
John R. Thomas*

*Georgetown University
INTRODUCTION

Twenty years of our gathering for the Fordham International Intellectual Property Conference have seen the United States patent regime transition from a Golden to a Silver Age. During the inaugural 1992 conference, the United States stubbornly persisted
in idiosyncratic practices—notably a first-to-invent priority system\(^1\) and a seventeen-year patent term.\(^2\) Still a relatively new institution, the Court of Appeals for the Federal Circuit (“Federal Circuit”) had reached its maturity and accepted laudatory remarks from the Supreme Court.\(^3\) Observers trumpeted the high rate of filing at the U.S. Patent & Trademark Office (USPTO) as a point of pride, with emphasis placed upon the fact that more than half of all patents were issued to U.S. citizens.\(^4\) And the patent community remained a small, guild-like order of attorneys and agents.

Circumstances have changed considerably today. Two decades later, the United States to a large extent has fallen in line with the fundamental precepts of the international patent order.\(^5\) Courts of review have, at notable times, critically received the judgments of the Federal Circuit.\(^6\) Unimaginably high filing rates at the USPTO have become a source of alarm,\(^7\) with more than half of all patents now being issued to foreigners.\(^8\) The patent community has become far more fractured, with many observers holding diverse perspectives on the effectiveness and moral worth of the patent system.

Yet reason for tremendous optimism persists. The U.S. patent laws have nurtured an extraordinary array of technologies that

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\(^2\) See id. at 383.
\(^5\) Hasson, *supra* note 1, at 388 (noting that “the United States . . . has done its part to implement to goals of TRIPs effectively. . . . [and] has displayed its willingness to alter its domestic legislation in order to serve global and domestic goals.”).
would have been hard to perceive in 1992. New voices have, to a great extent, confirmed the inherent values of the U.S. patent system even as they challenge insiders to make it operate more justly and efficiently. The U.S. patent system, once archaic and hidebound, has again become an innovator. Reflecting upon the previous twenty years, and considering what the next two decades might hold, is the task of this essay.

I. THE END OF THE GOLDEN AGE

In the late 1970s, patent system reform was viewed as a way for the United States to advance out of the economic malaise in which the nation found itself. An antidote to a perceived “crisis of confidence” was the revitalization of the patent system through such mechanisms as the creation of the Federal Circuit\(^9\) and the enactment of the Hatch-Waxman\(^10\) and Bayh-Dole Acts.\(^11\) The resulting Golden Age of Patents—which might be even more colorfully referenced as the “Steroids Era”\(^12\)—led to an expansion of the scope of protection, the range of protectable subject matter, and the severity of damages imposed against adjudicated infringers.

As the past two decades progressed, observers increasingly came to believe that the U.S. patent system had gone too far. As Justice Breyer would note, “even when patents encourage innovation and disclosure, ‘too much patent protection can impede rather than promote the Progress of . . . useful Arts.’”\(^13\) Reports from the National Academies,\(^14\) Federal Trade Commission,\(^15\) and


\(^12\) See Allen K. Yu, *Within Subject Matter Eligibility—A Disease and a Cure*, 84 S. Cal. L. Rev. 387, 390 (2011) (referring to the patent system as “a property regime on steroids.”).


economists\textsuperscript{16} contributed to a chorus of concerns that ultimately echoed in the halls of Carlyle, Capitol Hill, and Madison Place, and led to significant changes in attitude and doctrines. The ability of the patent system to adapt to the changing needs of the innovative community over the past two decades provides potent testimony to the self-correcting capabilities of the common law. This gradual shift in the ethos of the U.S. patent system was punctuated by several defining moments that are discussed next.

\textbf{A. Legislative Reform}

In recent years some commentators have characterized Congress as an ineffective intervener in the patent system\textsuperscript{17} or have attempted to discourage such interaction in the future.\textsuperscript{18} In fact, not only have the past two decades witnessed continuous legislative involvement with respect to patents, this interaction is the most defining feature of this era. Whether acting in its oversight capacity with respect to the USPTO or introducing changes to the Patent Act, every Congress over the past two decades—from the 102nd Congress that convened in 1992 to the 112th Congress of 2012—has impacted the patent law.

Two legislative enactments were most significant. The first was the American Inventors Protection Act of 1999 (AIPA)\textsuperscript{19} that, as enhanced by the Intellectual Property and High Technology Technical Amendments Act of 2002,\textsuperscript{20} brought extraordinary and lasting changes to U.S. patent law. The AIPA introduced for the first time in the United States pre-grant publication of pending


\textsuperscript{17} \textit{See Craig Allen Nard, Legal Forms and the Common Law of Patents}, 90 B.U. L. \textsc{Rev.} 51, 52 (2010).


applications, 21 provisional rights, 22 and prior user rights. 23 The establishment of inter partes reexamination 24 was a harbinger of the opposition-like post-grant processes soon to come.

The AIPA also introduced the concept of a patent term guarantee. 25 Under this system, administrative delays in awarding a patent may result in an extension of its term. 26 One study estimates that an astounding eighty percent of patents receive term extension due to USPTO delays. 27 The legislation also introduced the “Request for Continued Examination” or RCE. 28 This mechanism allows applicants to obtain further review of their applications without the need to file a continuing application or continued prosecution application. 29 The RCE has proven relatively popular for applicants, in 2010 representing approximately thirty percent of all applications filed at the USPTO. 30 Yet the RCE has also proven burdensome for the USPTO—the agency has struggled to reduce inventor reliance upon these applications as it attempts to reduce its inventory of unexamined applications. 31

More recently, Congress enacted the Leahy-Smith America Invents Act (AIA). 32 The most significant reform to U.S. patent law since the nineteenth century, the AIA caused the United States to switch to a first-to-file priority regime, 33 shift to a full-fledged system of prior user rights, 34 and severely limit the best mode

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22 Id. § 154(d).
23 Id. § 273.
24 Id. §§ 311–319.
25 Id. § 154(b).
26 Id.
29 Id.
33 Id. sec. 3, § 100, 125 Stat. at 285.
34 Id. sec. 5, § 273, 125 Stat. at 297.
requirement. The AIA also introduced post-grant review proceedings that are akin to the opposition proceedings found elsewhere and also adopted the global norm of assignee filing. The unilateral adoption of global norms promises to reduce the burdens upon U.S. firms that seek patent rights abroad and gives the United States a stronger voice in the international intellectual property community.

Along with these two pieces of landmark legislation, Congress has frequently introduced additional amendments to the U.S. Patent Act over the past two decades. For example, 1996 legislation limited the availability of patent protection on methods of medical treatment. Later, section 271, the core infringement statute, has been amended to account for pharmaceutical patent litigation, the activities of state actors, and the requirements of the World Trade Organization’s (WTO) TRIPS Agreement. The CREATE Act of 2004 adjusted the law of obviousness in order to account for team research. Even more recently, the omnibus health care reform legislation, the Patient Protection and Affordable Care Act, changed the Patent Act with respect to biologics. All told, the current U.S. Patent Act is a far more complex and nuanced statute than it was two decades ago.

Finally, even where expressions of congressional interest did not lead to actual changes to the Patent Act, they often had an extraordinary influence upon judicial developments. Over the past decade, developments in U.S. patent law have followed an unusual two step-procedure beginning with, the airing of considerable industry concerns during a congressional hearing, followed by, the

35 Id. sec. 15, § 282, 125 Stat. at 328.
36 Id. sec. 6, §§ 321–329, 125 Stat. at 305.
37 Id. sec. 4, § 118, 125 Stat. at 296.
issuance of a judicial opinion some months later that endeavors to address those concerns. For example, legislative proposals to alter the concerning injunctive relief, venue, damages, willful patent infringement, and extraterritorial protection preceded the judicial opinions in eBay Inc. v. MercExchange, L.L.C.,\textsuperscript{44} In re TS Tech USA Corp.,\textsuperscript{45} Lucent Technologies, Inc. v. Gateway, Inc.,\textsuperscript{46} In re Seagate Technology,\textsuperscript{47} and Microsoft Corp. v. AT&T.\textsuperscript{48} Although correlation does not imply causation, it is hard to escape the conclusion that the Supreme Court and Federal Circuit were, at the very least, aware of congressional interest in reforming patent law doctrines before the courts themselves did so.

B. Markman

The honor of the most important judicial ruling of the past two decades must go to the Supreme Court’s 1996 decision, Markman v. Westview Instruments, Inc.\textsuperscript{49} There the Court confirmed the Federal Circuit’s earlier holding that claim construction constituted a question of law reserved to the courts.\textsuperscript{50} For contemporary readers of these two opinions, it is not hard to see that if the participating jurists fully realized the implications of this seemingly straightforward conclusion, they did not say so—for Markman forever altered the patent litigation process in the United States.\textsuperscript{51}

In the post-Markman era, claim construction hearings where the trial judge determines the meaning of claim language, have become a fixture of patent infringement lawsuits.\textsuperscript{52} Judicial construction of patent claims was intended to provide numerous benefits, including increasing the certainty of the scope of patent

\textsuperscript{44} 547 U.S. 388 (2006) (addressing the issue of awarding permanent injunctive relief to plaintiffs).
\textsuperscript{45} 551 F.3d 1315 (Fed. Cir. 2008) (addressing the issue of venue transfers).
\textsuperscript{46} 580 F.3d 1301 (Fed. Cir. 2009) (addressing the issue of damages).
\textsuperscript{47} 497 F.3d 1360 (Fed. Cir. 2007) (en banc) (addressing the issue of willful infringement).
\textsuperscript{48} 550 U.S. 437 (2007) (addressing the issue of the territorial extent of patent rights).
\textsuperscript{49} 517 U.S. 370 (1996).
\textsuperscript{50} Id. at 390–91.
\textsuperscript{52} See id.
rights, encouraging settlement, and providing the Federal Circuit—a court with elevated subject matter expertise—with the final word on the subject.\footnote{See Jonas McDavit, Putting the Cart Before the Horse: Obstacles to Using Issue Preclusion in a Post-Markman World, 34 AIPLA Q.J. 45, 50–54 (2006).} In order to accommodate these hearings, popular patent enforcement fora have taken the creative step of promulgating doctrine-specific procedural rules to augment the Federal Rules of Civil Procedure.\footnote{See Peter Menell et al., Patent Claim Construction: A Modern Synthesis and Structured Framework, 25 BERKELEY TECH. L.J. 711, 787–88 (2010).}

The jury remains out on \textit{Markman}. One particularly blunt jurist described the case as leading jurists to “sophistry and fiction”\footnote{Lucas Aerospace, Ltd. v. Unison Indus., L.P., 890 F. Supp. 329, 333 n.7 (D. Del. 1995).}, whereas, to practitioners, claim construction can be seen as a “series of seemingly contradictory axioms and promulgations.”\footnote{Andrew B. Dzeguze, Did \textit{Markman} and \textit{Philips} Answer the Right Questions? A Review of the Fractured State of Claim Construction Law and the Potential Use of Equity to Unify It, 15 TEX. INTELL. PROP. L.J. 457, 458 (2007).} As well, the Federal Circuit is widely regarded as reversing too many claim constructions.\footnote{See David L. Schwartz, Pre-Markman Reversal Rates, 43 LOY. L.A. L. REV. 1073, 1075 (2010).} Because essentially all other rulings in patent cases depend upon a sustainable interpretation of the claims—for example, whether the patented invention would have been obvious in view of the state of the art or whether the accused product infringes\footnote{See \textit{id.} at 1078.}—a Federal Circuit reversal often implies an entirely new trial on remand.\footnote{See, \textit{e.g.}, \textit{id.} at 1087.} Still, some level of uncertainty may be socially desirable in that highly certain claims may be difficult to draft and overly enforced.\footnote{See Harry Surden, Efficient Uncertainty in Patent Interpretation, 68 WASH. & LEE L. REV. 1737, 1758 (2011).} More practically, the \textit{Markman} process also encourages trial judges to become more deeply involved in patent trials.\footnote{See, \textit{e.g.}, Schwartz, \textit{supra} note 57, at 1083.}

The Federal Circuit has issued over one thousand opinions directed towards assessing the meaning of claims since \textit{Markman}
was handed down. Over the next two decades it seems unlikely that the efforts of litigants and the courts towards this subject will decrease. Yet whether the collective efforts of the patent community can diminish the uncertainty attending claim construction remains to be seen.

C. The Death of the Doctrine of Equivalents

A defining feature of the shift from the Golden Age to the Silver Age has been the precipitous decline in judicial application of the Doctrine of Equivalents. Perhaps the poster child of an inventor-friendly patent system, the Doctrine of Equivalents was applied robustly by the Federal Circuit in its infancy. By any measure, however, successful use of the Doctrine of Equivalents has dropped dramatically over the past two decades. As a result, it appears that more so than any time in the modern history of the U.S. patent system, patent plaintiffs who wish to win must rely almost exclusively upon a theory of textual infringement.

Different rationales have been advanced to explain this phenomenon. Some suggest that the Markman process caused judges who had rejected a literal infringement argument to be negatively disposed to equivalency as well. Others believe that the Federal Circuit was far less likely to hold a patent invalid in comparison to its predecessor courts; as a result, district courts came to rely more heavily upon infringement rulings when resolving disputes. The singular nature of the Federal Circuit may have also played a role. When patent infringement appeals were consolidated at the Federal Circuit, that court’s jurists began hearing an increased number of cases involving the Doctrine of

62 Menell et al., supra note 54, at 718.
64 See Schwartz, supra note 63, at 1203.
65 See id.
66 See, e.g., Allison & Lemley, supra note 5763, at 977–78.
67 Id.
Equivalents.\(^69\) As they gained more experience over a period of years, repeated assertions that particular claim wordings covered distinct accused infringements may have simply become less compelling.\(^70\) After all, just how many times can a claimed manual product cover an automatic device; a mechanical switch be akin to an electrical one; and a resilient component serve as an equivalent to a malleable part? Familiarity may have bred contempt.

To some, the fall of the Doctrine of Equivalents may be a salutatory development.\(^71\) After all, each inventor may obtain as many claims as he is willing to pay for. He may even seek to reissue a patent where his initial claim drafting efforts proved insufficient.\(^72\) But to others, a robust Doctrine of Equivalents allows “inventors to procure a small number of broadly constructed patent claims.”\(^73\) Perhaps one contributing factor to the enormous increase in the number of patent filings at the USPTO is the judicial desire for precision claim drafting rather than resort to theories of nontextual infringement.\(^74\) Given that the patent system is one in which many enter, but few leave with valuable intellectual property rights, whether society as a whole—and the USPTO in particular—is best served by a cabined Doctrine of Equivalents remains an open question.\(^75\)

\textit{D. State Street Bank}

The past twenty years have witnessed the spectacular rise and fall of U.S. patents on such post-industrial inventions as business methods and tax strategies. Surely the high-water mark of protectionism was the 1998 decision in \textit{State Street Bank & Trust}...
Co. v. Signature Financial Group, Inc. The Federal Circuit there rejected the “ill-conceived” business methods exception to patentable subject matter. The Court of Appeals further held that a data-processing system for implementing an investment structure consisted of patentable subject matter because it claimed not merely an abstract idea, but rather a programmed machine that produced “a useful, concrete and tangible result.”

Following the issuance of the lenient standard of State Street Bank, the entire range of human endeavor appeared to constitute patentable subject matter. Patents issued on such diverse inventions as tax avoidance schemes, sports methods, insurance techniques, and marketing strategies. Identifying a newly issued patent from an improbable discipline became a common parlor trick in the intellectual property industry. After all, who can forget patents on products and processes for character assessment, generating dinner party conversation, promoting understanding among couples, exercising a cat, or swinging on a swing?

The controversial legal principles promulgated in State Street Bank have for the most part been repudiated. The Supreme Court opinion in Bilski v. Kappos expressly rejected State Street Bank’s holding that anything useful could potentially be patented. The Court’s more recent opinion in Mayo v. Prometheus also emphasized the significance of patentable subject matter doctrines within the patent system. Congress has also become involved,

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76 149 F.3d 1368 (Fed. Cir. 1998).
77 Id. at 1375.
78 Id. at 1373 (quoting In re Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994)).
80 See, e.g., U.S. Patent No. 7,666,848 (filed May 6, 2004).
81 See, e.g., U.S. Patent No. 5,966,693 (filed May 7, 1996).
82 See, e.g., U.S. Patent No. 8,234,514 (filed July 12, 2008).
87 U.S. Patent No. 6,368,227 (filed Nov. 17, 2000).
88 130 S. Ct. 3218, 3231 (2010).
legislatively eliminating patents on human organisms and severely limiting patents on tax strategies through the Leahy-Smith America Invents Act.

For the U.S. patent system, State Street Bank was an experiment that yielded dubious results. The world has seen little evidence of improved innovation in business methods, finance, tax strategies, the social sciences, and other disciplines that for a decade or so were broadly patentable. A more certain legacy of State Street Bank will include an increase in USPTO workload and a growth in deep-seated concern about the integrity of the patent system. As innovation continually redefines existing fields of endeavor and establishes new ones, this experience suggests the wisdom of expanding the patent system with both caution and input from impacted industry.

E. The BlackBerry Case

Each generation may be assigned a leading case that draws public attention to the patent system not because it develops new legal principles, but rather for its ambition and impact upon everyday lives. For an older cohort, that case was probably Polaroid v. Kodak. That litigation resulted in a damages award of $873 million and ultimately caused Kodak to abandon the instant camera business altogether. Polaroid v. Kodak conveyed a forceful message to innovators and investors about the value of U.S. patent rights as defined by the Federal Circuit.

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91. Id. § 14, 125 Stat. at 327–28.
Over the past twenty years, the leading piece of litigation is arguably *NTP, Inc. v. Research In Motion, Ltd.*, better known as the BlackBerry case. A jury had found Research In Motion (RIM) guilty of willful infringement of NTP’s patents concerning wireless e-mail communication services, a judgment affirmed by the Federal Circuit. As a result, a vast number of BlackBerry users in the United States faced the unsettling prospect of an imminent cessation of service pursuant to a court-ordered injunction. However, prior to the district court’s decision on issuing a permanent injunction, NTP and RIM signed a $612.5 million licensing and settlement agreement. The settlement ended the litigation and ensured uninterrupted operation of the BlackBerry service.

The BlackBerry case sent a number of potent signals. The case was litigated on a contingency basis, resulting in a lucrative payout for NTP’s counsel and encouraging this controversial practice going forward. The Federal Circuit also held that NTP’s U.S. patents could cover activity performed in Canada. The recognition that U.S. patent rights could reach abroad, despite the absence of a specific Patent Act provision authorizing extraterritorial coverage, suggests the self-recognition of the U.S. system within an international patent order.

This litigation also introduced to a broader community the concept of patent trolling and the Federal Circuit’s “general rule” that upon a finding of infringement, a court should issue a permanent injunction against adjudicated infringers. NTP provided no mobile e-mail service of its own; indeed, it marketed

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97 418 F.3d 1282 (Fed. Cir. 2005).
98 Id. at 1325–26.
100 Id.
101 Id.
103 NTP, 418 F.3d at 1317 (referring to NTP’s method’s claims, which has a different “use” analysis than those for a system or device).
no products or services whatsoever. Yet under prevailing legal principles NTP could control public access to the fabulously popular BlackBerry products and services. Although RIM averted an injunction through a costly settlement, NTP’s success undoubtedly inspired a growing number of non-practicing patent owners to seek to monetize their intellectual property entities through licensing and litigation.

More impactful than any academic study, the BlackBerry litigation suggested to many that the patent system was out of alignment with mainstream legal concepts and the needs of the high technology community. Little wonder then that the Supreme Court became increasingly interested in the patent system about the time of the BlackBerry case, and that the harbingers of the Leahy-Smith America Invents Act began to reach the floor of the House of Representatives. The BlackBerry case inspired significant changes to the U.S. patent system, ones that we are still working through in 2012.

F. New Voices

Two decades ago, discussion of the patent system was arguably limited almost exclusively to the patent bar. The study of patent law was confined to an isolated corner of the legal academy, few individuals who were not admitted to practice before the USPTO knew much about patents at all, and most law firms engaged in patent practice did little else. The primary venue for organized discussion of the field was the American Intellectual Property Law Association (AIPLA), the national bar association for patent

105 See Jennifer Lane, NTP, Inc. v. Research In Motion, Ltd.: Inventions are Global, But Politics are Still Local—An Examination of the BlackBerry Case, 21 BERKELEY TECH. L.J. 59, 65 n.50 (2006).
106 See Heinzl & Sharma, supra note 99.
lawyers. Yet this discussion was less in the nature of debate than of reaffirmation of existing views. Most of those who did think about patent law in 1992 saw things the same way—namely, that more robust patent rights were not only in their own professional interest, but also in the national interest.

Today new voices wield influence within the patent system. The National Academies and Federal Trade Commission issued influential reports that helped shape the Leahy-Smith America Invents Act.\textsuperscript{110} Lobbying groups with such Orwellian names as the Coalition for 21st Century Patent Reform,\textsuperscript{111} Coalition for Patent Fairness,\textsuperscript{112} and Innovation Alliance\textsuperscript{113} also influenced the text of the legislation and its current implementation at the USPTO.\textsuperscript{114} And thanks to the Bayh-Dole Act,\textsuperscript{115} the university community also asserts its perceived interests in patent matters, particularly through the Association of University Technology Managers.\textsuperscript{116}

The practice of patent law has also been dramatically transformed over the past two decades. For most of their history, U.S. patent professionals operated within a more collegial, unified bar that lacked the natural divisions found among antitrust, labor, and other sorts of lawyers. Of late, however, the patent bar appears to be far more fractured. Patent lawyers representing pharmaceutical firms have in recent years expressed vehement disagreement with those working for electronics and consumer


\textsuperscript{112} \textsc{Coalition for Patent Fairness}, http://www.patentfairness.org (last visited Sept. 6, 2012).

\textsuperscript{113} \textsc{Innovation Alliance}, http://www.innovationalliance.net (last visited Sept. 6, 2012).


device providers. In-house counsel have clashed with law firms. Moreover, patent lawyers have increasingly joined general practice firms following the collapse of venerable specialty firms such as Darby & Darby, Fish & Neave, and Pennie & Edmonds—a trend that has arguably increased the mainstreaming of patent law.\(^{117}\)

The number and diversity of academics with interests in patent law has also exploded over the past twenty years in the United States. Once an obscure specialty that lived a marginal life among the professorate, patent law is now taught in the majority of the nation’s law schools and is the subject of numerous articles in leading law reviews each year. Scholarship continues to inform and enrich our understanding of the patent regime, a welcome development for what was once one of the most under-theorized of legal disciplines.

II. THE NEXT TWENTY YEARS

The past two decades saw a number of surprising developments. In 1992, few had predicted that business method patents would be a focus of judicial and congressional scrutiny, that *Markman* hearings were on the horizon, or that Congress would alter such fundamentals as a seventeen-year term, first-to-invent priority principle, and best mode requirement. This history suggests that forecasting key moments of the next twenty years constitutes at best a precarious proposition. This Article nonetheless explores themes that may come to dominate the discussion at the next twenty Fordham International Intellectual Property Law and Policy Conferences.

A. The Rise of Regulatory Exclusivities

As suggested by the phrase “patent medicine,” patents have long played a leading role within the intensely science-based pharmaceutical industry.\(^{118}\) That role seems destined to decrease

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118 Patent medicines were “preparations that often contained ingredients such as opium and alcohol and claimed to cure many if not all diseases.” *Patent Medicines, Drugstore*
over the next two decades. The reason is that a new intellectual property right, regulatory exclusivities, is poised to become the primary source of exclusivity for health-based inventions including small-molecule pharmaceuticals, medical devices, and biologics.

As originally structured by the Orphan Drug Act and the Hatch-Waxman Act, regulatory exclusivities were relatively short-term rights that supplemented the patent system. Orphan drugs were afforded seven years of relatively limited regulatory exclusivity for diseases and conditions affecting fewer than 200,000 patients in the United States. New chemical entities not previously approved by the FDA receive five years of protection, but if the FDA requires a clinical trial with respect to a product that does qualify as a new chemical entity, then three years of protection are provided. The Food and Drug Administration (FDA) Modernization Act of 1997 then augmented these terms by six months as a reward for conducting pediatric trials of drugs.

More recent legislation has expanded these exclusivities in terms of scope and duration. Congress recently provided for twelve years of regulatory exclusivity for biologics. And some have noted that the analogous European regime provides for eight years of exclusivity before authorization for a generic may be submitted and two further years before it may be approved. These dates are augmented by an additional year if the sponsor obtains further authorization for one or more new therapeutic indications for the product. It takes little imagination to assert that the regulatory exclusivity periods for small-molecule

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123 Id. § 355(j)(5)(F)(iii) (2010).
127 Id.
pharmaceuticals under the Hatch-Waxman Act should be extended to the terms available in Europe.

With health care forming a key political issue for the United States, Congress seems likely to revisit the issue of intellectual property rights for healthcare innovation in the near future. Yet amending the Patent Act lacks convenience in comparison with fortifying regulatory exclusivity. Fine-tuning the patent laws to meet the needs of the healthcare industry may upset the balance of protection and competition in other industries. Further, the WTO TRIPS Agreement requires signatories to provide patent protection “without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” But TRIPS seems to prohibit discrimination in favor of drug patents as well as against them. On the other hand, TRIPS places few restrictions upon the award of regulatory exclusivities by WTO members; indeed, unlike patents, they are arguably not even required.

Enhanced regulatory exclusivity offers other advantages for brand-name drug companies over stronger patent protection. First, patents provide not so much the right to exclude but the right to try to exclude. Generic firms frequently make successful arguments that the brand-name firm’s patents are invalid or not infringed. In contrast, regulatory exclusivity operates without the need for owners to bring costly and risky infringement actions, and from its more limited duration, regulatory exclusivity is a better temporal fit with the life cycle of a pharmaceutical product. Regulatory exclusivity periods typically do not begin until a product is on the market, while some of a patent’s term may run before that time.

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129 Id. at art. 39.
131 Id.
133 Id. at 351–52.
The proposed Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act, or MODDERN Cures Act,\(^{134}\) provides an example of a framework of innovation incentives that emphasizes regulatory exclusivity over patents. Under that proposed legislation, the drug sponsor must identify a therapy that fulfills an “unmet medical need” to the FDA.\(^{135}\) As part of this identification, the sponsor indicates the patents associated with that “dormant therapy” and asserts that they will provide fourteen or fewer years of effective protection.\(^{136}\) The sponsor also files a waiver of those rights.\(^{137}\) If the FDA agrees with the sponsor and ultimately grants marketing approval, then the sponsor obtains fifteen years of marketing exclusivity.\(^{138}\) All of the identified patents are given an extended term of up to fifteen years after the product is approved.\(^{139}\) Any term after the fifteen years is then disclaimed via the voluntary waiver.\(^{140}\) It remains to be seen how much traction the MODDERN Cures Act will see in Congress, but the legislation provides a significant paradigm shift for patents and regulatory exclusivities—one that might come to dominate the innovative healthcare industry over the next twenty years.

B. The Changing Nature of National Treatment

The hollowed principle of national treatment forms the core paradigm of the Paris Convention for the Protection of Industrial Property (Paris Convention).\(^{141}\) The Paris Convention in turn has long served as the foundational international agreement underlying the global patent order.\(^{142}\) Yet national treatment will likely

\(^{135}\) Id. § 201(a)(2)(A).
\(^{136}\) Id. § 201(d).
\(^{137}\) Id. § 201(b)(3).
\(^{138}\) Id. § 202(a)(1).
\(^{139}\) Id.
\(^{140}\) Id.
undergo a significant, softening transformation in coming years, motivated by the extraordinary popularity of the patent system.

Today virtually every national patent office faces a large inventory of unexamined patent applications. The USPTO in particular has engaged in several creative responses in order to address its backlog. One reaction that seems to have staying power is the agency’s bid to privilege domestic customers. Under the new “Three-Track Proposal,” foreign applicants will be effectively required to obtain a patent in their homeland before the USPTO will consider their domestic applications. The USPTO will then provide what is effectively an expedited review of those applications based in part upon examination tasks previously performed abroad.

This system comports with the principle of national treatment only through a clever sleight of hand. Preferred treatment is not afforded to U.S. nationals per se; rather, it is given to those who filed in the USPTO first, regardless of their nationality. However, because a firm’s home market is typically its most important, filing in one’s own patent office first is the current norm. Whether the Three-Track Proposal will influence traditional international filing practice, pushing more foreigners to file first at the USPTO, remains to be seen.

An international patent regime centered upon the office of first filing is likely not the sort of high-minded collaboration that optimistic supporters of patent worksharing envisioned. Yet this system would amount to cooperation of a sort. And given the crushing workloads faced by patent offices around the world, the decline of the national treatment principle proposed by the USPTO seems inevitable.

144 Id.
146 See Thomas, supra note 143, at 11–12.
147 See id.
148 See id. at 9.
C. Parallel Importation

The high and growing costs of health care in the United States suggest that the parallel importation of patented pharmaceuticals will again be the subject of serious discussion. Members of Congress are well aware that prescription drugs often cost more in the United States than in other countries. In order to realize cost savings, many individuals import medications from abroad—but in doing so they commit a patent infringement under current Federal Circuit case law.\textsuperscript{149} Congress appears virtually certain to alter this state of affairs in coming years, assuming that the Supreme Court does not act first.

In the 112th Congress, Senate Bill 319, the Pharmaceutical Market Access and Drug Safety Act of 2011 would expressly allow for the parallel importation of pharmaceuticals.\textsuperscript{150} Most of the bill is directed towards amendments to food and drug law, but the legislation also accounts for the patent implications of parallel importation.\textsuperscript{151} In particular, section 4(d) of Senate Bill 319 would amend the Patent Act to provide that importation into the United States a drug that was first sold abroad by or under authority of the owner or licensee of such patent does not constitute a patent infringement.\textsuperscript{152} The effect of Senate Bill 319 would be to incorporate into the U.S. Patent Act, at least on a pharmaceutical-specific basis, a doctrine known as “international exhaustion.”\textsuperscript{153} Although this bill appears to have little chance of enactment in 2012, it provides a glimpse into a likely future addition to the Patent Act.

The courts may beat Congress to the punch, at least with respect to the notion of international exhaustion. On April 16, 2012, the U.S. Supreme Court granted certiorari in \textit{Kirtsaeng v.}


\textsuperscript{150} \textit{S. 319}, 112th Cong. \textsect 4(d) (2011).

\textsuperscript{151} \textit{See Id.}

\textsuperscript{152} \textit{Id.} \textsect 4(d).

\textsuperscript{153} \textit{See id.; See also Vincent Chiappetta, The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and a Few Other Things, 21 MICH. J. INT’L L. 333, 340–42 (2000) (describing the difference between national and international exhaustion).}
John Wiley & Sons, Inc., a parallel importation case involving copyrights. The question presented to the Court is:

How do Section 602(a)(1) of the Copyright Act, which prohibits the importation of a work without the authority of the copyright’s owner, and Section 109(a) of the Copyright Act, which allows the owner of a copy “lawfully made under this title” to sell or otherwise dispose of the copy without the copyright owner’s permission, apply to a copy that was made and legally acquired abroad and then imported into the United States?155

The Ninth Circuit has held that the Copyright Act’s reference to works “lawfully made under this title” means “lawfully made in the United States.”156 Under this view, U.S. copyright law adopts a “domestic exhaustion” principle under which the parallel importation of a protected work of authorship constitutes a copyright infringement.157 An equally plausible ruling is that the phrase “lawfully made under this title” means merely that the manufacture of the work was authorized by the U.S. copyright holder—even if the manufacturing took place outside the United States.158 Under this view, U.S. copyright law would adopt an “international exhaustion” principle under which the parallel importation of legitimate gray market goods does not constitute an infringement.159

The Court’s ruling in Kirtsaeng is of great moment to the patent system. Congress has not yet stipulated the exhaustion principles pertinent to patent law. But the Federal Circuit has followed the first line of reasoning above to conclude that the U.S.

156 See Omega S.A. v. Costco Wholesale Corp., 541 F.3d 982, 988 (9th Cir. 2008).
157 See Chiappetta, supra note 153, at 340–42 (using the term “national exhaustion” instead of “domestic exhaustion”).
159 See id. at 205–08.
patent system does not accept international exhaustion. Should the Court rule differently in *Kirtsaeng*, the Federal Circuit case law would likely be viewed as overturned as well.

Through one mechanism or the other, the next two decades will likely see the abrupt introduction of international exhaustion into the U.S. patent system, at least with respect to pharmaceuticals. As a result, current experience with respect to the free movement of patented goods in the European Union provides a likely precursor to U.S. patent regime of the future. As a voluminous literature has already been realized, the impact of this change upon orderly markets, patient safety, and innovation incentives in the United States would be profound.

**D. Future Legislation**

When President Obama signed the AIA into law on September 16, 2011, some may have supposed that Congress would be out of the patent business for quite some time. After all, the new law had a long pendency of many years on the Hill. Further, the most recent predecessor legislation dealing with multiple patent principles, the AIPA, had been enacted in 1999. These factors may suggest either that Congress passes any sort of patent bill only with considerable difficulty, or alternatively that Congress does not act rashly with respect to patent reform.

Still other factors suggest that Congress remains keenly interested in patent matters and is likely to again intervene sooner, rather than later in the field. Members of Congress and their staff

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160 See, e.g., Jazz Photo Corp. v. Int’l Trade Comm’n, 264 F.3d 1094, 1105 (Fed. Cir. 2001).


have climbed a steep learning curve to develop expertise in a sophisticated field, suggesting greater receptivity to difficult patent concepts that may not have attracted legislative interest in previous years. The grandly named patent lobbying groups, such as the Coalition for Patent Fairness and the Coalition for 21st Century Patent Reform, continue to exist and remain active on the Hill.\footnote{165}

Moreover, patent matters frequently brush up against issues of more central congressional concern, in particular health care.

Further, while the AIA is the lengthiest piece of patent legislation ever enacted in the United States,\footnote{166} it was by no means a comprehensive patent bill. A comparison of early drafts of the legislation with the new law reveals that many contentious issues remain left on the table. Among them was a proposed shift to ecumenical pre-grant publication of pending applications, changes to the law of inequitable conduct, venue reform, and significant alterations to the rules governing the award of damages.\footnote{167} Recent judicial opinions have addressed some of these issues, but unsurprisingly they have not addressed the concerns of all stakeholders.\footnote{168}

At a minimum, in the near future we can surely expect the introduction of a “technical amendments” bill that tinkers with some of the provisions of the AIA once the bar and USPTO have had time fully to digest it. As suggested by such legislation

\begin{footnotes}
\item 167 See, e.g., America Invents Act, H.R. 1249, 112th Cong. § 18(d) (2011) (discussing proposed patent venue infringement actions); America Invents Act: Hearing on H.R. 1249 Before the Intellectual Property, Competition, and the Internet Subcomm. of the House Comm. on the Judiciary, 112th Cong. (2011) (statements of Secretary Kappos supporting removal of changes to damages venue considerations from bill and Congresswoman Lofgren supporting “more work” on the inequitable conduct provisions and the one-year grace period for publication of applications).
\end{footnotes}
subsequent to the AIPA—the Intellectual Property and High Technology Technical Amendments Act of 2002—this bill may itself include significant changes that belie its modest title. In sum, an increasingly complex Patent Act was a hallmark of the past two decades, a trend that should continue going forward.

E. USPTO Rule-Making Authority

For most of its long history the USPTO has been a relatively sleepy agency that played a minor role in intellectual property policy matters. For an entity that issued each U.S. patent, the USPTO actually played a relatively minor role even within the patent system. Innovation policy matters were dealt with by Congress and the courts. The position of the head of the agency was something of a sinecure; other elite personnel were viewed as something of a clannish and insular group that was insensitive to concerns of patent applicants.

This view of the USPTO, already outmoded, is likely to become wholly archaic over the next two decades. The agency has become increasingly innovative as it has launched an array of programs and initiatives that have been successful in reducing its backlog of filed but unexamined applications. It has been praised for the transparency of its decision-making processes. It has attracted new staff with exceptional professional backgrounds. And by opening a branch office in Detroit, to be followed by others in locations distant from Alexandria,

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171 See generally id. at 5.
Virginia, the agency will have an increasingly national presence. These branch offices should not only improve the ability of the agency to hire and retain quality examiners, they should also improve relationships with the diverse industries and user communities found in the United States.

If the USPTO can continue to expand its growing reputation for accuracy, productivity, and resourcefulness, the congressional grant of rule-making authority to the agency seems a distinct possibility over the next two decades. Current law provides the USPTO with the ability, among others, to establish regulations that “govern the conduct of proceedings” before it. However, it should be appreciated that “Congress has not vested the [USPTO] with any general substantive rulemaking power . . . .” Congress has thought seriously about expanding the agency’s authority, however, and the possibility that the USPTO will one day enjoy the same rulemaking ability as its peer agencies is not out of the question.

This conferral of authority would cause the U.S. patent system to operate quite differently than it does today. In 2012, the courts engage in day-to-day governance of the U.S. patent system, a quite unusual, patrician regime that lacks political accountability. Under this system, the courts set, for example, the standard of obviousness in individual judicial proceedings; the agency must then follow these holdings. USPTO possession of rulemaking authority would flip this system on its head. The agency would engage in rulemaking procedures to set the standard of obviousness with public input; the courts would then follow the

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178 For example, in the 110th Congress, H.R. 1908 would have allowed the USPTO to “promulgate regulations to ensure the quality and timeliness of applications and their examination . . . .” Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 14(a) (2007).
180 See id.
181 See id.
promulgated rule. Whether the patent system will advance into a system of democratic governance over the next two decades, or remain under its current, sui generis regime of concentrated command by a handful of elites remains to be seen.

F. Patent Aggregation

The past few years have witnessed the accumulation of vast armories of patents by manufacturing firms, service providers, and independent aggregators alike. Current entities such as Acacia Research, Round Rock Research, and RPX have quietly assembled large portfolios of patents both for defensive purposes and as assets capable of monetization. The largest aggregator, Intellectual Ventures, is believed to hold as many as 60,000 patents—a number that ranks fifth among patent holders based in the United States.

The trend towards patent aggregation will surely continue over the next two decades, but on an order of magnitude and level of sophistication that will seem staggering by the standards of 2012. A distinctive possibility within our lifetimes is that the top ten patent holders in the United States may, in combination, hold on the order of one-quarter of all U.S. patents—and an even higher percentage of commercially valuable ones. Finally, although the aggregation phenomenon is most pronounced in the United States, it seems likely to be heading overseas over the next twenty years.

Expanding patent aggregation holds numerous implications for the U.S. patent system. First, this concentration of patents implies market power which, in turn, suggests the increasing mobilization of the antitrust law to police patent law’s excesses. Second, savvy accused infringers may increasingly enlist an aggregator in order to identify a patent within their portfolio capable of sustaining a countersuit against their accusers. This strategy, if widely employed, could limit the value of patents held by manufacturers and service providers.

183 Id. at 24.
184 See id.
185 See id.
But on the other hand, the patent system has traditionally sustained fragmented proprietary rights held by diverse owners. This environment has contributed to the difficulties faced by manufacturers and service providers to determine whether patent rights apply to their marketplace offerings. It has also effectively softened the impact of patent rights. Proprietors would appear more reluctant to assert one or two patents aggressively as doing so might call their validity into question. Owners of a dozen or more patents covering a particular technology would seem far less reticent. Systematic consolidation of patent rights might significantly change these circumstances, suggesting possible changes to public perception of the patent system and to patent law doctrines governing transfer of patent rights and remedies law.

CONCLUSION

Since the first Fordham International Intellectual Property Conference, the U.S. patent system has changed in fundamental ways. A number of defining moments have marked its transition from a perhaps overbold Golden Age to a Silver Age of greater maturity, nuance, and at times doubt. Numerous challenges face the contemporary patent regime in the United States, yet most should agree that its current configuration better suits the global technology community it is designed to serve. And even as the U.S. patent law has evolved, it has sustained and nurtured a range of technologies that could have scarcely been imagined twenty years ago. So will it again, over the next two decades and beyond.