparate clinicians, other authorized entities, and patients, while ensuring security, privacy, and other protections.").

57. *Id.*; *see also* N.Y. STATE DEP'T OF HEALTH, *supra* note 56 ("[A]spects of the technical infrastructure include electronic health records and personal health records, and clinical informatics services which refer to the tools required for the aggregation, analysis, decision support and reporting of data for various quality and public health purposes.").

58. U.S. CONST. art. I, § 8, cl. 8.

59. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (noting that productive efforts fostered by incentives in the patent laws "will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.").

In keeping with this mandate, Section 1 of the original Patent Act of 1793 defines patent eligible subject matter as including "any new and useful art, machine, manufacture[,] or composition of matter, or any new and useful improvement [thereof]."[60] The Supreme Court has long considered the language of Congress as being expansive in scope, noting in at least one instance that it "embodied [Patent Act author Thomas] Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.'"[61] An oft-cited excerpt from legislative history accompanying the 1952 Patent Act, the most recent iteration, further clarifies Congress' intent for patent-eligible subject matter to "include anything under the sun that is made by man."[62] The Supreme Court itself has "more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed."[63] Section 101 has therefore often been described as a "coarse eligibility filter" for inventions which otherwise can satisfy the remaining statutory criteria for patentability, namely those that are novel, useful, and non-obvious.[64]

However coarse the filter may be, it has consistently been considered to preclude patent eligibility for those discoveries that are mere "manifestations of . . . nature, free to all men and reserved exclusively to none."[65] The Supreme Court has "long held that § 101, which defines the subject matter eligible for patent protection, contains an implicit exception for '[l]aws of nature, natural phenomena, and abstract ideas.'"[66] It has "interpreted § 101 and its predecessors in light of this exception for more than 150 years."[67] Of particular concern is that monopolization of "the basic tools of scientific and technological work" should not be patentable, as it might otherwise "tend to impede innovation more than it would tend to promote it."[68] However, courts must be wary in applying these exclusionary principles in a way that would "eviscerate patent law," as "all

60. Act of February 21, 1793, ch. 11, § 1, 1 Stat. 318, 319 (1793) (current version at 35 U.S.C. § 101 (1952)).

61. Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) (quoting Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), *in* 5 WRITINGS OF THOMAS JEFFERSON 74, 75–76 (H.A. Washington ed., 1854)).

62. *Id.* at 309 (citing S. REP. NO. 82-1979, 5 (1952); H.R. REP. NO. 82-1979, 6 (1952)).

63. Bilski v. Kappos, 130 S.Ct. 3218, 3226 (2010) (quoting Diamond v. Diehr, 450 U.S. 175, 182 (1981)) (internal quotation marks omitted).

64. Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010).

65. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

66. Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347, 2350 (2014) (quoting Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013)).

67. *Alice*, 134 S. Ct. at 2354 (citing *Bilski*, 130 S.Ct. at 3218; O'Reilly v. Morse, 56 U.S. 62, 112–121 (1854); Le Roy v. Tatham, 55 U.S. 156, 175 (1853)).

68. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012) (quoting *Benson*, 409 U.S. at 67).

inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[69]

Turning more particularly to the issue of "business method patents," it should first be noted that such inventions under English law have been deemed patentable since at least 1778, fifteen years prior to the enacting of the original U.S. Patent Act.[70] Business method patents have been issued in the United States as well since at least the late 1700s.[71] The 1952 iteration of the Patent Act further replaces the word "art" with "process," "in order to clarify its meaning," but otherwise maintains the language from 1793.[72] There is no apparent qualification to the term, and indeed it has been noted that § 101 "extends patent eligibility to any process[,] not 'some' or even 'most,' but all processes that are not 'a law of nature, natural phenomena, or abstract idea.'"[73] Perhaps more importantly, the term "process" by itself does not presuppose any technological requirements, but rather has "been broadly defined by the courts as 'a series of acts.'"[74] Briefly stated, a comprehensive review of statutory and judicial authority yields a general acknowledgement as to the patentability of business methods.[75]

Some persistent doubt remains among inventors and academics alike as to the historical accuracy, and ongoing vitality, of this acknowledgement.[76] However, we note that any conclusions regarding the eligibility of "pure" business methods are likely beyond the scope of the present discussion, and no further clarity is proposed here.[77] Paradigmatic

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69. *Id.*

70. *See, e.g.*, D.F. Renn, *John Knox's Plan for Insuring Lives: A Patent of Invention in 1778*, 101 J. INST. ACTUARIES 285, 286 (1974) (describing the English grant of letters patent for a "[p]lan for assurances on lives of persons from 10 to 80 years of Age").

71. *See, e.g.*, U.S. Patent No. X241 (issued Mar. 19, 1799); U.S. Patent No. 2310X (issued Apr. 28, 1815).

72. 98 CONG. REC. A415 (1952) (statement of Rep. Bryson).

73. Jamie Hopkins & John A. Pearce II, *Workable Solutions to the Challenges of Patenting an Innovative Process*, 14 J. HIGH TECH. L. 316, 320 (2014) (citing Reply Brief of Petitioner-Appellant at 6, Bilski v. Kappos, 130 S. Ct. 3218 (2010) (No. 08-964) 2009 WL 3453657).

74. *Id*.

75. *Id.* (citing NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1319 (Fed. Cir. 2005)); *see also* Cochrane v. Deener, 94 U.S. 780, 787–88 (1876) ("That a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed . . . . A process . . . is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery. In the language of the patent law, it is an art.").

76. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218, 3245–46 (2010) (Stevens, J., concurring) (discussing in detail and citing to "an overarching theme, at least in dicta: Business methods are not patentable arts"); *see also* Bernard Chao, *Finding the Point of Novelty in Software Patents*, 28 BERKELEY TECH. L.J. 1217 (2013) (proposing a test "to rein in harmful business method software patents without affecting more deserving industrial patents.").

77. Note, *e.g.*, that even Justice Stevens, while rejecting patent-eligibility for "business methods," has shrunk back from conflating analysis of such inventions with respect to

inventions regarding HIT analytics may instead be considered as being in the field of decision support, or otherwise technically oriented. Reduction to practice of such inventions is procured through technical innovation, and more particularly by computer implementation, in stark contrast with the stereotypical business method patents of legal precedent.

In recent years, however, the issues regarding business method patents have become increasingly interrelated with those for computer implementations, or "software patents," and this nexus is a primary catalyst for the concerns of this Article. Software itself has long been a bone of contention with regards to patent eligibility.[78] Indeed, the U.S. Patent and Trademark Office ("PTO") itself, along with numerous foreign jurisdictions, has maintained that software is *per se* ineligible, absent the recitation of otherwise statutory subject matter such as a non-transitory computer-readable medium.[79] However, U.S. courts have never explicitly precluded software from patent eligibility, and indeed have demonstrated and periodically tweaked parameters by which software implementations may be deemed patentable.

Patent drafters have essentially taken their cues from the courts and, at least since 1995, frequently have fashioned "software" claims which are directed to a computing device or a "computer-readable medium" including code, instructions, program modules, or the like executable to perform a process.[80] As the continuing effectiveness of such "Beauregard claims" is in serious doubt, prudent claim drafters will adapt new techniques, based on a spectrum of precedent which includes those briefly described below.

B. Modern Precedent Regarding Software and Business Method Patents

Since the Supreme Court first addressed the patent-eligibility of computer software in 1972, the law has changed considerably, perhaps in keeping with the sweeping changes in how software affects daily life. Whereas this initial opinion of the Court, in *Gottschalk v. Benson*,[81] has

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"whether a piece of software" implemented by machine could be patented. *Bilski*, 130 S. Ct. at 3247–48 n.40 (2010) (Stevens, J., concurring).

78. *See, e.g.*, Mark A. Lemley, et al., *Life after Bilski*, 63 STAN L. REV. 1315, 1317 (2011) ("The patentability of software and business methods has a long and tortured history.").

79. *See, e.g.*, U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2106(I) R-11.2013 (9th ed. 2014) [hereinafter MPEP] ("Non-limiting examples of claims that are not directed to one of the statutory categories" as including: "i. transitory forms of signal transmission (for example, a propagating electrical or electromagnetic signal *per se*), *In re* Nuijten, 500 F.3d 1346, 1357 (Fed. Cir. 2007) . . . . vi. a computer program *per se*, *Gottschalk v. Benson*, 409 U.S. at 72, 175 USPQ at 676-77.").

80. *See In re* Beauregard, 53 F.3d 1583 (Fed. Cir. 1995) (ushering in a category of "computer-readable medium" claims colloquially referred to as "Beauregard claims").

81. Gottschalk v. Benson, 409 U.S. 63 (1972).

often been interpreted as holding that software was not patent eligible, it is clear that the Court in subsequent cases has withdrawn from any blanket prohibition against patenting software.[82] Equally apparent, however, is that inventions based solely on computer software implementation are not patent-eligible.[83] Rather, the Court's jurisprudence in this arena may aptly be summarized as the incremental deduction of circumstances by which computer software (or related processes) may, or may not, be patented. The Court has highlighted particular decisions as precedential "guideposts" for adjudicating subject matter eligibility of software patents,[84] and therefore it is with these decisions that we continue.

The *Benson* Court held that a method of programming a general-purpose computer to convert binary-coded decimal numerals to their equivalent pure binary numerals was not a "process" within the purview of the Patent Act, but rather an "algorithm" from which specific applications could be developed.[85] The patent did not claim a particular "new and useful" application, and if ruled to be eligible, would have preempted known and future unknown uses of the algorithm in any field, for any purpose, and for any machinery, or even no machinery at all.[86] Of particular relevance in recent cases, the *Benson* Court also ruled that computer implementation did not limit the invention, as the algorithm had no alternative practical application, and therefore "simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle."[87]

A few years later, the Court in *Parker v. Flook* similarly characterized the invention at issue as nothing more than "a formula for computing an updated alarm limit," such that the claims effectively amounted to a monopoly on the formula itself.[88] This case has subsequently been oft-cited for the "proposition that the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'"[89] However, the *Flook* Court notably backed away from any broad preclusive effect on software patents themselves, noting that "[n]either the dearth of precedent, nor this decision, should therefore be interpreted as reflecting a judgment that patent protection of certain novel and useful computer programs will not promote

82. *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347, 2357–59 (2014) (discussing cases in which the Court has analyzed patent eligibility for software).

83. *See id.*

84. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1298–1301 (2012).

85. *Benson*, 409 U.S. at 71–73).

86. *Id.* at 67–68.

87. *Alice*, 134 S.Ct. at 2357–58 (citing *Benson*, 409 U.S. at 64).

88. Parker v. Flook, 437 U.S. 584, 586 (1978).

89. *Bilski*, 130 S. Ct. at 3230 (quoting Diamond v. Diehr, 450 U.S. 175, 191–92 (1981)).

the progress of science and the useful arts, or that such protection is undesirable as a matter of policy."[90]

In *Diamond v. Diehr*, the Court shortly thereafter found a computer-implemented process to be eligible, but the computer and its programming were not relevant to the holding.[91] Rather, the fact that a claimed mathematical equation was "well-known" did not preclude patent eligibility where it used a "thermocouple" in a process designed to solve a technological problem in "conventional industry practice."[92] In other words, while the equation itself could not be patent-eligible, a specific inventive application which incorporates the equation was not barred under § 101.[93]

In view of this precedent, the newly-formed U.S. Court of Appeals for the Federal Circuit developed and implemented a test for patent eligibility wherein claims were analyzed to determine if an "algorithm" was recited, and if so, whether the algorithm was applied to physical elements or process steps.[94] Computer software-implemented patents were therefore patentable under the right conditions, but the number of such patents actually being issued during the 1980s and early 1990s was nonetheless relatively limited.[95]

One case from this time period of particular relevance, at least in the context of this Article, is *In re Meyer*, in which the U.S. Court of Customs and Patent Appeals (immediate predecessor of the Federal Circuit) addressed a patent application directed to a process for gathering neurological testing data, and using a formula to determine the functionality of certain neurological elements.[96] Although the claimed method was computer-implemented, the Court rejected the notion that mere citation to a computer could make the claim eligible where the steps were otherwise substantially directed to a "mathematical algorithm," *i.e.*, the "thinking processes of a neurologist."[97]

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90. *Flook*, 437 U.S. at 595.

91. *Diehr*, 450 U.S. at 175 (1981); *see also Alice*, 134 S. Ct. at 2358 ("[T]he claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.").

92. *Diehr*, 450 U.S. at 178.

93. *Id.* at 187; *see also* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1292 (2012) ("In *Diehr*, the overall process was patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole.").

94. The so-called Freeman-Walter-Abele test survived in some form for over twenty years as a principal test for determining subject matter eligibility, particularly for algorithms. *See In re* Bilski, 545 F.3d 943, 959, n.17 (Fed. Cir. 2008).

95. *See* JAMES BESSEN, ET AL., THE SOFTWARE PATENT EXPERIMENT 5 (2004), *available at* http://www.researchoninnovation.org/softpat.pdf (noting the dramatic increase during this time period thusly: "about 1,000 software patents a year were granted in the early 1980s, increasing to about 5,000 a year in 1990. The rate doubled again by the by 1996. Nearly 25,000 software patents were granted in 2002.").

96. *In re* Meyer, 688 F.2d 789, 793 (C.C.P.A.1982).

97. *Id.* at 794–95.

A truly favorable environment for software patents finally commenced in 1994 with the Federal Circuit's ruling in *In re Alappat*, which eliminated the "physical elements" requirement for algorithms, at least in the context of apparatus claims.[98] Rather, a "general purpose" computer, once specially programmed with software to execute particular functions, becomes patent-eligible as a "specific machine to produce a useful, concrete, and tangible result."[99] Patent drafters could now artfully dodge many, if not most, § 101 considerations with respect to appropriately recited software claims.

The effects of *Alappat* were insignificant, however, compared to what followed when "[t]he so-called 'rise' or 'proliferation' of business method patents was kick-started in 1998"[100] by the Federal Circuit in *State Street* and *AT&T*.[101] In these cases the court extended the "useful, concrete, and tangible results" test from *Alappat* to further determine the patent-eligibility of business methods.[102] These Federal Circuit decisions substantially coincided with the "dot-com era," the speculative investment bubble that centered on Internet companies and lasted from the mid-1990s to approximately 2000.[103] It is thus no surprise that the number of applications filed for patents claiming methods related to online business practices "increased markedly."[104] The internal operations of the PTO were quickly overwhelmed with the intense pursuit of computer implemented business method inventions.[105]

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98. *See In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994).

99. *Id*.

100. Jamie Hopkins & John A. Pearce II, *Workable Solutions to the Challenges of Patenting an Innovative Process*, 14 J. HIGH TECH. L. 316, 318 (2014).

101. *See* State St. Bank & Trust Co. v. Signature Fin. Grp. Inc., 149 F.3d 1368 (Fed. Cir. 1998); AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352 (Fed. Cir. 1999).

102. *State St. Bank*, 149 F.3d at 1373 ("Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a [patent-eligible invention] . . . because it produces 'a useful, concrete and tangible result'. . . ."); *see also AT&T*, 172 F.3d at 1358 ("Because the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle, on its face the claimed process comfortably falls within the scope of § 101.").

103. *See* BRUCE D. SUNSTEIN, PATENT PREPARATION AND PROSECUTION UNDER UNCERTAIN PATENT ELIGIBILITY STANDARDS 2 (2007), *available at* http://www.sunsteinlaw.com/media/BDS_Patent_Preparation.pdf (noting the explosion in patent filings corresponding to the "dot-com boom," at least part of which was "certainly attributable not just to the *State Street Bank* decision but also to an economic environment in 2000 that rewarded entrepreneurial activity involving Internet-based businesses").

104. 1 R. CARL MOY, MOY'S WALKER ON PATENTS § 5:31 (4th ed. 2013) (citing Jenna Greene, *Staking a Claim: How State Street Has Spurred a Rush on the PTO*, LEGAL TIMES, Apr. 10, 2000, at 14).

105. *See* Chung K. Pak, *Patenting E-Commerce Inventions: Perspective From an Administrative Patent Judge*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 447, 449 (2003) ("The number of new applications of these types filed in Class 705 (designated as business and management data processing class) increased from 1370 in Fiscal Year 1998 to 2600 in Fiscal Year 1999 and to 7800 in Fiscal Year 2000. The number of patents issued from these

Even after the dot-com bubble implosion of 2000–2001 software patents and computer implemented business method patents continued to issue at a breakneck pace.[106] However, a decade later in *In re Bilski* the Federal Circuit "took a step away from its broad application of the common law exceptions" and developed the "machine-or-transformation" test as "the sole test to determine subject matter eligibility, abandoning all prior tests for patentable subject matter."[107] When the Supreme Court issued its ruling in *Bikski v. Kappos* in 2010, most notably rejecting the "machine or transformation" test as a universal standard for patent subject matter eligibility, the Court nonetheless found it to be a "useful and important clue, an investigative tool."[108] Some concerns in the patent bar were alleviated when the Supreme Court refrained from any "categorical rule denying patent protection" for computer programs, and indeed seemed to imply that the "machine or transformation" test was particularly ill-suited for "technologies from the Information Age."[109] This did not save the claims at issue, however, which were unanimously rendered ineligible by the Court as being directed to the mere "abstract idea" of hedging risk, limited only by field of use and mere "token postsolution components" or activities.[110] Alleged infringers reacted accordingly, and "[f]ollowing *Bilski*, the number of cases challenging business-related patents at the Federal Circuit predictably increased."[111]

C. The "Death of Hundreds of Thousands of Patents"?

In 2012, the Supreme Court revisited the issue of patent eligibility in the case of *Mayo Collaborative Services v. Prometheus Laboratories*, which related to patents for a diagnostic and treatment method for autoimmune diseases.[112] The *Mayo* Court introduced a two-part analytical framework for distinguishing patents that claim judicial exceptions from those that claim eligible subject matter in the form of particular applications

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types of applications increased from a total of 447 prior to 1986 to a total of 2,850 as of the end of Fiscal Year 1999.") (internal citations omitted).

106. *See* SUNSTEIN, *supra* note 103, at 2 ("Although the dot-com boom peaked in the year 2000, patent filings in Class 705 peaked a year later at 9,288. This one-year latency may reflect a delayed impact of the economic retreat. Following the dramatic drop in stock prices, particularly of technology-based start-ups following the dot-com boom in years after 2000, filings in Class 705 declined in 2002, but since than have climbed back rather steadily, so that in 2006 the number of filings— 8,959—has nearly returned to 1999 levels.").

107. Maayan Perel, *Reviving the Gatekeeping Function: Optimizing the Exclusion Potential of Subject Matter Eligibility*, 23 ALB. L.J. SCI. & TECH. 237, 255 (2013).

108. Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010).

109. *See id.* at 3227–28.

110. *Id.* at 3231.

111. RAYMOND T. NIMMER, LAW OF COMPUTER TECHNOLOGY § 2:17 (2014).

112. Mayo Collaborative Servs. v. Prometheus Labs., Inc.,132 S. Ct. 1289, 1290–91 (2012).

of those exceptions.[113] First, a determination must be made as to whether the claims at issue are directed to one of the judicially-defined exceptions to patent-eligibility.[114] If so, the elements of the claims are considered both individually and "as an ordered combination" to determine whether additional elements present an "inventive concept," or something "significantly more" than just the exception itself.[115]

Commentators initially dismissed the *Mayo* test as being inapplicable outside of the context of "natural law" exceptions, and indeed the U.S. Patent and Trademark Office responded directly to the ruling with new guidelines or instructions to that effect.[116] However, in June of 2014 the Supreme Court unequivocally ruled in *Alice Corporation v. CLS Bank* that the *Mayo* test was to be applied across the spectrum of patents, including those claiming an "abstract idea" exception as well as those claiming "laws of nature."[117] The *Alice* Court further cited the *Mayo* test in rejecting arguments that generic computer recitations could transform an "abstract idea" into a patent-eligible invention.[118] Accordingly, what is hereinafter referred to as the *Alice* test is to be prospectively relied upon in determining subject matter eligibility for any computer-implemented invention, whether an apparatus, method, or otherwise. Computer system and Beauregard-styled "computer readable medium" claims, without more than the mere presence of generic and conventional hardware components, are indeed given no better treatment with respect to § 101 than representative method claims.[119]

Initial reaction to the *Alice* ruling was immediate and polarized, as proponents of software patents widely considered the Court to have, at least for the time being, "slammed the door shut for many, if not most, software patents."[120] Within weeks of *Alice*, district courts and the U.S. Patent Trademark Appeals Board had rejected a substantial number of computer-

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113. *Id.* at 1294.

114. *Id.* at 1296–97.

115. *Id.* at 1298, 1294.

116. *See* United States Patent and Trademark Office, *2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature*, July 3, 2012, *available at* http://www.uspto.gov/sites/default/files/patents/law/exam/2012_interim_guidance.pdf (providing guidance in view of *Mayo* for claims which "involve laws of nature/natural correlations," but further expressly noting that "[p]rocess claims that are directed to abstract ideas, such as the claims in *Bilski*, should continue to be examined using" prior guidance dating from 2010).

117. *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347, 2357 (2014) ("Because the claims at issue are directed to the abstract idea of intermediated settlement, we turn to the second step in *Mayo*'s framework.").

118. *Id.* at 2358.

119. *Id.* at 2360.

120. Gene Quinn, *The History of Software Patents in the United States*, IPWatchdog (Nov. 30, 2014, 10:30AM), http://www.ipwatchdog.com/2014/11/30/the-history-of-software-patents-in-the-united-states/id=52256/.

implemented patents with reference to the Supreme Court's guidance.[121] In some cases, the United States Patent and Trademark Office even issued rejections to patent applications that had already gone through examination and were considered allowable.[122] One of the dissenting opinions from the Federal Circuit's earlier ruling had gone so far as to predict that the majority's decision would ultimately result in "the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents."[123]

Worth noting, however, is that nowhere in the *Alice* decision did the Supreme Court even use the word "software," and the Court more explicitly stated, albeit in dicta, "that many computer-implemented claims are formally addressed to patent-eligible subject matter."[124] Further, only a concurring minority of Justices opined that business method patents should be categorically ineligible.[125]

PART III. DRAFTING PATENT CLAIMS FOR INVENTIONS IN HIT ANALYTICS

Our opinion is that prospective inventions should not, and will not, be dismissed as patent-ineligible solely because they are implemented using software. Further, even business methods will very likely be allowable in the appropriate contexts. We recommend that inventors pursue patent protection of their inventions with tempered expectations however, as conventionally broad recitations will likely be rejected with impunity, by both of the courts and the U.S. Patent and Trademark Office.

In the remainder of this Article, we focus on avenues by which patent protection may be obtained for HIT analytics, even in the present environment.

We begin by encouraging inventors to consider their inventions, not in terms of what they provide, but rather how they provide it. In the HIT space, it is increasingly likely that virtually any patent claim will include, or otherwise can be distilled to, an "abstract idea" in view of current law. This

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121. *See* Dennis Crouch, *New Section 101 Decisions: Patents Invalid*, PATENTLYO, http://patentlyo.com/patent/2014/09/section-decisions-invalid.html (last visited Jan. 21, 2015).

122. Peggy Focarino, *Update on USPTO's Implementation of* 'Alice v. CLS Bank', USPTO (Aug. 4, 2014), http://www.uspto.gov/blog /director/entry/update_on_uspto_s_ implementation (noting that previously issued "notices of allowance" had been withdrawn "due to the presence of at least one claim having an abstract idea and no more than a generic computer to perform generic computer functions").

123. CLS Bank Int'l. v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1313 (Fed. Cir. 2013) (*en banc*) (Moore, J., dissenting in part), *aff'd*, 134 S. Ct. 2347 (2014).

124. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2359 (2014).

125. *Id.* at 2361 (Sotomayor, J., concurring in the judgment).

will be apparent from a review of the most recent guidance from the USPTO. We argue however that applicants for patent protection may be well advised to embrace sweeping characterizations of their claimed inventions, or at least accept them, and subsequently demonstrate that the claim as a whole goes substantially beyond the abstract idea.

We next look to case law for guidance, noting that many of the objections to software-implemented HIT patents could be traversed simply by reciting claims to inventions with clear and unambiguous boundaries.[126]

We further propose that patent applicants consider squarely implementing available mechanisms for functional claiming, cautiously but unequivocally drafting at least some claims which are likely to be exceedingly narrow but also patent-eligible.

A. Satisfying the *Alice* Test – Or: How I Learned to Stop Worrying and Love the Abstract Idea

The first step in the *Alice* test for patent eligibility is inherently plagued with contradictions. It is universally accepted that we must begin by determining whether a claim is directed to a judicial exception, such as an abstract idea.[127] However, courts at every level expressly refuse to define exactly what an "abstract idea" entails.[128] We find that a claim is "directed to" a judicial exception when an abstract idea "is recited (i.e., set forth or described) in the claim."[129] Yet, it is acknowledged that "at some level all inventions embody, use, reflect, rest upon, or apply a law of nature, natural phenomenon, or abstract idea,"[130] at least strongly implying that an abstract idea *must* be identified as a preliminary step in *any* patent-eligibility inquiry.[131] Therefore, at least as a preliminary matter, it may be

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126. *See, e.g.*, Peter S. Menell, *A Method for Reforming the Patent System*, 13 MICH. TELECOMM. & TECH. L. REV. 487, 505–06 (2007) ("The boundaries of software and business method patents are inherently ambiguous.").

127. *See, e.g.*, U.S. PATENT AND TRADEMARK OFFICE, DEP'T OF COMMERCE, 2014 INTERIM GUIDANCE ON PATENT SUBJECT MATTER ELIGIBILITY 10 (2014) [hereinafter USPTO INTERIM GUIDANCE], *available at* http://www.ipwatchdog.com/materials/interim-101-guidance-12-2014.PDF.

128. *See, e.g.*, *Alice*, 134 S. Ct. at 2356–57 (refusing to "delimit the precise contours of the 'abstract ideas' category"). Indeed, some have analogized this task as being "evocative of Justice Stewart's most famous phrase." McRO, Inc. v. Atlus U.S.A., No. SACV 13-1870-GW(FFMx), 2014 WL 4772196, at *5 (C.D. Cal., Sept. 22, 2014) (citing Jacobellis v. State of Ohio, 378 U.S. 184, 197 (1964) (Stewart, J. concurring) ("I shall not today attempt further to define the kinds of material I understand to be embraced within that shorthand description; and perhaps I could never succeed in intelligibly doing so. But I know it when I see it . . . .")).

129. USPTO INTERIM GUIDANCE, *supra* note 127, at 11.

130. *Id*.

131. *See* Accenture Global Servs., GmbH v. Guidewire Software, 728 F.3d 1336, 1341 (Fed. Cir. 2013) (rehearing en banc denied Dec. 12, 2013) (noting with respect to the 35 U.S.C. § 101 inquiry that the court "must first identify and define whatever fundamental concept appears wrapped up in the claim") (internal citations omitted).

prudent for the inventor to recognize that an abstract idea is present at some level of the invention being claimed.

With respect to HIT inventions, this premise rings particularly true. Abstract ideas have been identified in USPTO guidance and "by the courts by way of example, including fundamental economic practices, certain methods of organizing human activities, an idea 'of itself,' and mathematical relationships/formulas."[132] As previously noted, the HIT inventions as contemplated in this Article are typically algorithmic in nature, analytical, predictive or otherwise provided for decision support, and often divorced from any specific device. At a certain level, many of these inventions may arguably be characterized as including or embodying fundamental economic practices (e.g., cost-benefit analyses, resource allocation), ideas (e.g., intended results), or mathematical relationships (e.g., comparisons, statistical or other naturally occurring correlations). Some HIT innovations may even read directly upon specific examples identified by precedent, for example, those which involve: "comparing new and stored information and using rules to identify options;"[133] "using categories to organize, store and transmit information;"[134] "organizing information through mathematical correlations;"[135] or "a formula for updating alarm limits."[136]

Part of the difficulty in devising a cogent theory for addressing patent eligibility is that, absent further guidance, different scholars, examiners and judges will have different perspectives on whether an abstract idea is present. For example, some precedent indicates that an abstract idea will not be identified unless it is expressly recited in the claim language itself.[137] Others have withdrawn entirely from the task of identifying an abstract idea outside the scope of controlling precedent.[138] However, most of the indications seemingly point to abstract ideas as derived from an overall understanding of the invention, a general purpose, an intended result, or other relevant generality.

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132. USPTO INTERIM GUIDANCE, *supra* note 127, at 13 (citing *Alice*, 134 S. Ct. at 2355–56).

133. *Id*. at 14 (citing SmartGene, Inc. v. Advanced Biological Labs., SA, 555 F.App'x 950 (Fed. Cir. 2014)).

134. *Id*. (citing Cyberfone Sys. v. CNN Interactive Grp., 558 F.App'x 988 (Fed. Cir. 2014).

135. *Id*. (citing Digitech Image Tech., LLC v. Electronics for Imaging, Inc., 758 F.3d 1344 (Fed. Cir. 2014)).

136. *Id*., (citing Parker v. Flook, 437 U.S. 584 (1978)).

137. *See, e.g.*, PNC Bank v. Secure Axcess, LLC, CBM2012-00100 (PTAB Sept. 9, 2014) (rejecting eligibility challenge because the "Petitioner d[id] not tie adequately the claim language to the purported abstract concept," nor was the purported concept squarely within established precedential boundaries for "abstract ideas").

138. *See, e.g.*, DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1257 (Fed. Cir. 2014) (noting with respect to a patent claim at issue that "identifying the precise nature of the abstract idea is not as straightforward as in *Alice* or some of our other recent abstract idea cases.").

Accordingly, we argue that for many patent applicants in this space, it makes sense to embrace a broad characterization of the "abstract idea" at the heart of an invention. Rather than outright denial that the claim is directed to such an exception, the exception may be more effectively distinguished in view of the particular manner in which the invention is claimed. Otherwise stated, an invention that is directed to a specific application of the exception does not preempt all applications of the exception and may therefore be considered patent-eligible, a tactic which is paradoxically easier in practice when the identified "abstract idea" is sweeping in breadth.

The skeptical practitioner might reasonably argue that, for many USPTO and judicial proceedings, a preliminary finding that an abstract idea is present is effectively tantamount to ineligibility. We do not dispute that attention to the second prong of the *Alice* test has often been cursory at best. However, this prong is nonetheless required by law, and we contend that HIT patent applicants should consider arguing that something "significantly more" than an abstract idea is recited, rather than trying to disentangle the Gordian Knot of "abstract idea" analysis.

Some comfort may be taken in that the two-prong test from the *Alice* and *Mayo* opinions is at least facially more favorable for HIT patents than the previous "machine-or-transformation" (MOT) test. Citing generously from Supreme Court precedent, the Federal Circuit in *In re Bilski* had fashioned the MOT test to serve as "the sole test governing § 101 analyses," wherein a process is only patent-eligible if: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."[139] The Supreme Court subsequently dialed back on the "sole test" requirement, but held that the MOT test was nonetheless "a useful and important clue, an investigative tool, for determining whether some claimed inventions are patent eligible processes."[140] Under strict application of the MOT test, nearly all HIT inventions, as defined for the purposes of this Article, would typically be denied patent protection. The contemplated HIT innovations are typically untethered with respect to any particular device or non-generic computing system, nor are they 'transformative' so as to comply with legal precedent.[141]

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139. *In re* Bilski, 545 F.3d 943, 954–56 (Fed. Cir. 2008) (citing Gottschalk v. Benson, 409 U.S. 63, 70 (1972) ("Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines."); *Flook*, 437 U.S. at 589 n.9 (noting that the Court has "only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing.")).

140. Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010).

141. *See, e.g.*, Cybersource Corp. v. Retail Decisions, Inc., 654.F.3d 1366, 1375 (Fed. Cir. 2011) ("The mere manipulation or reorganization of data, however, does not satisfy the transformation prong" of the MOT test).

B. Satisfying the *Alice* Test – Claiming Inventions with Particularity

We argue that innovations in HIT are, however, clearly patent-eligible in view of the *Alice* test if they are recited with an adequate degree of particularity. Even assuming, *arguendo*, that an "abstract idea" may be at the heart of nearly every claimed invention,[142] such claims may be eligible if they "also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon "the abstract idea itself."[143] Succinctly put, inventions must be recited at a lower level of abstraction. As is so often the case, "the devil is in the details," and patent drafters may consider initially identifying any "abstract idea" or "law of nature" that underlies the invention at issue. Rather than running away from the exception, it can be embraced and expressly distinguished through detail of implementation.

An example of inventions which are claimed with varying degrees of abstraction may be instructive. A claim drawn generically to *any* method of predicting the presence of a condition {x} in a patient would likely be ineligible. Regardless of the type of condition, or whether the process was computer-implemented, this claim would likely be considered to preempt all uses of an abstract idea. For a particular type of condition, simply adding steps, features or correlations which are inherent with respect to that condition would also fail to make the method eligible for patenting- even if there were no previously known processes for predicting such a condition. In other words, a new result of a generic process is not patent-eligible, but rather the process itself must include steps describing a particular way in which the result is achieved. The steps may individually be known to experts in a given field, as long as the combination of steps amounts to *one* among many possible methods for predicting the presence of that condition.

In *Mayo*, the Supreme Court looked to precedent to reinforce its conclusions as to what constitutes a claim to something 'significantly more' than the underlying exception.[144] We can derive important clues from the same inquiries. In *Flook*, the Court described the invention at issue as being ineligible for patenting, not merely because of the presence of an unpatentable formula, but also because the patent application did not "purport to explain how to select the appropriate margin of safety, the weighting factor, or any of the other variables," nor "any disclosure relating to the chemical processes at work, the monitoring of process variables, or

142. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012) (recognizing that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas").

143. *Id*. at 1294.

144. *Id*. at 1298–1300.

the means of setting off an alarm or adjusting an alarm system."[145] The *Mayo* Court contrasted these findings with the case in *Diehr*, wherein "additional steps of the process integrated the equation into the process as a whole."[146]

At a minimum, we must endeavor to identify and claim additional steps that integrate the "abstract idea" into a specific application. Otherwise stated, an invention is more likely to be patent-eligible if it is characterized as a specific solution to a specific problem associated with the abstract idea. Generally reciting implementation of the abstract idea on a generic computer, using generic computer components, does not amount to "significantly more" than the abstract idea itself.[147] Inventors should make sure, even where the intended result may be novel, that claimed steps do not themselves merely "consist of well-understood, routine, conventional activity already engaged in by the scientific community."[148] And those steps, when viewed as a whole, should add something "significant beyond the sum of their parts taken separately."[149]

Claim drafters may further consider the express recitation of underlying algorithms with respect to one or more claimed steps, either in the body of the claims themselves or as referenced from the specification. A hierarchy of flowcharts, for example, and perhaps more than one algorithm for certain steps in a primary (i.e., broadest) flowchart will typically preserve the greatest scope of protection. Referring again to the aforementioned exemplary invention, where the process of predicting the presence of a condition {x} may include a step of comparing a measured value {y} with a value {z}, a sub-process for how this particular step is performed may in some cases be sufficient to render the claim as a whole eligible.

From a practical perspective, it is self-evident that a hierarchy of claim scope is desirable, and detailed disclosure allows for maximum flexibility, not only in obtaining patent protection now, but also in sustaining the validity of a patent over time. The likely tolerance of future generations for broad patent protection is impossible to foresee, and we would recommend that applicants practice diligence in the initial disclosure. For example, it may be stated of patent law generally that it "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"[150] The Supreme Court has accordingly framed the "underlying functional concern [as] a *relative* one: how much future innovation is foreclosed relative to the contribution of the

145. Parker v. Flook, 437 U.S. 584, 586 (1978).
146. *Mayo*, 132 S.Ct. at 1298–99.
147. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2360 (2014).
148. *Mayo*, 132 S. Ct. at 1298.
149. *Id.*
150. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989).

inventor."[151] By expanding the scope of the contribution, i.e., the written description, at the outset, we are better able to respond to public reconsideration of the "social cost" of patents with respect to "legitimate competition and innovation."[152]

C. Taking Advantage of Statutory Allowances for Functional Claiming

One added benefit of such detailed disclosure, although the mere mention may likely be decried by many within the patent bar, is that it enables the drafting of one or more "means-plus-function" ("MPF") claims for certain software inventions. Although instances of such claiming have progressively decreased over the years, we argue that these claims may offer not only a stronger likelihood of surmounting the threshold of § 101 eligibility as opposed to alternative method step claiming, but may even provide broader scope in some cases.

The statutory definition of MPF claim elements is governed by 35 U.S.C. § 112(f).[153] Section 112(f) was originally instituted by Congress to expressly allow for broad functional language in combination claims.[154] The Federal Circuit has held that the "'broadest reasonable interpretation' that an examiner may give means-plus-function language is that statutorily mandated in paragraph six. Accordingly, the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination."[155] The Patent Office therefore must interpret MPF claim elements as "the structure, material or act described in the specification as performing the entire claimed function and equivalents to the disclosed structure, material or act," such that these elements "will, in some cases, be afforded a more narrow interpretation

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151. *Mayo*, 132 S. Ct. at 1303.

152. Bilski v. Kappos, 130 S. Ct. 3218, 3255 (2010) (Stevens, J., concurring) (citing Dreyfuss, *Are Business Methods Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 276 (2000)).

153. 35 U.S.C. § 112(f) (2012); see 35 U.S.C. § 112 para. 6 (1952) for inventions effectively dated prior to the America Invents Act.

154. See P. J. FEDERICO, COMMENTARY ON THE NEW PATENT ACT (1954), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 161 (1993), which discusses the changes to section 112: "The last paragraph of section 112 relating to so-called functional claims is new. It provides that an element of a claim for a combination (and a combination may be not only a combination of mechanical elements, but also a combination of substances in a composition claim, or steps in a process claim) may be expressed as a means or step for performing a specified function, without the recital of structure, materials or acts in support thereof. It is unquestionable that some measure of greater liberality in the use of functional expressions in combination claims is authorized than had been permitted by some court decisions, and that decisions such as that in Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1 (1946), are modified or rendered obsolete, but the exact limits of the enlargement remain to be determined."

155. *In re* Donaldson Co., 16 F.3d 1189, 1194 (Fed. Cir. 1994) (*en banc*).

than a limitation that is not crafted in [MPF] format."[156] This promise of narrow interpretation has caused patentees to shun the usage MPF claims, but this lack of breadth may indeed be the salvation for claims which could otherwise be considered ineligible.

As previously noted, when the disclosed structure or material is a computer programmed to carry out an algorithm, 'the disclosed structure is not the general purpose computer, but rather that special purpose computer programmed to perform the disclosed algorithm.'"[157] Therefore, for MPF claim elements implemented by general purpose computers or processors, the corresponding structure must include the algorithm disclosed in the specification for performing the claimed function.[158] Algorithms in this context are not required to include code, but rather may be expressed "in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure" to a person having ordinary skill in the art.[159]

With respect to the patent eligibility inquiry, we suggest here that MPF claim elements will generally fall within the scope of patent-eligible subject matter. By definition, disclosed algorithms may not be disregarded when considering patent-eligibility for MPF claim elements.[160] At the very least, such claims would therefore be far more likely to pass muster than conventional method claims, all things otherwise being equal. There is however no controlling Supreme Court precedent with respect to patent eligibility in the context of MPF claims. In separate opinions from the *en banc* Federal Circuit *CLS Bank* decision, the presence of MPF claim elements was noted in some of the patentee's dependent claims,[161] but this issue was not addressed by the *Alice* Supreme Court.

The multi-tiered disclosure which we advocate here may be particularly useful, not only for those who affirmatively implement MPF claim elements, but as added protection in the event of future shifts in the patent law. Some prominent academics such as Professor Mark Lemley have advocated for courts to subject broad functional claims to the limitations of § 112(f), regardless of whether the term "means" has been

156. MPEP, *supra* note 79, § 2181.

157. *In re* Aoyama, 656 F.3d 1293, 1297 (Fed. Cir. 2011) (quoting WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1349 (Fed. Cir. 1999)); *see also In re* Alappat*,* 33 F.3d 1526, 1545 (Fed. Cir. 1994).

158. Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech., 521 F.3d 1328, 1333 (Fed. Cir. 2008); *see also* Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1340 (Fed. Cir. 2008); *WMS Gaming, Inc.*, 184 F.3d at 1349 .

159. *Finisar,* 523 F.3d at 1340; *see also* Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1366 (Fed. Cir. 2003); Typhoon Touch Inc. v. Dell Inc., 659 F.3d 1376, 1385 (Fed. Cir. 2011).

160. MPEP, *supra* note 79, § 2181(II)(B).

161. CLS Bank Int'l. v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1309, 1316 (Fed. Cir. 2013) (*en banc*) (Rader, J., dissenting) (Moore, J., dissenting), *aff'd* 134 S. Ct. 2347 (2014).

implemented.[162] Jurists may be taking notice, as in another opinion from the *en banc* Federal Circuit *CLS Bank* decision, Judge Linn cited such work and noted that "Congress could limit the scope of software patents by requiring functional claiming."[163] If strict application of § 112(f) limitations should ever be provided in the context of HIT inventions as contemplated herein, we would indeed find it most reassuring to have the flexibility of detailed disclosure in our patent specifications.

The prudent inventor may nonetheless be concerned about the narrow scope of protection provided by MPF claim elements, but we believe that may be addressed with careful disclosure of the corresponding structure and algorithm. Courts have consistently held that the algorithms supporting MPF limitations need only include the steps necessary to perform the claimed function.[164] At the highest tier of structural definition, even a two-step algorithm may be relied upon as corresponding to the claimed function.[165] Additional steps may of course be useful to clarify the invention, but can be provided in sub-processes, or in other words define additional tiers of detail for steps in the broader algorithm.

PART IV. CONCLUSION

Health care in the United States is suffering tremendously from rapidly escalating costs and inefficient care coupled with increasing demands. A vital part of the answer to this problem is innovations in healthcare information technology and the best way to foster such ingenuity is to ensure that inventions in this field are able to be patented. This Article proposes a two-fold solution. First, the USPTO and courts should not categorically deem prospective inventions in HIT analytics patent-ineligible simply because they are implemented using software. Second, patent applicants should embrace sweeping characterizations of their claimed inventions, recite claims with clear and unambiguous boundaries, and take advantage of the statutory allowances for functional claiming. By doing so, these patents could achieve their constitutionally-mandated goal—to promote progress.

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162. Mark A. Lemley, *Let's Go Back to Patenting the 'Solution,' Not the 'Problem'*, WIRED (Oct. 31, 2012, 6:30 AM), www.wired.com/opinion/2012/10/mark-lemley-functional-claiming/.

163. *CLS Bank*, 717 F.3d at 1333 (Linn, J., dissenting) (citing Mark A. Lemley, *Software Patents and the Return of Functional Claiming* 42 (Stanford Pub. Law, Working Paper No. 2117302, 2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2117302## (arguing that the problems with software patents can be remedied through strict enforcement of the 35 U.S.C. § 112(f) limitations on functional claiming)).

164. *See, e.g.*, Harris v. Ericsson Inc., 417 F.3d 1241, 1254 (Fed. Cir. 2005).

165. *Id*.