

ARTICLE

TOWARD A DISTRIBUTIVE AGENDA FOR U.S. PATENT LAW

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ABSTRACT

As commonly understood, the U.S. patent system is a utilitarian regime that employs exclusive rights and market incentives to promote technological progress. Unlike international and foreign regimes, the domestic patent system less explicitly addresses non-utilitarian issues such as access, equity, and distributive justice in conferring and enforcing exclusive rights. This Article, however, challenges this conception of the U.S. patent system as unconcerned with distributive considerations on descriptive and normative grounds. First, contrary to prevailing characterizations, it reveals numerous “distributive mechanisms” within and associated with the U.S. patent system that widen access to patented technologies, encourage the development of technologies to serve marginalized communities, and broaden participation in the patent system itself. Second, it argues at a normative level that such emphasis on distribution is consonant with the normative foundations of U.S. patent law and its commonly understood objectives of promoting progress, maximizing utility, and enhancing efficiency. Third, building on these insights, this Article sketches the contours of a distributive agenda for U.S. patent law. It identifies roles for Congress, courts,

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and agencies—particularly the USPTO—to lower the cost of critical patented technologies, encourage the development of technologies particularly valuable to marginalized communities, and broaden and diversify the base of inventors obtaining protection for their creations.

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I. INTRODUCTION

It is widely accepted that the objective of the U.S. patent system is to establish incentives to invent.¹ As the Constitution states, Congress is authorized to create a patent system “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”² As commonly understood, the U.S. patent system is a utilitarian regime that utilizes exclusive rights and market incentives to promote the generation of new technologies.³ As such, it is less centrally concerned with “distributive matters” such as providing wide access to inventions, developing technologies to serve marginalized communities, or ensuring diverse participation in the patent system.⁴ Although numerous scholars have argued for U.S. patent law to consider issues of access, equity, and distributive justice,⁵ mainstream patent law still focuses overwhelmingly on maximizing technological output.

While the patent system’s reliance on exclusive rights and market incentives renders it a powerful engine for innovation, it exhibits significant distributive deficiencies. Exclusive rights

1. See, e.g., Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1031 (2005) (“Intellectual property protection in the United States has always been about generating incentives to create.”) [hereinafter Lemley, *Free Riding*].

2. U.S. CONST. art I, § 8, cl. 8.

3. See *Bilski v. Kappos*, 561 U.S. 593, 617 (2010) (Stevens, J., concurring) (“[T]he patent system is intended to protect and promote advances in science and technology. . . .”) (internal quotation marks omitted); John M. Golden, *Principles for Patent Remedies*, 88 TEX. L. REV. 505, 509 (2010) (“I generally assume a utilitarian goal that is standard in modern accounts: the patent system should act to promote the development, disclosure, and use of new technologies, ideally in a way that maximizes social welfare.”) [hereinafter Golden, *Principles*]; Ted Sichelman, *Purging Patent Law of “Private Law” Remedies*, 92 TEX. L. REV. 517, 529 (2014) (“In the United States, the overriding goal of patent law is to promote technological innovation.”) [hereinafter Sichelman, *Purging*]; Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 546 (2003) (“The U.S. patent system is unashamedly utilitarian”); Shlomit Yanisky-Ravid, *The Hidden Though Flourishing Justification of Intellectual Property Laws: Distributive Justice, National Versus International Approaches*, 21 LEWIS & CLARK L. REV. 1, 4 (2017) (“In the United States . . . intellectual property laws are based mainly on the utilitarian-economic-efficiency justification of the law and economics approach”).

4. Cf. Thomas W. Merrill & Henry E. Smith, *The Morality of Property*, 48 WM. & MARY L. REV. 1849, 1849 (2007) (“[Utilitarianism] adopts a framework largely indifferent to questions of individual rights and distributive justice, which many consider the hallmarks of a moral perspective.”).

5. See, e.g., Keith Aoki, *Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 719 (2007); Anupam Chander & Madhavi Sunder, Foreword, *Is Nozick Kicking Rawls’s Ass? Intellectual Property and Social Justice*, 40 U.C. DAVIS L. REV. 563, 564 (2007).

restrict output and raise prices, thus decreasing access to patented inventions.⁶ Price-based allocation is not problematic for the vast majority of patented technologies but may have dire implications for technologies critical to human well-being, such as medicines and diagnostics.⁷ Furthermore, a system predicated on market incentives will tend to allocate resources to develop technologies that maximize market value, thereby providing less than optimal incentives for technologies whose social value exceeds market value.⁸ Finally, a patent system with high entry costs will tend to favor wealthy, sophisticated patent applicants with access to legal expertise, thus diminishing the ability of under-resourced and marginalized communities to obtain legal protection for their inventions.

U.S. patent law's apparent neglect of distributive considerations is even more striking given that such considerations figure prominently in international patent law.⁹ Issues of access and equity cut to the core of longstanding debates over the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),¹⁰ an international agreement strengthening intellectual property rights adopted in conjunction with the establishment of the World Trade Organization (WTO). Several years after adopting the TRIPS Agreement, concerns over access to patented AIDS medicines motivated developing countries to argue that free trade and stringent intellectual property protection should not unduly compromise public health and access to medicines.¹¹

6. See Michael A. Carrier, *Resolving the Patent-Antitrust Paradox through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1048 (2003) [hereinafter Carrier, *Paradox*]. But cf. Oren Bracha & Talha Syed, *Beyond the Incentive—Access Paradigm? Product Differentiation & Copyright Revisited*, 92 TEX. L. REV. 1841, 1842 n.1 (2014) (examining the theory of product differentiation, by which intellectual property rights enhance both incentives to create as well as access to new creations).

7. See Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 931 [hereinafter Lee, *Distributive Commons*].

8. See Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 978 (2012).

9. See, e.g., Anupam Chander & Madhavi Sunder, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331, 1336 (2004); Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2823–24 (2006) [hereinafter Chon, *Development Divide*]; James Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D*, 40 U.C. DAVIS L. REV. 679, 681 (2007); Madhavi Sunder, *IP 3*, 59 STAN. L. REV. 257, 284, 292–94 (2006).

10. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

11. Chon, *Development Divide*, *supra* note 9, at 2843.

These concerns led directly to the WTO's adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which affirmed "WTO members' right to protect public health and, in particular, to promote access to medicines for all."¹² Thus, while issues of distributive justice have been front and center within international patent law, they remain largely peripheral to mainstream accounts of U.S. patent law.¹³ U.S. government policy has largely favored strong protection for intellectual property rights, particularly in international forums.¹⁴ But in doing so, official policy neglects the distributive deficiencies of patents in this country, where people are priced out of the market for critical technologies.

This Article offers a descriptive and normative challenge to the notion that U.S. patent law is unconcerned with distributive considerations. In doing so, it adopts a broad conception of "distributive justice" as a normative principle concerned with widespread and equitable allocation of resources, as distinct from the commonplace utilitarian objective of maximizing aggregate welfare.¹⁵ On a descriptive level, it argues that the U.S. patent system already possesses numerous "distributive mechanisms" that widen access to critical patented technologies, encourages the development of technologies to serve marginalized communities, and broadens participation in the patent system itself. On a normative level, this Article argues that such distributive mechanisms are wholly appropriate and advance the broad and diverse objectives of the U.S. patent system. Turning to prescriptions, it sketches the contours of a distributive agenda for domestic patent law—not one imposed on the patent system by exogenous pressure, but one that arises organically from the patent system's own ideological commitments.¹⁶ There is already a distributive impulse in U.S. patent law. Rather than stymie it, Congress,

12. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 ILM 755 (2002) (adopted Nov. 14, 2001).

13. See Yanisky-Ravid, *supra* note 3, at 28–40 (comparing the emphasis on efficiency in U.S. intellectual property law with several distributive initiatives of the World Intellectual Property Organization).

14. See, e.g., Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 842–43 (2003) (describing the U.S. government's advocacy of intellectual property protection in the formation of the WTO).

15. See Lee, *Distributive Commons*, *supra* note 7, at 920–21; Yanisky-Ravid, *supra* note 3, at 11; cf. Shubha Ghosh, *The Fable of the Commons, Exclusivity and the Construction of Intellectual Property Markets*, 40 U.C. DAVIS L. REV. 855, 858–59 (2007).

16. Cf. Yanisky-Ravid, *supra* note 3, at 18 (arguing that distributive justice is neither external to intellectual property law nor a lens for retrospectively interpreting it but intrinsic to its constitution).

courts, and executive agencies should embrace this impulse and craft statutes, doctrines, and regulations to fully realize its potential.

This Article proceeds in four parts. Part I discusses the conventional conception of the U.S. patent system as creating a neutral system of exclusive rights and market incentives to promote technological development. Part II offers a descriptive critique of this conception by exploring numerous ways in which the patent system and related regimes curtail exclusivity to broaden access to technology, depart from market neutrality to favor socially valuable technologies, and preferentially treat some cohorts of patentees over others. Part III turns to normative analysis, arguing that distributive efforts are fully consonant with the patent system's objectives of promoting progress, maximizing social utility, and enhancing efficiency. Part IV turns to prescriptions and sketches the outlines of a distributive agenda for U.S. patent law.

II. THE RHETORICAL PREDOMINANCE OF EFFICIENCY, MARKET ALLOCATION, AND NEUTRALITY IN U.S. PATENT LAW

As noted, the Constitution authorizes a patent system to promote the progress of useful arts.¹⁷ Of course, "progress" is an indeterminate term subject to many interpretations.¹⁸ Courts, policymakers, and commentators have largely (and without explicit justification) interpreted "progress" in a utilitarian light and characterized the aim of the patent system as promoting incentives to invent.¹⁹ As Madhavi Sunder observes, however, such "intellectual property utilitarianism does not ask who makes the goods or whether the goods are fairly distributed to all who need them."²⁰ Rather than prioritize these progressive inquiries, the patent system has coalesced around a utilitarian objective that economists would characterize as maximizing efficiency.²¹

17. U.S. CONST. art. I, § 8, cl. 8.

18. See *infra* Part III.

19. See Lemley, *Free Riding*, *supra* note 1, at 1031. But see Dan L. Burk, *Diversity Levers*, 23 DUKE J. GENDER L. & POL'Y 25, 28–29 (2015) ("But the concept of progress need not be confined to utility and might plausibly encompass incommensurables such as human flourishing or dignity.").

20. Sunder, *IP*³, *supra* note 9, at 259.

21. Yanisky-Ravid, *supra* note 3, at 7; cf. ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY LAW 6 (2011) [hereinafter MERGES, JUSTIFYING].

Within the patent system's focus on maximizing efficiency, the market assumes a central role.²² The patent system confers exclusive rights that create market incentives to invent and develop new technologies. As economists recognize, the technical information inherent in an invention is both nonrival and nonexcludable.²³ Such information is a "public good" that is subject to undersupply in a purely competitive economy.²⁴ Considering one often-invoked example, the technical information embodied in a new pharmaceutical is costly to produce yet easily appropriable once created.²⁵ In a regime of pure competition, free-riding firms could simply copy the drugs of innovating firms, thus undermining incentives to invest in research and development.²⁶ Patents confer exclusive rights on public goods, thus shoring up these incentives. The centrality of the market to the patent system is underscored by the fact that scholars often characterize patents as a solution to "market failure."²⁷

The prominence of efficiency and the market within the patent system dovetails with another important value in U.S. patent law: neutrality.²⁸ In theory, the patent system creates a neutral market for technology that enables the invisible hand of supply and demand to allocate resources for technological development. Accordingly, the patent system is loath to impose *ex ante* value judgements on inventions. For instance, in the

22. See Susan E. Cozzens, *Distributive Justice in Science and Technology Policy*, 34 SCI. & PUB. POLY 85, 87 (2007) (noting that the primary distributive mechanism in utilitarian regimes is the market); Harry First, *Controlling the Intellectual Property Land Grab: Protect Innovation, Not Innovators*, 38 RUTGERS L.J. 365, 369 (2007).

23. See THOMAS JEFFERSON, THE WRITINGS OF THOMAS JEFFERSON VOLUME VI, at 180–181 (Washington ed., 1854); *Graham v. John Deere*, 383 U.S. 1, 8 n.2 (1966).

24. Paula E. Stephan, *The Economics of Science*, 34 J. ECON. LIT. 1199, 1225 (1996) (stating that because of problems of appropriability, public goods are subject to underproduction).

25. See, e.g., Joseph A. Dimasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016) (estimating the cost of bringing a new FDA-approved drug to market at \$2.87 billion).

26. Notably, unlike statutory patent law, the common law generally favors imitation and copying of new innovations to encourage competition and reduce prices. See, e.g., *Cheney Bros. v. Doris Silk Corp.*, 35 F.2d 279 (2d Cir. 1929).

27. See, e.g., Jonathan M. Barnett, *Private Protection of Patentable Goods*, 25 CARDOZO L. REV. 1251, 1254 (2004); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMPLE L. REV. 181, 182 (2009).

28. Cf. Frank I. Michelman, *Ethics, Economics, and the Law of Property*, in ETHICS, ECONOMICS, AND THE LAW 3, 3 (J. Roland Pennock & John W. Chapman eds., 1982) ("[T]he norm for social ordering invoked by economic analysis—that is, the norm of efficiency—seems as neutral, as indisputable, as any such norm could be.").

seminal case of *Lowell v. Lewis*, Justice Story rejected an argument that an invention should fail the utility requirement if it were not substantively better than the prior art. Rather than have the Patent Office or a court impose this value judgment on an invention, the market should simply decide its fate. According to Justice Story, “whether [a claimed invention] be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.”²⁹

Relatedly, the norm of neutrality eschews attempts to favor one set of technologies or inventors over others.³⁰ As Dan Burk and Mark Lemley observed, “[i]n theory, . . . we have a uniform patent system that provides technology-neutral protection to all kinds of innovation.”³¹ The United States helped hardwire a commitment to technological neutrality into international patent law in TRIPS Article 21.1, which states that “patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology.”³² Indeed, stakeholders in the U.S. patent system today still argue in favor of the “strict technology-neutrality of the patent system.”³³ Casting doubt on proposals to sort or prioritize patent applications based on the costs and benefits of their underlying technologies, Robert Merges observed that “[t]he history and culture of our patent system reflects a broad egalitarian streak. In the patent system, by custom ‘all patents are created equal.’ Any mechanism for separating patent applications would necessarily buck this tradition.”³⁴

The rhetorical dominance of efficiency and market-based neutrality leaves little space for other values or justifying theories within the U.S. patent system. For example, natural

29. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (Cir. Ct. D. Mass. 1817).

30. Cf. Sarah Tran, *Expediting Innovation*, 36 HARV. ENVTL. L. REV. 123, 147 (2012) [hereinafter Tran, *Expediting Innovation*].

31. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003) (showing the subtle ways in which the patent system actually diverges from this norm).

32. TRIPS, *supra* note 10, at art. 27.1.

33. Biotechnology Industry Organization, Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System (Nov. 19, 2010), <https://www.bio.org/sites/default/files/files/20101119.pdf> [<https://perma.cc/629D-RVUH>]; Matthew Rimmer, *Patents for Humanity*, 3 W.I.P.O. J. 198, 212 (2012).

34. Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 597 (1999).

rights or Lockean labor theory provides a plausible rationale for conferring exclusive rights on inventions.³⁵ After all, an inventor mixes her labor with various resources to create a new technology, thus arguably acquiring ownership claims on it. However, courts have long rejected natural rights or Lockean labor justifications for granting patents, emphasizing instead the utilitarian objective of promoting society-wide technological progress.³⁶ Similarly, so-called “personhood theory,” which justifies intellectual property protection of creations as extensions of a creator’s persona, provides another potential basis for granting patents.³⁷ Tellingly, the related concept of “moral rights” provides a powerful justification for continental copyright regimes and even finds limited expression in U.S. copyright law.³⁸ However, personhood theory enjoys virtually no traction in U.S. patent law.³⁹

The patent system’s focus on utilitarianism and efficiency has also largely foreclosed consideration of moral and ethical issues in granting exclusive rights. For example, U.S. patent law has adopted an expansive notion of patentable subject matter that does not consider morality in determining the patentability of inventions.⁴⁰ Unlike the United States, many

35. See JOHN LOCKE, SECOND TREATISE OF GOVERNMENT 17–31 (Richard H. Cox ed., Harlan Davidson, Inc. 1982) (1704) (outlining Locke’s labor theory regarding property); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933) (“An inventor . . . gives something of value to the community by adding to the sum of human knowledge.”); cf. Robert P. Merges, *Locke Remixed* :-), 40 U.C. DAVIS L. REV. 1259 (2007) (arguing in defense of Lockean labor theory in the context of remix culture); MERGES, JUSTIFYING, *supra* note 21, at 31–68.

36. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330–31 (1945) (“The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences.”); *id.* at 331 n.1 (noting that the purpose of patents is “much deeper and the effect much wider than individual gain”) (quoting TNEC Hearings, Part 3, p. 857); see *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966) (“The patent monopoly was not designed to secure to the inventor his natural right in his discoveries.”); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917) (“[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is to promote the progress of science and useful arts.”); Margaret Chon, *Postmodern “Progress”: Reconsidering the Copyright and Patent Power*, 43 DEPAUL L. REV. 97, 141 (1993) (“Jefferson clearly did not see the patent or copyright as being a natural right; rather he viewed it as a fungible right which was within the state’s discretion to grant.”) [hereinafter Chon, *Progress*].

37. See Jay P. Kesan, *Intellectual Property Protection and Agricultural Biotechnology: A Multidisciplinary Perspective*, 44 AM. BEHAV. SCI. 464, 491–92 (2000).

38. See 17 U.S.C. § 106A (2000) (codifying the Visual Artists Rights Act of 1990); Roberta Rosenthal Kwall, “*Author-Stories: Narrative’s Implications for Moral Rights and Copyright’s Joint Authorship Doctrine*,” 75 S. CAL. L. REV. 1, 5, 26 (2001).

39. Stephanie Plamondon Bair, *The Psychology of Patent Protection*, 48 CONN. L. REV. 297, 311 (2015).

40. See 35 U.S.C. § 101 (defining patentable subject matter as “any new and useful

transnational and foreign patent regimes contain explicit provisions for excluding technologies from patentability based on “public morality.”⁴¹ Other jurisdictions, for instance, have invoked these provisions to subject morally controversial inventions, such as a mouse genetically engineered to develop cancer, to ethical scrutiny.⁴² As Margo Bagley has highlighted, the United States is an outlier in maintaining a “patent first, ask questions later” approach that does not subject new technologies to searching moral inquiry in determining protectability.⁴³ The market-oriented, value-neutral nature of U.S. patent law is also evident in the demise of the doctrine of beneficial or moral utility, which used to deem an invention *not* useful if it contravened prevailing social mores.⁴⁴ Older cases denied or invalidated patents on gambling machines and methods of execution based on a lack of moral utility.⁴⁵ Modern cases have severely narrowed the beneficial utility doctrine, such that by the mid-twentieth century, courts recognized an invention’s *deceptive* character as the very utility that could merit its patentability.⁴⁶

In sum, principles of utility, efficiency, market allocation, and neutrality have achieved normative dominance in U.S. patent law.

process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (suggesting that “anything under the sun that is made by man” is patentable).

41. TRIPS, *supra* note 10, at art. 27.2 (“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.”); European Patent Convention art. 53, Oct. 5, 1973, 1065 U.N.T.S. 199 (prohibiting patents on “inventions the publication or exploitation of which would be contrary to ‘order public’ or morality. . .”). *But see* Leahy-Smith America Invents Act § 33(a) (prohibiting the issuance of patent “on a claim directed to or encompassing a human organism”).

42. Bagley, *supra* note 3, at 519–21.

43. *Id.* at 474.

44. *See* *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817) (No. 8568) (“All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the [patent] act in contradistinction to mischievous or immoral.”); Bagley, *supra* note 3, at 488–90.

45. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY* 217–19 (4th ed. 2007); Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1062–68 (1988).

46. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364 (Fed. Cir. 1999); *see also Ex parte Murphy*, 200 U.S.P.Q. 801 (P.T.O. Bd. App. 1977) (rejecting a prohibition against patenting gambling devices on the ground that they lacked beneficial utility). Recent developments in the life sciences have renewed interest in the moral utility doctrine, particularly its potential applicability to human-animal chimeras, cloning, and inventions encompassing human beings. *See, e.g.*, Bagley, *supra* note 3, at 490–91.

Among other implications, this orientation appears to leave short shrift for considering issues of access, equity, and distributive justice in the domestic patent system.⁴⁷ The next Part, however, will challenge this claim on descriptive grounds.

III. DISTRIBUTIVE MECHANISMS IN THE U.S. PATENT SYSTEM

While commitments to promoting market allocation and overall innovative output dominate justifications for U.S. patent law, the patent system exhibits a curious degree of normative diversity in its actual operation. Contrary to prevailing characterizations, this Part argues that a variety of “distributive mechanisms” already operate in the U.S. patent system and related regulatory regimes. In this context, distributive mechanisms refer to statutes, doctrines, and rules aimed principally at widely distributing the fruits of the patent system or addressing the needs of underrepresented populations.⁴⁸ This Part categorizes these distributive mechanisms into three groups. First, patent law and related regimes enhance access to patented technologies of high social need, particularly medicines and diagnostics, even when doing so may depress incentives to invent. Second, patent law and related regimes deviate from market-based allocation of resources by promoting the development of technologies of high social value, particularly those that serve marginalized communities. Third, the patent system eschews neutrality by extending preferential treatment to small, low-income, and underrepresented entities seeking to patent their inventions.

A. *Enhancing Access to Essential Technologies*

At their core, exclusive rights such as patents tend to decrease output, which increases price and decreases access to a new technology.⁴⁹ Such output constraints particularly burden low-income individuals who cannot afford patent-inflated prices. While policymakers and the public at large tolerate decreased

47. See Louis Kaplow & Steven Shavell, *Why The Legal System is Less Efficient than the Income Tax in Redistributing Income*, 23 J. LEGAL STUD. 667, 667 (1994) (“In economic analysis of law, normative judgments about legal rules are usually based on the rules’ efficiency, regardless of their effects on the distribution of income.”); Kenneth J. Arrow, *Distributive Justice and Desirable Ends of Economic Activity*, in ISSUES IN CONTEMPORARY MACROECONOMICS AND DISTRIBUTION 134, 135 (George R. Feiwel ed., 1985).

48. See Arrow, *supra* note 47.

49. See Carrier, *Paradox*, *supra* note 6.

access as a necessary inducement for creating new technologies,⁵⁰ in some instances such decreased access imposes significant social costs. For instance, while high prices and decreased access to the latest patented vacuum cleaner raise few alarms, such is not the case for constrained access to patented drugs and diagnostic methods.⁵¹ Accordingly, patent law and related regimes have developed mechanisms that deviate from strict enforcement of exclusive rights to more widely distribute patented technologies of high social need.

1. *Elimination of Remedies for Infringing Patented Medical Procedures.* In one instance, the objective of enhancing access to patented medical procedures led Congress to modify the law of patent infringement remedies. Two decades ago, Congress amended the patent statute in response to a 1995 case, *Pallin v. Singer*, where a physician sued another physician for infringing a patent claiming a technique for performing stitchless cataract surgery.⁵² Although the district court ultimately ruled that all of Pallin's patent claims were invalid,⁵³ the case produced alarm over exclusive rights on medical procedures. The American Medical Association denounced such patents and even lobbied Congress to eliminate them.⁵⁴ Congress responded in 1997 by enacting a new provision that eliminated most remedies for a medical practitioner's unauthorized performance of a patented "medical or surgical procedure on the body."⁵⁵ While individual physicians and health care entities engaged in infringement no longer face damages or an injunction, the provision preserves remedies against third parties (such as device manufacturers) that induce or contribute to infringement.⁵⁶

Several factors, including the objective of maintaining access to patented medical procedures, motivated this carve-out from patent remedies. Medical practitioners were offended by a

50. See *Diamond v. Chakrabarty*, 447 U.S. 303, 319 (1980) (Brennan, J., dissenting).

51. Cf. Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 277 (2016) ("The soaring cost of pharmaceuticals is one of the most pressing domestic policy issues in the United States today.").

52. *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407 (D. Vt. 1996); see Sabra Chartrand, *Why Is This Surgeon Suing?*, N.Y. TIMES, June 8, 1995, at D1; Chris J. Katopis, *Patients v. Patents? Policy Implications of Recent Patent Legislation*, 71 ST. JOHN'S L. REV. 329 (1997); Bagley, *supra* note 3, at 499–501.

53. *Pallin*, 1996 WL 274407 at *1.

54. Chartrand, *supra* note 52, at D1; Katopis, *supra* note 52, at 333.

55. 35 U.S.C. § 287(c) (2012).

56. *Id.*

physician's attempt to extract royalties from another,⁵⁷ and they viewed the assertion of exclusive rights on a medical procedure as contravening the Hippocratic Oath⁵⁸ and traditional sharing norms of the medical profession.⁵⁹ When the debate entered Congress, however, consternation over professional norms mingled with distributive concerns about access to medical procedures. Members of Congress argued that patents on medical procedures would decrease access to important technologies and raise healthcare costs.⁶⁰ Along these lines, congressional testimony raised objections that patents on such procedures would compromise patient care and alter the physician-patient relationship.⁶¹ Based in significant part on a desire to promote access to a certain class of high-value technologies, Congress selectively eliminated remedies for infringing patented medical procedures.

2. *Equitable Practice and the Public Interest.* Moving from the legislative to judicial sphere, distributive considerations are also evident in courts' equitable practice. Drawing on equitable principles, courts have recognized that patents are imbued with the public interest and have sought to curtail patent enforcement that harms the public. For example, in the 1945 case of *Vitamin Technologists v. Wisconsin Alumni Research Foundation*, the Ninth Circuit considered the University of Wisconsin's patents on technologies that enriched the vitamin D content of foods through radiation.⁶² Representing local dairy interests, the University of Wisconsin refused to license its patent for use with margarine, a cheaper alternative to butter that was popular among poor communities. This refusal particularly harmed the significant numbers of people, many of them poor, who suffered from rickets, a disease caused by vitamin D deficiency.⁶³

57. Katherine J. Strandburg, *Legal but Unacceptable: Pallin v. Singer and Physician Patenting Norms*, in INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 321, 330 (Rochelle Cooper Dreyfuss & Jane C. Ginsburg eds., 2014).

58. Chartrand, *supra* note 52.

59. Strandburg, *supra* note 57, at 17–18; see American Medical Association, Reports of Council on Ethical and Judicial Affairs, *Ethical Issues in the Patenting of Medical Procedures*, FOOD & DRUG L.J. 341, 351 (1998) (concluding that it was unethical for physicians to “seek, secure or enforce patents on medical procedures”).

60. Chartrand, *supra* note 52, at D5.

61. Katopis, *supra* note 52, at 355. Notably, congressional debate also revealed that, at that time, over 80 nations did not recognize medical and surgical patents. *Id.* at 359–60.

62. *Vitamin Technologists v. Wis. Research Alumni Found.*, 146 F.2d 941 (9th Cir. 1945).

63. *Id.* at 943.

Although the Ninth Circuit ruled that the patents were invalid, it observed that equitable principles would have weighed against enforcing them. Drawing on the constitutional concept of “progress,” the court characterized a patent as a privilege “which is conditioned by a public purpose.”⁶⁴ Noting cases where courts refused to grant injunctions based on patent misuse, the court stated that it would constitute a “public offense” to withhold such patented technologies—and the benefits of vitamin D enhanced margarine—from poor communities suffering from rickets.⁶⁵

In more direct ways, equitable interests in enhancing access to technology have also informed remedies analysis. Over the course of several decades, the Court of Appeals for the Federal Circuit developed a “general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.”⁶⁶ However, decisions both before and after the creation of the Federal Circuit sometimes denied injunctions to prevailing patentees to enhance access to inventions safeguarding human health. For instance, in *City of Milwaukee v. Activated Sludge, Inc.*, the Seventh Circuit refused to enjoin Milwaukee’s use of a patented sewage treatment process, citing concerns about the public interest and public health.⁶⁷ More recently, in *Hybritech, Inc. v. Abbott Laboratories*, the district court invoked the public interest in refusing to (preliminarily) enjoin Abbott’s infringement of patented diagnostic test kits.⁶⁸ In so doing, the court expressed particular sensitivity to the distributive implications of enforcing exclusive rights, stating that “[w]hatever else the court does, it will not cut off the supply of monoclonal test kits for cancer patients who are now using the Abbott product.”⁶⁹ Furthermore, the court observed that “the public interest is served by the availability of safe, sure reliable test kits for hepatitis.”⁷⁰

Notably, the Supreme Court’s 2006 decision in *eBay Inc. v. MercExchange, L.L.C.* rejected the Federal Circuit’s general rule in favor of injunctions and held that courts should apply a traditional equitable test to determine the appropriateness of an

64. *Id.* at 944.

65. *Id.* at 945.

66. *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005), *rev’d*, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

67. *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934).

68. *Hybritech, Inc. v. Abbott Lab.*, 1987 WL 123997 (C.D. Cal. 1987), *aff’d*, 849 F.2d 1446 (Fed. Cir. 1988).

69. *Id.* at *22.

70. *Id.*

injunction.⁷¹ This framework explicitly directs courts to consider the impact of an injunction on the public interest in determining whether to grant such equitable relief.⁷² While it is not clear if courts will apply this equitable framework in a manner consistent with *City of Milwaukee* and related cases,⁷³ *eBay* creates greater flexibility to deny injunctions based on the public interest in maintaining access to a patented technology.

Other areas in the patent system where decision-making bodies assess the public interest also offer opportunities to advance distributive aims. For instance, under § 337 of the Tariff Act of 1930, the International Trade Commission (ITC) can issue exclusion orders against the importation of infringing products.⁷⁴ However, the ITC can decline to issue an exclusion order or narrow the scope of such an order “after considering the effect of such exclusion on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and the United States consumers.”⁷⁵ While denials of exclusion orders on such grounds are extremely rare, in theory they offer a mechanism for curbing exclusive rights to promote distributive interests. For example, in *In re Fluidized Supporting Apparatus*, the ITC declined an exclusion order because of the public interest in maintaining access to covered beds for burn victims where the patentee could not supply enough beds to meet demand.⁷⁶ In this and other cases, the public interest and distributive considerations may weigh against strict enforcement of exclusive rights.

71. *eBay*, 547 U.S. at 391 (2006). In order to obtain an injunction, “[a] plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.” *Id.*

72. *Id.*

73. See Andrew Beckerman-Rodau, *The Aftermath of eBay v. MercExchange*, 126 S. Ct. 1837 (2006): *A Review of the Subsequent Judicial Decisions*, J. PAT. & TRADEMARK OFF. SOC’Y 607, 632, 657 (2007) (finding that courts continue to grant injunctions in the vast majority of cases but deny injunctions where the patentee does not directly compete with the infringer or is a non-practicing entity); *eBay*, 547 U.S. at 395 (Roberts, C.J., concurring) (predicting that courts will continue to issue injunctions in most cases).

74. 19 U.S.C. § 1337 (2006); see generally Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529 (2009).

75. 19 U.S.C. § 1337(d)(1).

76. *In re Certain Fluidized Supporting Apparatus and Components Thereof*, Inv. Nos. 337-TA-182, 337-TA-188, 1984 WL 273801 (Oct. 1984); see Kumar, *supra* note 74, at 568.

3. 3.28 U.S.C. § 1498 Rights. Other statutory regimes related to patent law can also curb exclusivity to serve distributive ends. 28 U.S.C. § 1498 provides that if the federal government utilizes a patented technology without authorization, the patentee's only remedy is to recover "reasonable and entire compensation" for such use.⁷⁷ Patentees may not enjoin the government's use, nor may they receive certain traditional and enhanced damages. This provision arises from governmental sovereign immunity, and the legislative history of § 1498 clearly contemplates the use of this authority to serve the public interest: "the Government ought to have the right to appropriate any invention necessary or convenient for natural defense or for beneficent public use . . . without previous arrangement or negotiation with the owner."⁷⁸ The federal government has routinely used § 1498 to practice patents related to national defense.⁷⁹ Additionally, in the 1950s, federal agencies began utilizing § 1498 to procure patented pharmaceuticals at reduced cost.⁸⁰ In one example, the Defense Department negotiated to purchase a patented antibiotic from an Italian manufacturer rather than the U.S. based patentee, thus saving 72%.⁸¹ This practice continued in the 1960s, and in one 3-year period, the federal government's procurement of 50 generic drugs via § 1498 saved \$21 million.⁸² For reasons that are somewhat unclear, the government's use of § 1498 to reduce pharmaceutical prices declined in the 1970s.⁸³

Recent controversies over the high price of patented pharmaceuticals have renewed interest in § 1498. Amidst concerns over anthrax attacks in 2001, the federal government threatened to utilize § 1498 to obtain generic versions of Cipro, a patented antibiotic.⁸⁴ Negotiations by then Secretary of Health and Human Services Tommy Thompson compelled patentee Bayer

77. 28 U.S.C. § 1498 (2012).

78. H.R. REP. NO. 1288, at 2 (1910); *see also* 56 CONG. REC. 8780 (1910) (statement of Rep. Dalzell) ("Now I assume no one will contend that the Government ought to be prohibited from appropriating to its use any patent that it deems to be necessary, in the interest of the public service.").

79. Brennan et al., *supra* note 51, at 280, 302.

80. *Id.* at 304.

81. *Id.*

82. MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974); Brennan et al., *supra* note 51, at 305.

83. Brennan et al., *supra* note 51, at 306–07.

84. Keith Bradsher & Edmund L. Andrews, *A Nation Challenged: Cipro; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES (Oct. 24, 2001), <http://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html>.

to reduce its price by half.⁸⁵ More recently, 2016 Democratic presidential candidate Bernie Sanders has advocated using § 1498 to lower the cost of patented pharmaceuticals for veterans.⁸⁶ In particular, Senator Sanders has argued for breaking the patent on Gilead's medicine for Hepatitis C (HCV), which initially cost \$84,000 for a full course of treatment.⁸⁷ In doing so, he contended that "[o]ur nation's veterans cannot, and should not, be denied treatment while drug companies rake in billions in profits."⁸⁸ Relatedly, Hannah Brennan and her coauthors have argued for the federal government to use § 1498 to purchase and distribute generic versions of patented medicines.⁸⁹ They also advocate using § 1498 to enhance access to HCV medicines, which would have particularly strong distributive consequences given that this disease disproportionately afflicts "people disadvantaged by poverty, unemployment, homelessness, substance use, lack of health insurance and access to health services, ethnic discrimination, and the epidemic of incarceration."⁹⁰

4. *The Bayh-Dole Act.* Distributive mechanisms are also present in the Bayh-Dole Act, a statute that governs the patenting of federally funded inventions.⁹¹ Congress enacted the Bayh-Dole Act in 1980 to allow and encourage recipients of federal funds (such as universities) to take title to patents arising from federally funded research.⁹² Thus, for instance, if a university scientist receives a grant from the National Institutes of Health (NIH) to perform biomedical research, and this research yields a patentable invention, the university can take title to the patent. While this seems to provide a "double subsidy" for universities, which receive both federal funds and patent rights, the government maintains certain rights in such inventions. In particular, under 35 U.S.C. § 203, a federal funding agency can exercise "march-in rights" to

85. Brennan et al., *supra* note 51, at 303.

86. Letter from U.S. Sen. Bernie Sanders to U.S. Dep't of Veterans Affairs Sec'y Robert McDonald (May 12, 2015), *available at* <https://www.sanders.senate.gov/download/051215-letter/?inline=file> [<https://perma.cc/LMQ6-LQFN>] [hereinafter Sanders letter].

87. *Id.* at 1.

88. *Id.*

89. Brennan et al., *supra* note 51, at 279–80.

90. Brian R. Edlin & Emily R. Winkelstein, *Can Hepatitis C Be Eradicated in the United States?*, 110 ANTIVIRAL RES. 79, 85 (2014).

91. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

92. See generally Lee, *Distributive Commons*, *supra* note 7, at 951–52; Peter Lee, *Patents and the University*, 63 DUKE L.J. 1, 31 (2013) [hereinafter Lee, *Patents and the University*].

compulsorily license a patent subject to the Act.⁹³ Notably, several of the statutory criteria for exercising march-in rights potentially implicate distributive considerations. The Act permits a federal agency to grant a nonexclusive, partially exclusive, or exclusive license if it determines that:

- (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; [or]
- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees.⁹⁴

These provisions, particularly the focus on “health or safety needs” clearly appear to authorize the use of march-in rights to promote access to patented technologies arising from federal funds.

While march-in rights have the potential to distributive taxpayer-funded, patented inventions more widely, federal agencies have been extremely reluctant to exercise these rights. In the past several decades, NIH has received march-in petitions to compulsorily license patents covering stem cell separation technology,⁹⁵ HIV/AIDS drugs,⁹⁶ a glaucoma medication,⁹⁷ and a treatment for Fabry disease,⁹⁸ but it has denied all of them. In so

93. 35 U.S.C. § 203 (2012).

94. 35 U.S.C. § 203(a)(1–3).

95. Office of the Dir., Nat’l Insts. of Health, Determination in the Case of Petition of CellPro, Inc., Aug. 1, 1997, available at <https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf> [<https://perma.cc/64FQ-DJAN>] [hereinafter NIH, CellPro Determination]; see Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095 (1999).

96. Office of the Dir., Nat’l Insts. of Health, In the Case of NORVIR Manufactured by Abbott Laboratories, Inc., July 29, 2004, at 1, available at <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf> [<https://perma.cc/LPV8-BQPJ>]; see David Malakoff, *NIH Weighs Demand to Force Sharing of AIDS Drug Patents*, 304 SCIENCE 1427, 1427 (2004); Office of the Dir., Nat’l Insts. of Health, Determination in the Case of Norvir Manufactured by Abbvie, Nov. 1, 2013, <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf> [<https://perma.cc/44TS-CQAB>]; Charlotte Harrison, *NIH Denies March-in Rights on Norvir Patent*, 12 NATURE REVS. DRUG DISCOVERY 898 (2013).

97. Essential Inventions, Petition to Use Authority under Bayh-Dole Act to Promote Access to Latanoprost, Jan. 29, 2004, at 1, available at <http://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf> [<https://perma.cc/38YK-A2JR>].

98. Office of the Dir., Nat’l Insts. of Health, Determination in the Case of Fabrazyme

doing, NIH has articulated a very broad conception of the “public availability” of particular federally funded inventions that (in the agency’s view) renders march-in rights inappropriate.⁹⁹ For instance, in rejecting CellPro’s petition to exercise march-in rights on federally funded, privately patented stem cell separation technology, NIH stated that Johns Hopkins and Baxter had taken “effective steps to achieve practical application” and measures to “reasonably satisf[y]” health and safety needs because the technology was technically commercially available, even though at high cost.¹⁰⁰ Similarly, in denying Essential Inventions’ petition to exercise march-in rights on latanoprost, a patented glaucoma medication, NIH observed that patent licensee Pfizer was making this medication commercially available and that march-in rights were inappropriate as a mechanism for reducing drug prices.¹⁰¹

While NIH and other funding agencies have been reluctant to exercise march-in rights, they face increasing pressure to do so. Members of Congress have urged federal agencies to utilize march-in rights to “respond to the soaring cost of pharmaceuticals.”¹⁰² In a letter to NIH, several members of Congress urged NIH to issue reasonable guidelines for exercising march-in rights to “discourage drug price gouging.”¹⁰³ Similarly, the Center for American Progress has recommended that the government utilize march-in rights to address excessively priced pharmaceuticals.¹⁰⁴ Furthermore, several scholars have argued for increased use of march-in rights to widen access to patented inventions arising from federal funds.¹⁰⁵ Broader use of march-in

Manufactured by Genzyme Corporation, Dec. 1, 2010, at <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf> [<https://perma.cc/EF7V-WVTE>].

99. Lee, *Distributive Commons*, *supra* note 7, at 955–57.

100. NIH, CellPro Determination, *supra* note 95, at 9.

101. Office of the Dir., Nat’l Insts. of Health, In the Case of Xalatan Manufactured by Pfizer, Inc., Sept. 17, 2004, at 5, *available at* <https://www.ott.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf> [<https://perma.cc/NHB4-L2C3>].

102. Letter from Rep. Lloyd Dogget to Sylvia Mathews Burwell, Sec’y Health & Human Sers. and Francis S. Collins, Dir. of the Nat’l Inst. of Health (undated), <https://perma.cc/U8RH-3WUF> [hereinafter Dogget Letter].

103. *Id.*

104. TOPHER SPIRO ET AL., *Enough is Enough: The Time Has Come to Address Sky-High Drug Prices*, CTR. FOR AM. PROGRESS 29 (Sept. 18, 2015), <https://www.americanprogress.org/issues/healthcare/reports/2015/09/18/121153/enough-is-enough/> [<https://perma.cc/4RLZ-7T3B>].

105. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 311 (2003); Lee, *Distributive Commons*, *supra* note 7; Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393, 442 (2006).

rights could significantly expand access to medicine in this country. One empirical study showed that 153 new FDA-approved drugs, vaccines, or new indications for existing drugs arose from research at public service research institutions,¹⁰⁶ which depend heavily on federal funding. Another empirical study found that federal funding played at least an indirect role in nearly half of all new drugs approved from 1998 to 2005.¹⁰⁷

B. Encouraging Technologies of High Social Value

In addition to increasing access to patented technologies, the patent system and related regimes also deviate from pure market allocation of resources by prioritizing certain socially valuable technologies over others. Drawing on the efficiency rationale discussed above,¹⁰⁸ the patent system largely relies on exclusive rights and market incentives to allocate resources for innovation. One theoretical benefit of market-based allocation relative to central planning is that the market can aggregate information from millions of consumer preferences to efficiently coordinate resources for innovation.¹⁰⁹ However, market allocation can be less than optimal when the market values a sweeter smelling deodorant or better advertising for toothpaste¹¹⁰ over technologies that serve substantive human needs. As Amy Kapczynski observes, “In an IP system, price influences not only who has access to such goods, but also which goods are produced in the first place.”¹¹¹ While the norm of technological neutrality suggests that the patent system should not interfere in market allocations, it sometimes intervenes to prioritize technologies of high social value. In so doing, the patent system advances distributive ends, directing social resources to create technologies that serve the needs of neglected populations.

106. Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 N. ENG. J. MED. 535, 535 (2011).

107. Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation*, 30 HEALTH AFF. 332, 332 (2011).

108. See *supra* Part I.

109. Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1, 11–14 (1969); F.A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519, 519 (1945); see Kapczynski, *supra* note 8, at 974–75 (describing and criticizing this argument).

110. George J. Papagiannis et al., *Toward a Political Economy of Educational Innovation*, 52 REV. ED. RES. 245, 258 (1982) (citing JOHN K. GALBRAITH, *ECONOMICS AND THE PUBLIC PURPOSE* (1973)).

111. Kapczynski, *supra* note 8, at 978; see Peter Lee, *Social Innovation*, 92 WASH. U. L. REV. 1, 69 (2014).

1. *The Patents for Humanity Program.* The United States Patent and Trademark Office (USPTO) explicitly encourages the creation of technologies that serve marginalized communities through its Patents for Humanity program. In 2010, the USPTO solicited comments for an initiative to consider “pro-business strategies for incentivizing the development and widespread distribution of technologies that address humanitarian needs.”¹¹² In 2012, the USPTO launched the Patents for Humanity program, which rewards patent applicants, patent holders, and licensees who utilize their patented technology “to address humanitarian needs among an impoverished population or further research by others on humanitarian technologies.”¹¹³ The program defines a “humanitarian issue” as “one significantly affecting the public health or quality of life of an impoverished population,”¹¹⁴ and it defines “humanitarian research” as “making patented technologies available to others for conducting research on a humanitarian issue.”¹¹⁵ The reward is somewhat unusual: awardees receive a certificate that can accelerate certain matters, such as ex parte examination and an appeal, within the agency itself.¹¹⁶ The USPTO also recognizes awardees at a ceremony at its offices and on its website.¹¹⁷

As its name and structure suggests, the Patents for Humanity program is clearly aimed at serving distributive interests. It diverges from pure market allocation of resources for technological development and explicitly rewards those that the USPTO has deemed particularly socially worthy. The program was part of President Obama’s broader development agenda,¹¹⁸ and it targets

112. Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57,261, 57,261 (2010).

113. Humanitarian Awards Pilot Program, 77 Fed. Reg. 6,544, 6,544 (2012).

114. *Id.* at 6,545.

115. *Id.*

116. *Id.* While the certificates are nontransferable, legislation introduced in 2012 (that was not enacted) would have allowed awardees to transfer certificates to other parties. See Patents for Humanity Program Improvement Act of 2012, S. 3652, 112th Cong. (2d Sess. 2012).

117. USPTO, *Patents for Humanity, Learn More* (Apr. 10, 2017, 10:29 AM), <https://www.uspto.gov/patent/initiatives/patents-humanity/learn-more> [<https://perma.cc/L3P5-9ACZ>]; see, e.g., USPTO, *Patents for Humanity, 2016 Award Recipients* (Apr. 10, 2017, 10:28 AM), <https://www.uspto.gov/patent/initiatives/patents-humanity/2016-award-recipients> [<https://perma.cc/B8CT-URDF>].

118. USPTO, *USPTO Launches Patents for Humanity Pilot* (Feb. 8, 2012), <https://www.uspto.gov/about-us/news-updates/uspto-launches-patents-humanity-pilot> [<https://perma.cc/84VL-WQV4>] [hereinafter USPTO, Patents for Humanity]; see THE WHITE HOUSE, *Fact Sheet: Harnessing Innovation for Global Development* (Feb. 8, 2012), <https://obamawhitehouse.archives.gov/the-press-office/2012/02/08/fact-sheet-harnessing-innovation-global-development> [<https://perma.cc/83ND-JP3B>].

inventions that serve marginalized communities. Examples of technologies that may be eligible for the award include diagnostic equipment, water sterilization devices, mosquito controls, and land mine detection systems.¹¹⁹ Regarding humanitarian research, potential technologies eligible for recognition include “patented molecules, drug discovery tools, gene sequencing or splicing devices, special-purpose seed strains, data analysis software, or other patented research material.”¹²⁰ Technologies produced by recent winners have included an improved process for producing meningitis vaccine, a low-cost malaria detection device, a simple diagnostic test for preeclampsia, and a passive cooler for vaccines.¹²¹

Given its distributive, humanitarian character, it is not surprising that the Patents for Humanity program has received significant support from public interest organizations. Groups like Knowledge Ecology International, Doctors Without Borders, Oxfam, and Public Citizen have lauded the program “for considering new mechanisms to encourage innovation and licensing of technologies for humanitarian purposes.”¹²² As Dan Burk observes, the program mitigates a particular type of market failure—a scarcity of technologies addressing humanitarian needs—over and above the “classic” market failure addressed by patents generally—the underproduction of public goods.¹²³ Furthermore, he argues that the program illustrates that “patent incentives can and sometimes should be nudged in a direction that benefits particular classes of consumers.”¹²⁴ Not surprisingly, some industry representatives, including those from the pharmaceutical sector, have been more skeptical, noting that the program contravenes “the fundamental principle of non-discrimination” within the patent system.”¹²⁵ While the

119. USPTO, Patents for Humanity, *supra* note 118; *see also* David Kappos, DIRECTOR’S FORUM: A BLOG FROM USPTO’S LEADERSHIP (Feb. 8, 2012) (identifying irrigation systems, vaccines, and weather-resistant crop strains as technologies that serve humanitarian objectives).

120. Patents for Humanity Program, 79 Fed. Reg. 18,670, 18,672 (2014).

121. USPTO, *USPTO Announces Patents for Humanity Winners* (Sept. 29, 2016), <https://www.uspto.gov/about-us/news-updates/uspto-announces-patents-humanity-winners-0> [<https://perma.cc/9V5Q-53NM>].

122. KNOWLEDGE ECOLOGY INTERNATIONAL ET AL., COMMENTS ON INCENTIVIZING HUMANITARIAN TECHNOLOGIES AND LICENSING THROUGH THE INTELLECTUAL PROPERTY SYSTEM, https://www.uspto.gov/sites/default/files/patents/law/comments/humanitarian_b_sanjuan2010nov19.pdf [<https://perma.cc/7B7Q-YF3T>]; *see* Rimmer, *supra* note 33, at 210.

123. Burk, *supra* note 19, at 28.

124. *Id.* at 36.

125. PHARMA, COMMENTS ON INCENTIVIZING HUMANITARIAN TECHNOLOGIES AND

program has attracted criticism for not providing sufficiently robust incentives to create humanitarian technologies,¹²⁶ it represents an incremental step in that direction.¹²⁷

2. *Prioritized Review for High-Value Patents.* While patent doctrine extols technological neutrality, the USPTO has long favored some technologies over others based on judgments of relative social value. As per guiding statute, the USPTO has broad authority to govern its own proceedings and “expedite the processing of patent applications.”¹²⁸ Thus, for instance, while the USPTO generally processes applications in the order that it receives them,¹²⁹ it can advance for examination applications of “peculiar national importance to some branch of the public service” when the head of a federal department requests immediate action.¹³⁰ Furthermore, applicants may submit a petition to advance an application out of turn if a claimed invention will materially:

- (i) Enhance the quality of the environment;
- (ii) Contribute to the development or conservation of energy resources; or
- (iii) Contribute to countering terrorism.¹³¹

In the past, the USPTO has also offered accelerated examination to recombinant DNA inventions, technologies related to HIV/AIDs and cancer, and certain biotechnological inventions

LICENSING THROUGH THE INTELLECTUAL PROPERTY SYSTEM, at 6, Nov. 19, 2010, https://www.uspto.gov/sites/default/files/patents/law/comments/humanitarian_b_sanjuan2010nov19.pdf [<https://perma.cc/7B7Q-YF3T>]; Rimmer, *supra* note 33, at 212.

126. Rimmer, *supra* note 33, at 221.

127. Other regulatory regimes, notably the FDA’s “priority review voucher” program, similarly encourage the development of drugs for neglected diseases by establishing transferable vouchers for priority FDA review and offering expedited processing. Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85, § 1102, 121 Stat. 972, (codified as amended at 15 U.S.C. § 301 (2012)); see David Ridley et al., *Developing Drugs for Developing Countries*, 25 HEALTH AFF. 313, 315 (2006) (estimating that priority review vouchers could be worth over \$300 million for a blockbuster drug); Rimmer, *supra* note 33, at 201; Lesley Hamming, *The Promise of Priority Review Vouchers as a Legislative Tool to Encourage Drugs for Neglected Diseases*, 11 DUKE L. & TECH. REV. 390 (2012). But see Aaron S. Kesselheim, *Drug Development for Neglected Diseases - The Trouble with FDA Review Vouchers*, 359 NEW ENG. J. MED. 1981, 1981 (2008) (criticizing priority review vouchers as not “directly connect[ing] the incentive with the innovation”).

128. 35 U.S.C. § 2(b)(2) (2006); Sarah Tran, *Patent Powers*, 25 HARV. J.L. & TECH. 609, 656–57 (2012) [hereinafter Tran, *Patent Powers*].

129. See MPEP § 708 (8th ed. 2001) (Rev. 7, July 2008) (“Nonprovisional applications shall be taken up for examination . . . in the order in which they have been filed except . . . pursuant to 37 CFR 1.102.”).

130. 37 C.F.R. 1.102(b).

131. 37 C.F.R. 1.102(c)(2)(i)–(iii).

from small entities.¹³² This route proved to be exceedingly popular, and the USPTO then implemented new rules for accelerated examination that curtailed participation but retained the notion of prioritizing review of high-value patents.¹³³ One instantiation of USPTO prioritization of certain “high-value” technologies was its Green Technology Pilot Program.¹³⁴ The USPTO implemented the program in December 2009 to advance out of turn qualifying applications pertaining to “environmental quality, energy conservation, development of renewable energy, or greenhouse gas emission reduction.”¹³⁵ Through various iterations, the USPTO added and removed certain requirements for participating in the program; while not perfect, the program represents a promising use of the patent system to prioritize review of inventions of high social value.¹³⁶ Departing from the principle of technological neutrality, these programs reflect policy determinations “that one particular class of technologies was more socially valuable than others.”¹³⁷

The America Invents Act (AIA), which Congress enacted in 2011, affirms the USPTO’s discretionary authority to prioritize review of certain applications. Under the AIA, the USPTO may prioritize examination of applications “for products, processes, or technologies that are important to the national economy or national competitiveness”¹³⁸ The initial proposal addressing this authority mentioned “green technologies designed to foster renewable energy, clean energy, biofuels, agricultural sustainability, environmental quality, conservation, or energy

132. See Tran, *Patent Powers*, *supra* note 128, at 657.

133. See Tran, *Expediting Innovations*, *supra* note 30, at 139–40 (describing and critiquing these changes).

134. See Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 64,666–67; *see also* Press Release, U.S. Patent & Trademark Office, The U.S. Commerce Department’s Patent and Trademark Office (USPTO) Will Pilot a Program to Accelerate the Examination of Certain Green Technology Patent Applications (Dec. 7, 2009), http://www.uspto.gov/news/pr/2009/09_33.jsp [<https://perma.cc/4UT8-FBV2>]; *see* MATTHEW RIMMER, INTELLECTUAL PROPERTY AND CLIMATE CHANGE: INVENTING CLEAN TECHNOLOGIES 163 (2011); *see* Tran, *Expediting Innovation*, *supra* note 30, at 143–47 (describing and critiquing the Green Technology Pilot Program).

135. Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 64,666, 64,666 (2009); USPTO, *Accelerated Review of Green Technology Patent Applications*, <https://www.uspto.gov/inventors/independent/eye/201106/tipgreentech.jsp> [<https://perma.cc/K373-BXS5>]; MPEP § 708.02(a) (VIII) (describing other requirements for “normal” accelerated examination).

136. Tran, *Expediting Innovation*, *supra* note 30, at 146.

137. Tran, *Patent Powers*, *supra* note 128, at 657.

138. America Invents Act, Pub. L. 112-29, § 25, 125 Stat. 284 (codified at 35 U.S.C. § 2(b)(2)(G)).

efficiency” as potential targets for prioritization.¹³⁹ However, these examples were stripped from the final version of the amendment, and the AIA provides “almost no guidance as to what factors the USPTO should consider” when prioritizing examination.¹⁴⁰ Rather, the USPTO must simply consider the rather vague standard of a technology’s impact on the national economy or national competitiveness.¹⁴¹

The application of social value judgments to prioritize examination for various technologies holds significant implications for distributive efforts. While the prioritized examination programs thus far have not targeted technologies explicitly aimed at serving marginalized communities, many of them have that indirect effect. For instance, unlike individual consumer goods like televisions, technologies that address environmental concerns, energy security, and terrorism generate large spillovers that benefit all members of society, including the least fortunate. At a more conceptual level, the authority vested in the USPTO to prioritize some technologies over others starkly departs from the patent system’s historic commitment to technological neutrality¹⁴² and opens the door for prioritizing technologies that directly address the needs of marginalized communities. It is also worth noting that the cost of distributive mechanisms can differ widely, and prioritized examination is a relatively inexpensive one. Unlike denying injunctive relief,¹⁴³ which can depress incentives to invent, prioritized examination can powerfully advance distributive interests—by reducing pendency and increasing the effective term of protection—with relatively little countervailing costs.¹⁴⁴

3. *The Orphan Drug Act.* Moving outside of the patent system, the Orphan Drug Act explicitly utilizes exclusive rights to promote the development of technologies that serve neglected populations.¹⁴⁵ Given the high cost of research, development, and regulatory compliance, pharmaceutical companies have traditionally focused on developing treatments for common

139. 157 CONG. REC. S1052–53 (daily ed. Mar. 1, 2011) (statement of Sen. Menendez regarding Amendment No. 124).

140. Tran, *Patent Powers*, *supra* note 128, at 614, 648.

141. *Id.* at 614.

142. *See supra* Part II.

143. *See supra* Part II.A.2.

144. I am indebted to Sarah Wasserman Rajec for this observation.

145. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.).

diseases affecting sizable patient populations.¹⁴⁶ In doing so, they have largely neglected diseases afflicting small patient populations, thus leaving these patients with few or no treatment options. To address this deficiency, Congress enacted the Orphan Drug Act in 1983. The Act amends the Food, Drug, and Cosmetic Act¹⁴⁷ and seeks to promote the development of treatments for “orphan” diseases, which the Act defines as those affecting less than 200,000 Americans or for which U.S. sales are unlikely to recover development costs.¹⁴⁸ The Act provides several incentives for generating such treatments, including tax credits, grants, fast-track development, access to the Investigational New Drug Program, and fee waivers for drug applications.¹⁴⁹ However, the most important incentive for stimulating orphan drug development is seven years of marketing exclusivity.¹⁵⁰ This exclusivity operates independently of any patent exclusivity and may even extend to medicines that are not patentable.

The distributive impetus of the Orphan Drug Act is quite clear, and it has been highly successful.¹⁵¹ Given that traditional market incentives (including patents) are insufficient to motivate the development of treatments for rare diseases, the additional exclusivity of the Act helps create a viable market for such treatments. The Act has produced over 2,000 orphan designations and over 300 approved orphan drugs,¹⁵² particularly oncology products as well as treatments for infectious and respiratory diseases.¹⁵³ In addition to meeting public health needs, the Act has also spurred significant economic activity; in 2008, 43 orphan-designated drugs had annual sales of greater than \$1 billion.¹⁵⁴ However, there is still significant need for orphan drugs, as NIH estimates that there may be as many as 7,000 rare

146. Olivier Wellman-Labadie & Youwen Zhou, *The US Orphan Drug Act: Rare Disease Research Stimulator or Commercial Opportunity?*, 95 HEALTH POL'Y 216, 216 (2010); Hamming, *supra* note 127, at 395–96.

147. Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 (1994).

148. 21 U.S.C. § 360ee(b)(2) (1994); Wellman-Labadie & Zhou, *supra* note 146, at 216.

149. Wellman-Labadie & Zhou, *supra* note 146, at 217.

150. Marlene E. Haffner et al., *Two Decades of Orphan Product Development*, 1 NATURE REVS. DRUG DISCOVERY 821, 821 (2002); OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., THE ORPHAN DRUG ACT—IMPLEMENTATION AND IMPACT 8 (2001), available at <https://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf> [<https://perma.cc/HW82-3Y74>].

151. See Haffner et al., *supra* note 150, at 821; OFFICE OF INSPECTOR GEN., *supra* note 150, at 7.

152. Wellman-Labadie & Zhou, *supra* note 146, at 217.

153. *Id.* at 218.

154. *Id.* at 221.

diseases that affect 25–30 million Americans,¹⁵⁵ and scientists characterize approximately 250 new rare diseases each year.¹⁵⁶ Interestingly, creating a market for treating rare diseases has had more than one distributive effect; in addition to serving a neglected cohort of patients, exclusivity under the Orphan Drug Act has helped small biotech firms attract venture financing and enter the market.¹⁵⁷ Although the Act has received criticism for not stimulating the development of treatments for rarer and less lucrative diseases (outside of cancers), it reflects the potential for exclusive rights to create viable markets for technologies to serve neglected populations.¹⁵⁸

C. Widening Access to the Patent System

Beyond opening access to technologies and prioritizing the development of socially valuable technologies, the U.S. patent system also seeks to widely distribute the fruits of the patent system by broadening participation in patent protection itself. From its roots as a highly democratic regime with relatively low barriers to entry,¹⁵⁹ the U.S. patent system has become highly corporatized and concentrated. In 1885, only 12 percent of patents were issued to corporations; by 1998, only 12.5 percent of patents were issued to independent inventors.¹⁶⁰ Furthermore, the share of patents held by small entities (defined as those with 500 or fewer employees) declined from 30% of patents in 1995 to 20% in 2009.¹⁶¹ As Dan Burk and Mark Lemley observe, “[t]he overwhelming majority of patents today are granted to large corporations, and even those granted to individuals and small

155. *FAQs About Rare Diseases*, NAT'L INSTS. OF HEALTH, (Aug. 11, 2016), <https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases> [https://perma.cc/EG3F-XY2].

156. Enrique Seoane-Vazquez et al., *Incentives for Orphan Drug Research and Development in the United States*, 3:33 ORPHANET J. OF RARE DISEASES *2 (2008), available at <https://ojrd.biomedcentral.com/articles/10.1186/1750-1172-3-33> [https://perma.cc/69J2-4B5Q].

157. See Haffner et al., *supra* note 150, at 824; Wellman-Labadie & Zhou, *supra* note 146, at 226. Additionally, orphan drug research and development creates positive scientific spillovers that accelerate research on more common conditions. *Id.*

158. *Id.* at 225.

159. ZORINA KHAN, *THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790–1920* (2005).

160. Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000*, 88 CAL. L. REV. 2187, 2215–17 (2000).

161. Scott Shane, *Patents Granted to Small Entities in Decline*, SMALL BUS. TRENDS (July 19, 2010), <https://smallbiztrends.com/2010/07/how-smart-is-the-average-entrepreneur.html> [https://perma.cc/T644-Y959].

corporations are often incubated in large research universities.”¹⁶² Turning to the demographics of individual inventors, “women are at every level pervasively absent from the patent system,”¹⁶³ and U.S. women patent at only 8% of the rate of men.¹⁶⁴ Furthermore, empirical studies reveal that minority-owned technology companies hold fewer patents than similar nonminority-owned companies.¹⁶⁵ To address these inequalities, a variety of distributive mechanisms are attempting to enhance participation and diversity in the patent system.

1. *Small and Micro Entity Fee Reductions.* One way in which the patent system widens access to patenting is by charging lower fees to small entities. Patent applicants and grantees pay a variety of fees to the USPTO covering filing, search, examination, issuance, and maintenance.¹⁶⁶ As early as 1983, the appropriations bill for the USPTO allocated funds to reduce fees paid by independent inventors, nonprofits, and small businesses by 50%.¹⁶⁷ In 1999, Congress enacted the American Inventors Protection Act (AIPA),¹⁶⁸ which provided that the USPTO “shall recognize the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities.”¹⁶⁹ Accordingly, the USPTO offers small entities a 50% fee reduction.¹⁷⁰ The USPTO recognizes two classes of small entities: 1) for-profit entities of not more than 500

162. DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 41 (2009) [hereinafter BURK & LEMLEY, *PATENT CRISIS*]; see also John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099 (2000). With the rise of software patents, ownership of patents shifted somewhat back to individuals and small firms. Duncan Davidson, *Reverse Engineering Software under Copyrights Law: The IBM PC Bios*, in *OWNING SCIENTIFIC AND TECHNICAL INFORMATION: VALUE AND ETHICAL ISSUES*, 147–69 (Vivian Weil & John Snapper eds., 1989).

163. Burk, *supra* note 19, at 31; see Saurabh Vishnubhakat, *Gender Diversity in the Patent Bar*, 14 J. MARSHALL REV. INTELL. PROP. L. 67 (2014).

164. Jennifer Hunt et al., *Why are Women Underrepresented Amongst Patentees?*, 42 RES. POL'Y 831, 831 (2013); see also Waverly W. Ding et al., *Gender Differences in Patenting in the Academic Life Sciences*, 313 SCIENCE 665, 665 (2006) (finding women faculty members in the life sciences patent at about 40 percent the rate of comparably situated men).

165. 157 CONG. REC. H4484 (daily ed. June 23, 2011) (statement of Rep. Moore).

166. Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 78 (2013).

167. Pub. L. 97-237, 96 Stat. 317 (1982); see 128 CONG. REC. H3203 (1982).

168. See American Inventors Protection Act, Pub. L. No. 106-113, §§ 4711–4712, 113 Stat. 1501A-552, at 1501A-572 to 1501A-575 (1999).

169. *Id.* § 4712 (as codified at 35 U.S.C. § 2(b)(E) (2012)).

170. 35 U.S.C. § 41(h)(1) (2012).

persons that have not assigned invention rights to entities other than other small entities, independent inventors, and nonprofits and 2) independent inventors and nonprofit organizations.¹⁷¹

With the enactment of the AIA in 2011, Congress further enhanced access to the patent system for even smaller entities. To counter perceptions that the transition to a first-inventor-to-file system would disadvantage small inventors,¹⁷² the AIA created a new category of “micro entities.”¹⁷³ The distributive impetus for this change is quite clear; as the legislative history notes, “[a]s part of the ongoing effort to nurture U.S. innovation, Congress has long recognized that certain groups, including independent inventors, small business concerns, and non-profit organizations (collectively referred to as ‘small business entities’) should not bear the same financial burden for filing patent applications as larger corporate interests.”¹⁷⁴ The AIA retains the existing 50% fee reduction for small entities but reduces fees by 75% for micro entities,¹⁷⁵ which the legislative history of the Act characterizes as “only true, independent inventors.”¹⁷⁶

Notably, income plays a central role in defining one class of micro entities. Such entities must satisfy the criteria for small entities, must not be the named inventors on more than four previously filed patent applications, and must not have had a gross income exceeding three times the median household income in the year prior to filing an application.¹⁷⁷ These criteria prevent wealthy corporate interests, patent trolls, and “repeat players” (even those who are small, independent inventors) from qualifying

171. 13 C.F.R. § 121.802; 35 U.S.C. § 41(h)(1).

172. See Letter from Todd O. McCracken, President, Nat’l Small Bus. Ass’n to Susy Tsang-Foster, Legal Advisor, Office of Patent Legal Admin. USPTO (Oct. 5, 2012), http://www.uspto.gov/patents/law/comments/nsba_20121005.pdf (“By repealing the invention date as the priority date, compared to prior art, the AIA will dramatically increase the pressure on small businesses to establish filing date priority and require them to file more frequently and at every stage of development without the opportunity to perfect their inventions. The costs of these filings (including the hiring of patent attorneys, new patenting costs, etc.) and the considerable amount of time involved with more frequent invention reviews, preparation and related filings will be felt most strongly by the small business community.”); see David S. Abrams & R. Polk Wagner, *Poisoning the Next Apple? The America Invents Act and Individual Inventors*, 65 STAN. L. REV. 517, 521 (2013) (finding a decrease in patenting by individual inventors when Canada switched from a first-to-invent to a first-to-file system).

173. INVENTORSEYE, *AIA Changes: Micro Entity New Fees*, USPTO (Feb. 2013), <https://www.uspto.gov/custom-page/inventors-eye-advice> [<https://perma.cc/VY7A-7Z4Y>].

174. H.R. REP. NO. 112-91(I), at 80 (2011).

175. 37 C.F.R. § 1.16.

176. S. REP. NO. 111-18, at 22 (2009).

177. 35 U.S.C. § 123(a)(3) (2012).

as micro entities.¹⁷⁸ Interestingly, university scientists may also qualify as micro entities, which include applicants employed by higher education institutions or under an obligation to assign patent rights to such institutions.¹⁷⁹ While fee reductions have received criticism as neglecting the largest barrier to accessing the patent system—the expense of a patent attorney or agent¹⁸⁰—they represent an incremental step toward broadening participation.

2. Technical Assistance for Small Entities and Unrepresented Inventors. The USPTO widens access to the patent system in other ways as well. In 2009, the USPTO began developing a Patents Ombudsman Pilot Program, which provided direct access to a USPTO staff member to assist pro se applicants or their representatives during prosecution.¹⁸¹ Additionally, the AIA directed the USPTO to create a “Patent Ombudsman Program for Small Business Concerns” that shall provide “support and services relating to patent filings to small business concerns and independent inventors.”¹⁸² According to Representative Lamar Smith, “small businesses will always have a champion at the [USPTO] looking out for their interests and helping them as they secure patents for their inventions.”¹⁸³

The USPTO also operates pro bono and pro se programs to assist independent and unrepresented inventors. The AIA requires the Director of the USPTO to “work with and support intellectual property law associations across the country in the establishment of pro bono programs designed to assist financially under-resourced independent inventors and small businesses.”¹⁸⁴ Starting with a highly successful pilot program in Minnesota,¹⁸⁵

178. 35 U.S.C. § 123; see Daniel A. Tagliente, *Shooting Blanks: The Ineffectiveness of the Executive Branch’s Entrance into the Great Patent Troll Hunt*, 45 SETON HALL L. REV. 311, 319 (2015).

179. 35 U.S.C. § 123(d)(2).

180. Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1311 (2009) (reporting survey finding that respondents paid more than \$38,000 to acquire their most recent patent).

181. See Request for Comments on Patents Ombudsman Pilot Program, 74 Fed. Reg. 55,212 (2009).

182. Pub. L. No. 112-29 § 28, 125 Stat. 339 (2011); see *Patents Ombudsman Program*, USPTO <https://www.uspto.gov/patent/ombudsman-program> [<https://perma.cc/2EQ6-YNPN>].

183. 157 CONG. REC. H4424 (daily ed. June 22, 2011) (statement of Rep. Smith).

184. Pub. L. No. 112-29, § 32, 125 Stat. at 340; see John Calvert, *Pushing Ahead with the Pro Bono Assistance Program*, 12 J. MARSHALL REV. INTELL. PROP. L. 286 (2013); Jennifer M. McDowell & Saurabh Vishnubhakat, *The USPTO Patent Pro Bono Program*, 7 CYBARIS INTELL. PROP. L. REV. 1 (2015).

185. See Calvert, *supra* note 184.

the USPTO's Patent Pro Bono Program now encompasses a network of nonprofit organizations serving all 50 states.¹⁸⁶ The program connects independent inventors who make less than three times the federal poverty level with local and regional nonprofits to provide legal advice and technical assistance.¹⁸⁷ Additionally, the USPTO operates a pro se program for inventors lacking legal assistance. The program offers technical assistance and even maintains a separate art unit to serve such applicants.¹⁸⁸

3. *USPTO Study on Diversity of Applicants.* Beyond entity size, there are further movements to enhance participation in the patent system. For instance, the AIA requires the USPTO to “establish methods for studying the diversity of patent applicants, including those applicants who are minorities, women, or veterans.”¹⁸⁹ It is important to mention a caveat regarding this study, as the AIA expressly states that “[t]he Director shall not use the results of such study to provide any preferential treatment to patent applicants.”¹⁹⁰ In 2012, the USPTO published its methodology, observing that it is “committed to responding adequately to the concerns of Congress and the increasing need of the innovation economy to analyze and understand how the various parts of the Federal Government are responding to the needs of innovators.”¹⁹¹ The methodology involved matching patent applicant data with data from the Census Bureau's Center for Economic Studies, which was only able to match 64.3% of inventors provided by the USPTO.¹⁹² In 2013, the USPTO solicited input from the public at large,¹⁹³ and it published its findings in 2015.¹⁹⁴ The analysis covered both individual characteristics, such

186. *Id.*

187. *Inventors*, USPTO, <https://www.uspto.gov/patents-getting-started/using-legal-services/pro-bono/inventors> [<https://perma.cc/964C-R6PB>]; see Pro Bono Survey, 80 Fed. Reg. 27,150 (May 12, 2015) (requesting comments on a proposed survey to determine the effectiveness of regional pro bono hubs).

188. *Pro Se Assistance Program*, USPTO, <https://www.uspto.gov/patents-getting-started/using-legal-services/pro-se-assistance-program> [<https://perma.cc/K2PA-8K8B>].

189. Pub. L. No. 112-29 § 29, 125 Stat. 339 (Sept. 16, 2011).

190. *Id.*

191. USPTO, *Diversity of Applicant Methodology* (Mar. 16, 2012), https://www.uspto.gov/sites/default/files/aia_implementation/20120316-diversity_of_applicant_methodology.pdf [<https://perma.cc/NUF8-9WYA>].

192. USPTO, STUDY AND REPORT ON THE IMPLEMENTATION OF THE LEAHY-SMITH AMERICA INVENTS ACT 48 (2015).

193. Request for Comments on Methods for Studying the Diversity of Patent Applicants, 78 Fed. Reg. 72,064 (Dec. 2, 2013).

194. USPTO, MEMORANDUM ON THE STUDY OF DIVERSITY AMONG PATENT APPLICANTS (2015), <https://www.uspto.gov/sites/default/files/documents/Determination%20on%20Diversity%20of%20Applicants.pdf> [<https://perma.cc/S33Q-RSM5>].

as race, gender, age, and geography, as well as business characteristics, such as revenues, number of employees, and geography.¹⁹⁵

While the AIA specifically disclaims the use of these data to extend preferential treatment to certain classes of patent applicants, the development of outreach efforts is a logical next step. In introducing the amendment to develop methods to study diversity, Representative Gwen Moore applauded existing efforts by the USPTO to reach out to the Women's Chamber of Commerce and the National Minority Enterprise Development Conferences "to try to increase diversity with utilizing the patent process."¹⁹⁶ Representative Moore further cited empirical studies showing that minority-owned technology companies hold fewer patents than comparable nonminority businesses.¹⁹⁷ She also noted the example of celebrated African-American inventor George Washington Carver as well as controversies over whether Eli Whitney or slaves had invented the cotton gin to emphasize the importance of diversity and inclusiveness in the patent system.¹⁹⁸ Rep. Moore further observed that "[u]ntil we can truly understand the nature of this problem, we cannot address it or do the appropriate outreach."¹⁹⁹ Other stakeholders in the patent system, including the American Intellectual Property Law Association, also regard data gathering as an important first step in reaching out to underrepresented groups.²⁰⁰

IV. DISTRIBUTIVE OBJECTIVES AS PROGRESS

A. *General Principles*

While U.S. patent system is commonly understood as a value-neutral regime that utilizes strict exclusive rights and markets to coordinate the development and dissemination of inventions, it often diverges from this model. The previous Part demonstrated that, as a descriptive matter, the domestic patent system already contains numerous distributive mechanisms.

195. *Id.* at 2.

196. 157 CONG. REC. H9937–38 (daily ed. June 23, 2011) (statement of Rep. Moore).

197. *Id.*

198. *Id.* at H9938

199. *Id.*

200. American Intellectual Property Law Association, Comment Letter in Response to "Request for Comments on Methods for Studying the Diversity of Patent Applicants," 78 Fed. Reg. 72,064 (Dec. 2, 2013), at 2 (Jan. 31, 2014) ("We hope that the collection and analysis of data on the diversity of patent applicants encourages the USPTO to develop outreach efforts that target specific groups of underrepresented patent applicants.").

This Part shifts to normative considerations, arguing that enhancing access to patented technologies, prioritizing technologies that serve marginalized communities, and creating special rules to increase inclusiveness and diversity among patentees are not only fully consistent with the patent system's overarching goals, but also affirmatively support them.

At the most foundational level, the constitutional objective to promote “progress” can encompass many formulations of a patent system beyond a narrow preoccupation with exclusive rights, market value, and technological neutrality.²⁰¹ The Supreme Court has recognized that the objective of promoting progress both defines and limits Congress's power to establish a patent system,²⁰² but it has not precisely delineated what this term means.²⁰³ In the absence of a guiding interpretation, “there is no particular limitation explicit in the constitutional text or concept of progress that constrains it to advancement of economic value, or to promoting ever more capacious levels of creative output.”²⁰⁴ The Supreme Court has identified several public policy goals beyond technological advancement within the patent system's broad charge to promote progress, such as increasing employment and enhancing social welfare:

The patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development. The productive effort thereby fostered 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.²⁰⁵

Perhaps the most plausible interpretation of progress is that it encompasses multiple objectives. Certainly, a

201. Malla Pollack, *What is Congress Supposed to Promote?: Defining “Progress” in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 NEB. L. REV. 754, 756 (2001) (identifying four different meanings of “progress” prevalent at the framing of the Constitution); Chon, *Progress*, *supra* note 36, at 99.

202. See *Graham v. John Deere*, 383 U.S. 1, 5 (1966); see also Dotan Oliar, *Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Power*, 94 GEO. L.J. 1771, 1776–77 (2005) (arguing that the framers of the IP clause intended it to limit Congress's power).

203. Pollack, *supra* note 201, at 766 (observing that the Supreme Court has never construed “progress” in this context); Simone A. Rose, *The Supreme Court and Patents: Moving Toward a Postmodern Vision of “Progress”?*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1197, 1203 (2013).

204. Burk, *supra* note 19, at 28.

205. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974).

commonplace understanding of “progress” could include promoting wide access to technologies, developing technologies to serve substantive social needs, and broadening participation in the patent system.²⁰⁶ Drawing on historical sources, Malla Pollack has argued that at the time of the framing of the Constitution, “progress” was best understood as “spread” or “diffusion” rather than substantive technical innovation.²⁰⁷ Moving beyond originalism, other commentators have argued for a postmodern conception of progress that promotes distributive fairness and humanitarian values.²⁰⁸ As Brad Sherman has observed, “While there is no denying the important role that patents play in macro-economic policy, there is no reason why the patent system, as a regulatory tool, should only be used in the pursuit of economic ends, nor any reason why ‘external’ factors such as the impact of technology on the environment or health should not fall within the core remit of the patent system.”²⁰⁹

Among various conceptions of progress, the normative principle of utilitarianism has gained ascendancy among commentators.²¹⁰ However, close inspection reveals that this is usually a crabbed and narrow vision of utilitarianism that means maximizing *innovation* rather than *utility*. Indeed, a faithfully utilitarian view of the patent system demands rather than eschews sensitivity to distribution.²¹¹ At a foundational level, the objective of maximizing social utility can require redistribution of resources, particularly given the principle of diminishing marginal utility. Where someone’s millionth dollar increases her welfare less than the thousandth dollar received by someone else, total utility increases by distributing wealth from the former to the latter (though, of course, the prospects for long-term social welfare depend on whether and to what

206. Cf. Yanisky-Ravid, *supra* note 3, at 6 (arguing that intellectual property laws were originally based on principles of distributive justice and only later became coopted by law and economics).

207. Pollack, *supra* note 201, at 755; cf. *Golan v. Holder*, 565 U.S. 302, 327 (2012) (“The provision of incentives for the creation of new works is surely an essential means to advance the spread of knowledge and learning.”).

208. Chon, *Progress*, *supra* note 36, at 101–02; Rose, *supra* note 203, at 1247.

209. Brad Sherman, *Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery*, 25 EUR. INTELL. PROP. REV. 301 (2003).

210. See, e.g., Burk & Lemley, *supra* note 31 at 1578 (“[M]ost theorists agree on the general utilitarian framework of patent law.”).

211. Cf. Burk, *supra* note 19, at 28 (“Even within a conventional utilitarian framework, an increase in non-monetary benefits such as happiness or dignity might represent progress in social welfare, as more people would consider themselves better off.”).

extent redistribution compromises incentives to generate wealth).²¹² Along similar lines, utilitarian theorists have long observed that redistributing healthcare resources in ways that deviate from market allocations maximizes overall social welfare.²¹³ Analogously, within certain parameters, redistributing the gains of technological innovation from wealthier to less wealthy individuals tends to enhance overall social welfare.

Even if enhancing access to patented technologies depresses incentives to invent, they may be justified based on net gains to social welfare. As such, a market-based system with distributive safeguards produces greater social utility than one lacking such safeguards. While patent doctrine tends to favor bright-line rules and formalism,²¹⁴ utilitarian analyses are necessarily holistic and involve difficult tradeoffs regarding whether strict exclusive rights ultimately increase or decrease social welfare.²¹⁵ Here, economics can help shore up the argument for distributive mechanisms in the patent system. As Ian Ayres and Paul Klemperer have argued, the last increment by which patentees raise prices harms social welfare more than it helps (and motivates) a patentee.²¹⁶ Thus, for instance, reducing the probability of enforcing a patent, which will decrease incentives to invent, may actually increase overall welfare because of the significant social gains of enhanced access to that patented technology.

While such cost-benefit analyses are difficult to calculate, a net gain from relaxed exclusivity is particularly likely where the technology serves a high social need, such as with patented pharmaceuticals. Health is central to human flourishing and economic productivity, and Joseph Stiglitz has observed that “intellectual property regimes that create monopoly rents that

212. See William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 604 (2007) (“An essential, and relatively uncontroversial, component of the standard utilitarian argument for egalitarianism is the principle of diminishing marginal utility.”); cf. Arti K. Rai, *Pharmacogenetic Interventions, Orphan Drugs, and Distributive Justice: The Role of Cost-Benefit Analysis*, 19 SOC. PHIL. & POL’Y 246, 254 (2002) [hereinafter Rai, *Distributive Justice*].

213. Rai, *Distributive Justice*, *supra* note 212, at 254. Relatedly, studies reveal that inequality harms health outcomes for all members of a society, not just those who are poor. RICHARD G. WILKINSON, *UNHEALTHY SOCIETIES: THE AFFLICTIONS OF INEQUALITY* (1996).

214. See Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 25–29 (2010).

215. Cf. Olson, *supra* note 27, at 184.

216. Ian Ayres & Paul Klemperer, *Limiting Patentees’ Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 989 (1999).

impede access to health both create inequality and hamper growth more generally.”²¹⁷ Economists note that improved public health generates significant positive externalities.²¹⁸ However, within a complete, holistic utilitarian calculus, the benefits of enhancing health outcomes are not *external* to patent policy and should weigh in favor of selectively tempering exclusive rights

A focus on maximizing social utility also corrects for price-based biases in the market. The current patent system is configured to allocate resources for invention based on market value. But patents “fare poorly when market signals are weak proxies for social value.”²¹⁹ While market value is an appropriate and perhaps necessary proxy for social value in most instances, by definition market utility will sometimes differ from social utility.²²⁰ Given that a system constructed to maximize the former will not always maximize the latter, some correctives are necessary to maximize social utility. Thus, for instance, while the market may demand an app that allows people to find the cheapest airfare, an app that allows people to find the cheapest groceries may have much greater social utility, yet would be neglected. Distributive correctives can contribute to greater social value in the allocation of inventive resources than pure market allocation alone.

Relatedly, even if one adopts a specific conception of utilitarianism as maximizing efficiency, this too is fully consistent with and even demands distributive measures in the patent system. While commentators posit a conflict between efficiency and distributive justice,²²¹ that is not necessarily the

217. Joseph E. Stiglitz, *How Intellectual Property Reinforces Inequality*, N.Y. TIMES (July 14, 2013, 9:04 PM), <https://opinionator.blogs.nytimes.com/2013/07/14/how-intellectual-property-reinforces-inequality/>; cf. Lee, *Distributive Commons*, *supra* note 7, at 936–37 (exploring the “infrastructural” nature of health technologies).

218. Cf. David Woodward & Richard D. Smith, *Global Public Goods and Health: Concepts and Issues*, WORLD HEALTH ORG. 8, http://www.who.int/trade/distance_learning/gpgh/gpgh1/en/ [<https://perma.cc/DH7G-2KGS>].

219. Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303, 328 (2013).

220. Lemley, *Free Riding*, *supra* note 1, at 1083.

221. See Ghosh, *supra* note 15, at 859 (“Understanding intellectual property within the framework of distributive justice is a direct challenge to current trends to turn intellectual property into a proprietary system that supports a network of licenses.”); Morton J. Horowitz, *Conceptualizing the Right of Access to Technology*, 79 WASH. L. REV. 105, 107 (2004) (“[L]egal advocates who strive to craft a right of access of technology need to realize that they are swimming upstream against a vigorous counter current.”); cf. Tran, *Expediting Innovation*, *supra* note 30, at 133 (noting that socially valuable technologies such as those that address climate change generate significant public benefits beyond those enjoyed by the inventors).

case. For instance, full employment is one goal where equity and efficiency mutually support each other.²²² Indeed, distributive measures can actually enhance efficiency by mitigating the inefficiencies inherent in exclusive rights. The technical information at the heart of patented technologies is a public good, meaning it is nonrival and nonexcludable. Given that information can be consumed without diminishing its availability, the most efficient allocation of existing information is open access. However, the patent system introduces static allocative inefficiency by subjecting nonrival assets to exclusive rights.²²³ Distributive measures can widen access to resources that do not naturally exhibit scarcity, thus enhancing static efficiency.

Relatedly, economists have long recognized that monopoly pricing, which restricts supply and increases prices, creates deadweight loss.²²⁴ In essence, exclusive rights prevent a range of welfare-enhancing exchanges from taking place in order to maintain an artificially inflated price. Price discrimination, which can allow lower-income populations to pay lower prices for a good, can improve both distribution and incentives to invent, assuming that arbitrage is not sufficiently problematic.²²⁵ Enhanced access to certain patented technologies may increase another type of efficiency as well. The lure of supracompetitive profits from exclusive rights can induce wasteful “patent races” where parties engage in costly and duplicative efforts to obtain patent rights, thus distorting the allocation of resources for technological development.²²⁶ Reducing the economic value of some patents may increase efficiency by mitigating such races.²²⁷ In sum, considerations of progress, utilitarianism, and efficiency all favor distributive safeguards within a largely market-based patent system.

Of course, a well-established law and economics literature argues that legal rules should focus simply on promoting efficiency (as it is defined in that field) and leave distributive considerations to the tax-and-transfer system.²²⁸ Applied to

222. Arrow, *supra* note 47, at 139.

223. Cf. Rai, *Distributive Justice*, *supra* note 212, at 268 (“Under standard economic theory, patents are, almost by definition, an inefficient mechanism for stimulating innovation.”).

224. Olson, *supra* note 27, at 183.

225. See Brennan et al., *supra* note 51, at 279.

226. Golden, *Principles*, *supra* note 3, at 517.

227. See Brennan et al., *supra* note 51, at 322; Golden, *Principles*, *supra* note 3, at 517.

228. See, e.g., Kaplow & Shavell, *supra* note 47; see Yanisky-Ravid, *supra* note 3, at 25

patent law, this theory suggests that the patent system should simply maximize innovative output, leaving the government to tax patentees and use the proceeds to subsidize access to technologies for low-income communities. However, this theory is subject to several critiques. First, this theory mistakenly assumes a conflict between efficiency and redistribution.²²⁹ However, the previous analysis shows that distributive mechanisms actually enhance efficiency by exploiting the principle of diminishing marginal utility, generating spillovers from enhanced access to technologies, mitigating static inefficiency, and reducing deadweight loss. Second, this theory misunderstands the overarching aim of patent law. As widely understood, the patent system is a utilitarian system aimed at maximizing social welfare, and faithful application of utilitarian principles demands attention to distribution as well as overall innovative output.²³⁰ Third, a patent system utilizing market incentives to maximize innovation would neglect entire swaths of technologies particularly relevant to low-income communities. Even assuming the existence of a robust tax-and-transfer system to widen access to patented technologies, such a system may never even develop critical technologies in the first place.²³¹ Fourth, this theory is overly optimistic about the political feasibility of using the tax-and-transfer system to subsidize access to patented technologies. Given the political realities of the day, shoring up distributive mechanisms within the patent system is likely more feasible than relying on the political process to allocate tax funds to enhance access to patented technologies.²³²

Shifting to a very different perspective, characterizing patent law as a system of property rights further enhances the appropriateness of distributive safeguards. Setting aside progress, utilitarianism, and efficiency, traditionalists might justify a purely market-based patent system as representing a system of voluntary exchanges based on private property rights.²³³ As a preliminary response, it bears emphasizing that

(reciting arguments supporting this view).

229. See, e.g., Kaplow & Shavell, *supra* note 47, at 669 (characterizing a rule “intended to help achieve a redistributive goal” as an “inefficient legal rule”).

230. See Olson, *supra* note 27, at 183 n.1.

231. See Lee, *Distributive Commons*, *supra* note 7, at 996–97.

232. See also Yanisky-Ravid, *supra* note 3, at 26 (noting that wealthy individuals currently bear a disproportionately small tax burden, thus undermining the effectiveness of relying on the tax-and-transfer system to redistribute wealth).

233. Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 717–19 (2007).

the patent system is a regulatory system aimed at promoting technological progress, not ensuring entitlements to ironclad property rights.²³⁴ Going further, however, even if one accepts a characterization of patents as property rights, this actually *enhances* the appropriateness of subjecting them to distributive measures. The “patents-as-property” argument that patents are absolute exclusive rights rests upon an inaccurate and caricatured vision of property. Property rights are never inviolate and are frequently subject to distributive pressures.²³⁵ For instance, taxes and eminent domain reveal that “property law is not entirely hostile to redistribution, even mandatory redistribution, despite moral critiques to the contrary.”²³⁶ Furthermore, progressive property theorists argue that the social nature of property encompasses sensitivity to the equitable distribution of resources.²³⁷

Courts and commentators have carried forward this more nuanced, contingent vision of property to patent law. The Supreme Court has recognized that characterizing patents as property does not suggest that patentees are entitled to an injunction upon a finding of infringement.²³⁸ Michael Carrier has synthesized over fifty property doctrines to argue that intellectual property rights may be curtailed to serve interests of development, necessity, and equity.²³⁹ Drawing on historical sources, Maggie Chon argues that the conception of patents as property held by James Madison and Thomas Jefferson emphasized the right to access knowledge and skepticism of strict exclusivity.²⁴⁰ In sum, characterizing patents as a kind of property right strengthens rather than diminishes the appropriateness of subjecting them to distributive principles.

234. First, *supra* note 22, at 368 (“[W]e need to approach issues involving . . . intellectual property law in general, from the point of view of protecting the public policy behind intellectual property law, not from the point of view of protecting the private rights of an ‘innovator.’”).

235. Cf. Morris R. Cohen, *Property and Sovereignty*, 13 CORNELL L.Q. 8, 19 (1927) (“Property owners, like other individuals, are members of a community and must subordinate their ambition to the larger whole of which they are a part.”).

236. Carol M. Rose, *The Moral Subject of Property*, 48 WM. & MARY L. REV. 1897, 1914 (2007).

237. See, e.g., Ezra Rosser, *The Ambition and Transformative Power of Progressive Property*, 101 CAL. L. REV. 107 (2013).

238. *eBay v. MercExchange L.L.C.*, 547 U.S. 388, 392 (2006) (“But the creation of a right is distinct from the provision of remedies for violations of that right.”)

239. Michael A. Carrier, *Cabining Intellectual Property through a Property Paradigm*, 54 DUKE L.J. 1 (2004).

240. Chon, *Progress*, *supra* note 36, at 143–44.

Relatedly, considerations of moral and political legitimacy also weigh in favor of distributive safeguards within a largely market-oriented patent system. Shubha Ghosh emphasizes the “conventional welfarist assumption in normative economics that for most problems we need to consider efficiency and distributive goals together, and design governance institutions to reach a desirable (i.e., politically justifiable) mix of efficiency and distributive justice.”²⁴¹ Economist Kenneth Arrow similarly observes that “while a market economy excels in generating productive efficiency, no social institution has ever felt justified solely by material product.”²⁴² Thomas Merrill and Henry Smith remind us that “no system of property rights can survive unless property ownership is infused with moral significance,”²⁴³ and perceptions of injustice can motivate people to flout intellectual property rights.²⁴⁴ The moral legitimacy of the patent system also implicates notions of corrective justice; given that the patent system incorporates systemic biases against several marginalized classes,²⁴⁵ mechanisms to promote access to inventions and inventive opportunities shore up the patent system’s legitimacy. In a broader sense, distributive mechanisms implicate political process questions. Several of the mechanisms described here arose from interest-group lobbying; for example, the American Medical Association pushed to curtail patents on medical procedure patents,²⁴⁶ and independent inventors and universities lobbied for micro-entity fee reductions.²⁴⁷ Perhaps the best way to shore up distributive mechanisms in the patent system is to ensure wide participation in the political process for groups representing diverse views and interests, including those who seek greater distribution of the fruits of the patent system.

Ultimately, arguments based on progress, utilitarianism, efficiency, property rights, and political legitimacy produce a compelling case for infusing the U.S. patent system with distributive mechanisms. While these arguments provide broad rationales for enhancing access to essential technologies, developing technologies to serve marginalized communities,

241. Ghosh, *supra* note 15, at 871.

242. Arrow, *supra* note 47, at 138.

243. Merrill & Smith, *supra* note 4, at 1850.

244. Rose, *supra* note 236, at 1908.

245. Burk, *supra* note 19, at 29–30.

246. *See supra* Part II.A.1.

247. *See supra* Part II.C.1.

and broadening participation in the patent system, the following Section delves further into each of these areas.

B. *Specific Applications*

Moving from general principles to specific applications, the case for enhancing access to patented pharmaceuticals and diagnostics is particularly strong because of their centrality to human health and significant economic impact.²⁴⁸ Furthermore, there are sometimes sharp disparities between patent-inflated prices and the cost of developing these technologies.²⁴⁹ Pharmaceuticals comprise one of the most profitable industries, with profit margins for some companies estimated at 42%.²⁵⁰ To take one example, Gilead's patented treatment for HCV earned \$36 billion in its first three years, and its price far exceeds per unit costs of invention and production.²⁵¹ Tellingly, Gilead set its initial prices without reference to the actual cost of drug development, instead relying on a complex calculation involving the estimated "public outcry" from various potential prices.²⁵²

Where distributive measures do not unduly harm incentives to invent, significant welfare gains from increased access may justify curbing exclusive rights. In their letter to NIH arguing for increased use of march-in rights under the Bayh-Dole Act, members of Congress contended that "[b]ecause these rights would only be used when wrongdoing occurs, innovation should not be threatened."²⁵³ In particular, march-in rights are an especially compelling distributive mechanism because for these technologies, taxpayer funds have already

248. Healthcare spending represents one-fifth of the U.S. economy, and a substantial portion of that (\$297.7 billion in 2014) is spent on pharmaceuticals. Brennan et al., *supra* note 51, at 277. This is not an exhaustive list, as other technologies, such as those enhancing agricultural output, are also appropriate subjects for wide distribution. See Lee, *Distributive Commons*, *supra* note 7, at 919.

249. See Brennan et al., *supra* note 51, at 319 (advocating use of the § 1498 power when supracompetitive prices are likely to exceed risk-adjusted technological development costs and the public health benefits of enhanced access are substantial).

250. Liyan Chen, *Best of the Biggest: How Profitable Are the World's Largest Companies?*, FORBES (May 13, 2014, 9:50 AM), <https://www.forbes.com/sites/liyanchen/2014/05/13/best-of-the-biggest-how-profitable-are-the-worlds-largest-companies/>; see also Mark G. Edwards, *Biotechnology and Pharmaceutical Commercialization Alliances: Their Structure and Implications for University Technology Transfer Offices*, in 2 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION 1227, 1230 (Anatole Krattiger et al. eds., 2007) (noting that gross margins for pharmaceuticals regularly range from 75–95 percent for marketed drugs).

251. Brennan et al., *supra* note 51, at 278.

252. *Id.* at 290–91.

253. Dogget Letter, *supra* note 102.

subsidized research and development. More generally, as Dan Burk and Mark Lemley usefully remind us, “it is not necessary to capture positive externalities in order to justify investment in R&D; all that is required is that inventors capture sufficient returns to justify the investment.”²⁵⁴ Supracompetitive prices for patented goods may be *inefficiently* high,²⁵⁵ and curbing exclusive rights “can improve both efficiency and health.”²⁵⁶

Efforts to encourage the creation of technologies of high social value are also consistent with the patent system’s overarching goals.²⁵⁷ As discussed above,²⁵⁸ there is rhetorical appeal to the trope of the patent system operating as a neutral arbiter of objective selection criteria, relying on the market to determine whether a technology succeeds or “silently sink[s] into contempt and disregard.”²⁵⁹ Implicit in this conception is the view that the patent system should not impose *ex ante* value judgments on technologies, as evidenced by the United States’ rather unique aversion to subjecting patents to moral and ethical scrutiny.²⁶⁰ However, given that the vast majority of patents do not translate to any economic value, it is worthwhile nudging scarce inventive resources toward creating technologies of high social value. Within the dominant utilitarian model of the U.S. patent system, the USPTO has good justification to prioritize the examination of patent applications claiming technologies that serve substantive policy needs, such as those addressing environmental protection, energy security, or terrorism.²⁶¹ Put differently, given the USPTO’s scarce resources, some allocation system is necessary to prioritize the examination of hundreds of thousands of applications received every year.²⁶² “First come, first served,” is an intuitive and neutral method for organizing patent examination, and it is unobjectionable for the vast majority of applications. However,

254. BURK & LEMLEY, PATENT CRISIS *supra* note 162, at 46.

255. Brennan, *supra* note 51, at 294.

256. *Id.* at 281.

257. See Tran, *Expediting Innovation*, *supra* note 30, at 136 (“Expediting the processing of applications pertaining to socially valuable technologies, like green technologies, meshes perfectly with the PTO’s core mission, which is to ‘promote[] industrial and technological progress in the United States and strengthen[] the national economy.’”) (internal citation omitted).

258. See *supra* Part II.

259. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (Cir. Ct. D. Mass. 1817) (No. 8568).

260. See *supra* Part I.

261. 37 C.F.R. 1.102(c)(2)(i)–(iii).

262. See Tran, *Expediting Innovation*, *supra* note 30, at 160 (“Inventions of high social value are inherently predestined to create the greatest benefits for society and thereby fulfill this constitutional bargain better than inventions of little social worth.”).

such a system does not always maximize utility, and there is a strong need for mechanisms to prioritize review of applications covering particularly socially valuable technologies.

Having laid the normative foundation for the USPTO to prioritize some areas of technology over others, there is also a strong case for the USPTO to wield this authority to advance distributive ends. The technologies that the USPTO has formally prioritized relate to “national importance.” While they have a distributive character in that their long-range effects tend to benefit poor and marginalized communities, more explicit prioritization of technologies that serve such communities is in order. The USPTO has already begun doing so in its Patents for Humanity program. As Dan Burk observes, this program reflects the recognition “that some types of patentable innovation are more desirable than others, not necessarily due to the economic value that can be realized from the innovation, but because the innovation serves particular social goals such as alleviating suffering, improving health, or enhancing human flourishing.”²⁶³ Expedited processing offers one kind of incentive to motivate private parties to develop humanitarian technologies. More ambitiously, exclusive rights can create markets for neglected technologies, as seen in the success of the Orphan Drug Act.

The patent system should promote not only wide access to essential inventions but also wide access to the patent system itself. The argument for broadening the inventive base is especially compelling given that it advances both distributive ends and overall innovation. Here, U.S. patent law can learn from international intellectual property law as well as from its domestic intellectual property sibling, copyright. In the international realm, controversies over access to essential medicines have pitted advocates of distributive justice against supporters of strong intellectual property rights.²⁶⁴ However, scholars have compellingly argued that access to intellectual property rights by poor and marginalized communities can be a valuable tool for empowerment.²⁶⁵ For instance, Madhavi Sunder describes how local artisans in India are utilizing geographical indications in Darjeeling tea and Mysore silk to develop revenue streams that capitalize on the well-known

263. Burk, *supra* note 19, at 27.

264. See *supra* notes 9–14 and accompanying text.

265. Sunder, *IP*³, *supra* note 9, at 271 (“But now individuals, often from disadvantaged communities, are seeking *affirmative* intellectual property rights on their own.”).

quality of these goods.²⁶⁶ In the domestic realm, Molly Van Houweling argues that copyright, which attaches without cost upon fixation of some expression in a tangible medium, plays a distributive function by helping low-income creators attract investment.²⁶⁷ While patents can curtail access to essential technologies, obtaining patents on their own inventions can empower marginalized and low-income communities, thus achieving more equitable distribution of the fruits of intellectual property protection.

Additionally, enhancing the inventive base to include more small entities and independent inventors promises significant innovation gains. Numerous studies reveal that small entities are disproportionately innovative relative to large corporations.²⁶⁸ According to the Small Business Administration, from 2002–06, small innovative firms obtained patents at a rate of 26.5 per hundred employees while large innovative firms obtained patents at a rate of 1.7 per hundred employees.²⁶⁹ In addition to producing more patents per employee than large firms,²⁷⁰ small businesses tend to produce patents that are disproportionately important. Empirical research shows that small businesses are twice as likely as large firms to produce patents within the top 1% of most cited patents.²⁷¹ Turning to industrial organization, commentators have argued that patents promote innovation not only through providing incentives to invent, but also by enabling the existence of small, research-intensive, highly innovative firms that patent technologies and license them to larger, downstream companies for development.²⁷² Patenting by

266. *Id.* at 271.

267. Molly Shaffer Van Houweling, *Distributive Values in Copyright*, 83 TEX. L. REV. 1535, 1538 (2005).

268. BURK & LEMLEY, *PATENT CRISIS*, *supra* note 162, at 41; *see* Richard J. Rosen, *Research and Development with Asymmetric Firm Sizes*, 22 RAND J. ECON. 411 (1991); P. R. Beije & J. Groenewegen, *A Network Analysis of Markets*, 26 U. ECON. ISSUES 87, 101–02 (1992); WILLIAM J. BAUMOL, *THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM* (2002).

269. Anthony Breitzman & Patrick Thomas, *SMALL BUS. ADMIN., OFFICE OF ADVOCACY, ANALYSIS OF SMALL BUSINESS INNOVATION IN GREEN TECHNOLOGIES* 11 (2011), <http://www.sba.gov/sites/default/files/rs389tot.pdf> [<https://perma.cc/CS2P-P5UE>].

270. *See generally* C.J. Isom & David R. Jarczyk, *SMALL BUS. ADMIN., OFFICE OF ADVOCACY INNOVATION IN SMALL BUSINESSES: DRIVERS OF CHANGE AND VALUE USE* (2009), https://www.sba.gov/sites/default/files/rs342tot_0.pdf [<https://perma.cc/JD3Y-R2ZC>].

271. CHI RESEARCH, INC., *SMALL BUS. ADMIN., OFFICE OF ADVOCACY, SMALL SERIAL INNOVATORS: THE SMALL FIRM CONTRIBUTION TO TECHNICAL CHANGE* 3 (2003), http://rdw.rowan.edu/cgi/viewcontent.cgi?article=1038&context=esm_facpub [<https://perma.cc/K92P-ZTJ9>].

272. *See* Ashish Arora & Robert P. Merges, *Specialized Supply Firms, Property Rights and Firm Boundaries*, 13 INDUS. & CORP. CHANGE 451, 454 (2004); Jonathan M. Barnett,

small entities thus promotes market entry by specialized firms and enables more innovative, vertically disintegrated industry structures.²⁷³

Given small businesses' disproportionate contribution to innovation and economic growth, the dearth of specific patent policies to support them is a significant missed opportunity.²⁷⁴ Of course, the prospect of broadening participation in the patent system bears some risk, as a proliferation of patents may exacerbate anticommons and patent thickets,²⁷⁵ thus dampening innovation. However, the innovation gains of market entry and access to venture capital promise to be significant. Small businesses are particularly dependent on patents to obtain venture financing,²⁷⁶ and cost is the most common reason cited by technology startups for not patenting a major technology.²⁷⁷ Ironically, small startups actually pay more than highly capitalized incumbents for patents because small entities file on mission-critical patents, typically rely on outside rather than in-house counsel, and face difficulties of monitoring the cost of outside counsel.²⁷⁸ Moving to even smaller inventive entities, empirical analysis shows that 76.4% of pro se patent applicants abandon their applications, compared to 34.8% for applicants represented by an attorney or agent,²⁷⁹ thus leaving many independent inventors out of the patent system.

Moving beyond entity size, enhancing other kinds of diversity in the patent system can also increase both equity and overall social welfare. Recently, there has been growing interest in the role of ethnic minority inventors in innovation,

Intellectual Property as a Law of Organization, 84 S. CAL. L. REV. 787 (2011); Dan L. Burk & Brett H. McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575, 578–88.

273. But see Peter Lee, *Innovation and the Firm: A New Synthesis*, 70 STAN. L. REV. (forthcoming 2018) (manuscript at 15–16) (on file with author) (highlighting the innovation gains of vertical integration).

274. See W. Keith Robinson, *Protecting American Innovators by Combating the Decline of Patents Granted to Small Entities*, 88 ST. JOHN'S L. REV. 379, 385 (2014).

275. See Michael E. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in INNOVATION POLICY AND THE ECONOMY 1, at 119 (Adam B. Jaffe et al. eds., 2001).

276. See John B. Maier, II & David A. Walker, *The Role of Venture Capital in Financing Small Business*, 2 J. BUS. VENTURING 207, 208 (1987).

277. Graham et al., *supra* note 180, at 1310; see Ted Sichelman & Stuart J.H. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111, 115 (2010).

278. Graham et al., *supra* note 180, at 1311–12 (quoting a technology executive).

279. Kate S. Gaudry, *The Lone Inventor: Low Success Rates and Common Errors Associated with Pro-Se Patent Applications*, 7 PLOS ONE e33141, at *3 (2012).

particularly given the prominent role of such groups in innovative clusters like Silicon Valley.²⁸⁰ While groups from South and East Asia are highly represented in the patent system, disproportionately low participation by other groups represents a missed opportunity.²⁸¹ Relatedly, the relative scarcity of women patentees hurts both the equitable distribution of the fruits of the patent system as well as overall innovation. Economic analysis reveals that “eliminating the patenting shortfall of female holders of science and engineering degrees would increase GDP per capita by 2.7%.”²⁸² Here, the modern patent system can learn from its historical roots; before the trend toward corporatization, the U.S. patent system was notable for its relatively low barriers to entry and its commitment to broad, democratic participation.²⁸³

Notably, increasing the diversity of participants in the patent system also promotes other distributive objectives as well. First, because at least some universities and nonprofits are committed to providing wide access to patented inventions for research and humanitarian purposes,²⁸⁴ encouraging their participation in the patent system also tends to promote access to patented technologies. Second, widening access to the patent system also has the effect of promoting the invention of technologies that serve the needs of marginalized communities. As the USPTO has recognized, “[u]niversities and small businesses are at the forefront of humanitarian endeavors, pioneering innovative ways to reach people in need.”²⁸⁵ Relatedly, the Association of American Universities and the Council on Governmental Relations were particularly supportive of the Patents for Humanity program and “strategies that would use the patent system to incentivize activity addressing humanitarian needs.”²⁸⁶ Furthermore, it seems likely that minority, women, and low-income inventors would be

280. Max Nathan, *Same Difference? Minority Ethnic Inventors, Diversity and Innovation in the UK*, 15 J. ECON. GEO. 129, 129 (2015).

281. *Id.* at 142.

282. Jennifer Hunt et al., *Why Don't Women Patent?*, at *2 (Nat'l Bureau of Econ. Research, Working Paper No. 17888, 2012).

283. See KHAN, *supra* note 159.

284. See Peter Lee, *Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law*, 58 EMORY L.J. 879 (2009); Lee, *Distributive Commons*, *supra* note 7.

285. *Patents for Humanity*, USPTO, <https://patentsforhumanity.devpost.com/> [<https://perma.cc/29A2-R8Y5>].

286. The Association of American Universities and the Council on Governmental Relations, Comment Letter in Response to Request for Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System, Nov. 19, 2010; Rimmer, *supra* note 33, at 214–15.

well situated to develop technologies sensitive to the needs of such communities. Distributive efforts to enhance access to essential technologies, develop inventions of value to underrepresented communities, and increase participation in the patent system may thus have a mutually reinforcing effect.

V. TOWARD A DISTRIBUTIVE AGENDA FOR U.S. PATENT LAW

U.S. patent law should embrace the reality that it already contains distributive mechanisms and that such mechanisms are wholly consistent with and advance the aims of the patent system. Rather than view such mechanisms as peripheral or exceptional, Congress, courts, and agencies—particularly the USPTO—should promote a more robust vision of the patent system’s distributive capabilities. Accordingly, this Part sketches the contours of a distributive agenda for U.S. patent law.

A. *Enhancing Access to Essential Technologies*

Congress should recognize that maximizing social welfare sometimes requires curtailing patent rights to enhance access to critical technologies. It has already done so in eliminating certain remedies for infringing patented medical techniques in response to *Pallin v. Singer*.²⁸⁷ The TRIPS agreement authorizes member states to exclude from patentability diagnostic, therapeutic, and surgical methods,²⁸⁸ and Congress should consider specific exclusions from patentable subject matter to enhance access to such technologies, particularly diagnostics that arise in a fairly low-cost manner from genetic discoveries.²⁸⁹ While exclusions from protectability can sweep broadly, compulsory licenses offer a more targeted mechanism for increasing access to a patented technology, such as a medicine, on a case-by-case and time-limited basis. While the TRIPS agreement allows countries to grant compulsory licenses,²⁹⁰ the United States has traditionally opposed them as undermining incentives to invent.²⁹¹ Members of Congress may be skeptical of compulsory licenses based on a belief that the patent system should maximize incentives to invent and

287. See *supra* Part II.A.1.

288. TRIPS, *supra* note 10, at art. 27.3(a).

289. Peter Lee, *The Supreme Court’s Myriad Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature*, 5 U.C. IRVINE L. REV. 1077, 1096 (2015) [hereinafter Lee, *Myriad Effects*].

290. TRIPS, *supra* note 10, at art. 31.

291. Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT’L L. & BUS. 666, 674–80 (1988).

that compulsory licenses benefit other countries' citizens at the expense of American patentees. However, proper recognition of the progressive, utilitarian, and efficiency-based rationales of the patent system, as well as the potential for compulsory licenses to enhance *domestic* welfare, should spur a renewed appreciation for these distributive mechanisms.²⁹²

Executive agencies play an important role in increasing access to patented inventions, primarily by exercising authority already granted to them by statute. This Article joins Brennan et al. in arguing for the federal government's expanded use of 28 U.S.C. § 1498 to lower prices for patented pharmaceuticals. As Brennan et al. argue, utilizing this authority to compulsory license or negotiate lower prices for HCV treatments is particularly important given the enormous patent markups of these medicines and their public health significance.²⁹³ Turning to the Bayh-Dole Act, the argument for executive agencies to exercise march-in rights is particularly compelling²⁹⁴ given that taxpayer funds have already subsidized these patented inventions. As noted, NIH has denied all the march-in petitions it has received based on an expansive conception of "public availability" that severely restricts the circumstances under which march-in rights would be appropriate.²⁹⁵ While NIH is rightly concerned about chilling innovation,²⁹⁶ it enjoys significant leverage over many patented health technologies arising from its financial support.²⁹⁷ While NIH should be judicious in exercising march-in rights, such rights represent a valuable mechanism for tempering market-based rationing of health technologies. Tellingly, members of Congress have already exhorted the Department of Veterans Affairs and NIH to exercise § 1498 rights and march-in rights to lower the cost of patented medicines.²⁹⁸ More ambitiously, they could legislate clearer and more aggressive standards for determining when a

292. Moving to a related area of law, Congress could also enhance access to patented inventions by providing more robust tax deductions for charitable donations of patents. See Xuan-Thao Nguyen & Jeffrey A. Maine, *Giving Intellectual Property*, 39 U.C. DAVIS L. REV. 1721 (2006).

293. Brennan et al., *supra* note 51.

294. See Rai & Eisenberg, *supra* note 105, at 311; Lee, *Distributive Commons*, *supra* note 7; Pulsinelli, *supra* note 105, at 442.

295. Lee, *Distributive Commons*, *supra* note 7, at 955–57.

296. Cf. *id.* at 974–75 (discussing NIH's short-lived "reasonable pricing" requirement in Cooperative Research and Development Agreements (CRADAs) with private drug companies).

297. See *id.* at 950.

298. See *supra* notes 86, 102–103 and accompanying text.

patented technology is not reasonably available to the public, thus triggering use of march-in rights.

Courts also play an important role in the U.S. patent system's distributive agenda. One area where distributional considerations would dovetail with current jurisprudential developments is patentable subject matter doctrine. The Supreme Court has recently decided four cases on patent eligibility, all of which constrain patentable subject matter.²⁹⁹ In doing so, the Court has consistently recognized a prudential interest in limiting patent protection to promote access to foundational resources, thus advancing subsequent innovation.³⁰⁰ Whether intended or not, curtailing the patentability of "inventions" such as methods for optimizing drug administration³⁰¹ or isolated DNA³⁰² to promote subsequent innovation also widens access to these technologies for patients, particularly those with low incomes. Indeed, while the Court's recent ruling that isolated DNA does not comprise patentable subject matter rested on the technicalities of natural-products doctrine,³⁰³ the plaintiffs in that litigation were primarily concerned about broadening access to costly clinical genetic diagnostic tests for breast and ovarian cancer.³⁰⁴ Given the centrality of distributive ends to the patent system overall, courts should more explicitly consider such factors in constraining patentable subject matter doctrine, particularly in the life sciences.

Another area where the courts can significantly advance distributive aims—even if motivated primarily by other concerns—is the law of patent exhaustion. The doctrine of exhaustion holds that certain patent rights are "exhausted" with the first legitimate sale of a patented article.³⁰⁵ Thus, for instance, a pharmaceutical company that has patented a drug could not bring a successful infringement suit against a patient who used the drug after legitimately purchasing it; the pharmaceutical company's right to control such use was

299. *Bilski v. Kappos*, 561 U.S. 593 (2010); *Mayo Collaborative Servs. v. Prometheus*, 566 U.S. 66 (2012); *Ass'n for Molecular Pathology v. Myriad*, 133 U.S. 2107 (2012); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 U.S. 2347 (2014).

300. *See, e.g., Bilski*, 561 U.S. at 649; *Mayo*, 566 U.S. at 71; *Ass'n for Molecular Pathology*, 133 U.S. at 2116.

301. *See Mayo*, 566 U.S. at 71; *cf. Rose, supra* note 203, at 1243–47.

302. *See Ass'n for Molecular Pathology*, 133 U.S. at 2117.

303. *Id.*

304. *Lee, Myriad Effects, supra* note 289, at 1078.

305. Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 HARV. J.L. & TECH. 483, 484–85 (2010).

“exhausted” upon receiving compensation for the drug. In *Impression Products, Inc. v. Lexmark International, Inc.*, the Supreme Court recently ruled that when a patentee sells an item with an express restriction on the purchaser’s right to reuse or resell that product, the patentee may not enforce that restriction through a patent infringement suit.³⁰⁶ Additionally, the Court held that *international* sales of patented articles exhaust U.S. patent rights.³⁰⁷ This latter holding is particularly relevant to distributive justice because it raises the possibility of parties purchasing patented articles overseas and then reselling them in the United States at lower prices. Such arbitrage would tend to decrease the prices of patented articles, such as pharmaceuticals, for domestic consumers (though it may lead patentees to raise prices in other jurisdictions).³⁰⁸ While the Court grounded its holdings in the common law’s antipathy toward restraints on alienation of chattels, these rulings have significant implications for enhancing access to patented articles.³⁰⁹ Subsequent courts will have to determine the exact contours of “sales” that “exhaust” patent rights.³¹⁰ While common-law principles disfavoring restraints on alienation are likely to guide the analysis,³¹¹ courts should also consider the distributive implications of expansive conceptions of exhaustion.

More directly, courts should consider the social benefits of wide access to a patented technology in injunctions analysis. The Supreme Court’s decision in *eBay v. MercExchange* established an equitable four-factor test to determine the appropriateness of injunctive relief.³¹² The fourth factor instructs courts to consider the public interest,³¹³ and the social benefits of broad access to critical patented technologies should weigh against an injunction, particularly where ongoing royalties can maintain incentives to invent.³¹⁴ Here, precedent

306. *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523, 1532–33 (2017).

307. *Id.* at 1538.

308. See Sarah R. Wasserman Rajec, *Impression Products, Inc. v. Lexmark Inc.: Will International Patent Exhaustion Bring Free Trade in Patented Goods?*, PATENTLY-O (June 1, 2017), <https://patentlyo.com/patent/2017/06/impression-international-exhaustion.html> [<https://perma.cc/3FGR-P47J>].

309. *Id.* at 14.

310. See Rajec, *supra* note 308.

311. *Impression Prods., Inc.*, 137 S. Ct. at 1533 (2017).

312. *eBay v. MercExchange L.L.C.*, 547 U.S. 388, 391 (2006).

313. *Id.* at 391.

314. See Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 WASH. L. REV. 39, 116 (2008).

may lay a foundation for future injunctions practice, as courts have on occasion considered benefits to public health in denying injunctions to prevailing patentees.³¹⁵

B. Encouraging Technologies to Serve Neglected Populations

Of course, the most straightforward way to stimulate the creation of technologies to serve neglected populations is direct federal funding. While this Article has focused on mechanisms within the patent system to achieve distributive ends, a wide variety of policy tools are available outside of the patent system to also advance these objectives. For example, NIH provides over \$30 billion for biomedical research every year,³¹⁶ and increased funding for rare diseases would be highly impactful. Furthermore, the success of the Orphan Drug Act should persuade Congress to consider expanding this program, perhaps to other fields of technology. While not a system of patent rights, this program shows the potential for exclusive rights to create viable markets for otherwise neglected technologies.

The USPTO plays an important role in promoting the development of technologies of high social need. It already does this through its Patents for Humanity program, its general authority to prioritize applications claiming technologies “important to the national economy or national competitiveness,”³¹⁷ and regulations prioritizing examination of inventions addressing the environment, energy, and terrorism.³¹⁸ In similar fashion, the USPTO should focus more on promoting the development of technologies to serve poor and marginalized communities, particularly in the domestic sphere. It is debatable, of course, whether prioritized examination is enough of an incentive to induce parties to develop such technologies. The USPTO should consider coupling prioritization with fee reductions to provide even greater incentive for such technologies. Selecting technologies to prioritize is a discretionary determination, and this Article joins others in arguing for enhancing the substantive rulemaking power of the USPTO.³¹⁹ Notably, the

315. See *supra* Part II.A.2.

316. *What We Do*, NAT'L INSTS. OF HEALTH, <https://www.nih.gov/about-nih/what-we-do> [<https://perma.cc/K92M-MJ22>].

317. 35 U.S.C. § 2(b)(2)(G) (2012).

318. 37 C.F.R. § 1.102(c)(2) (2016).

319. See Michael Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1747–48 (2011); John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1041 (2011); Jonathan S. Masur, *Regulating Patents*, 2010 SUP. CT. REV. 275, 279; Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest*

America Invents Act has already increased the USPTO's powers, particularly relative to the Federal Circuit.³²⁰ As Sarah Tran argues, "by having more freedom to prioritize socially valuable applications in the review process, the Patent Office could provide meaningful incentives for parties to innovate, and bring to market sooner, technologies of national importance, such as those relating to energy development, biomedical research, and information technology."³²¹ While definitional challenges arise in identifying what types of innovations to prioritize,³²² they are not insurmountable,³²³ as the USPTO's experience with the Patents for Humanity program demonstrates. Substantive rulemaking authority would also provide more flexibility for the USPTO to promote technological development to serve marginalized communities.

C. Widening Access to the Patent System

The USPTO should also take the lead in broadening participation in the patent system.³²⁴ Fee reductions for small and micro entities are a promising start, and the USPTO should expand on these efforts. The primary benefits that the USPTO can offer to any patent applicant are reduced fees and prioritized examination.³²⁵ Small entities already receive fee reductions, but Keith Robinson has argued for a Small Entity Prioritized Examination program as well.³²⁶ Tellingly, there is precedent for such a program in the form of a short-lived initiative to confer special status on applications from small

for *Managerial Control*, 157 U. PA. L. REV. 2051, 2056–57 (2009).

320. Tran, *Patent Powers*, *supra* note 128, at 611, 613.

321. *Id.* at 661.

322. *Cf.* Tran, *Expediting Innovation*, *supra* note 30, at 154–59.

323. *See id.* at 165–66 (emphasizing the value of interagency collaboration and communication to identifying classes of technology meriting prioritized examination).

324. One potential proposal that this Article does not endorse is the creation of a petty patent system. Petty patents require less stringent standards for protection and provide shorter terms than utility patents. They also cost less and take less time to examine and process, and in theory they represent an avenue for more inventors to participate in the patent system. However, petty patents may flood the marketplace with "low quality" patents, thus exacerbating potential anticommons effects, and may not directly encourage commercialization. *See* Robinson, *supra* note 274, at 402–03; Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. J. INT'L L. 151, 202 (1999).

325. *See* ARTI RAI ET AL., PATENT REFORM: UNLEASHING INNOVATION, PROMOTING ECONOMIC GROWTH & PRODUCING HIGH-PAYING JOBS, A WHITE PAPER FROM THE U.S. DEPARTMENT OF COMMERCE 5 (2008), http://www.esa.doc.gov/sites/default/files/patentreform_0.pdf [<https://perma.cc/MV6D-MZM4>] (noting that delay in patent prosecution is particularly harmful to startups, for which time is of the essence).

326. Robinson, *supra* note 274, at 413–21.

biotechnology entities.³²⁷ Extrapolating from this proposal, the USPTO should consider offering a combination of fee reductions and prioritized examination to underrepresented inventive entities. In order to fully accommodate small and low-income inventors, such accelerated examination should not require onerous and costly pre-examinations of prior art, as the USPTO has required in other contexts.³²⁸ Fee reductions, however, may have an unanticipated negative effect. Given the USPTO's institutional interest in enhancing its revenues, fee reductions for small (and micro) entities "may have the inadvertent effect of biasing the PTO toward granting patents associated with large enterprises."³²⁹ As such, a better alternative would be for Congress to create a fund to cover 50% and 75% of fees for small and micro entities, respectively, thus subsidizing these entities while still providing full revenues to the USPTO.³³⁰ Given that fee reductions of 50% and 75% are ultimately arbitrary, Congress should also consider fully subsidizing patent fees, particularly for pro bono and unrepresented inventors.

While fee reductions and expedited examination have received much attention, the most significant barrier to accessing the patent system is the cost of legal and technical expertise.³³¹ As such, the USPTO should expand its pro bono and pro se programs to lower barriers to entry for independent inventors. The pro bono program has seen early success in connecting low-income inventors with volunteer patent attorneys and agents.³³² Given the democratic roots of the U.S. patent system and the distributive and innovation gains of wide participation,³³³ greater technical assistance and funding for low-income and pro se inventors is warranted.

327. See USPTO, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 708.02(XII) (8th ed. rev. 1, Feb. 2003), available at https://www.uspto.gov/web/offices/pac/mpep/old/E8R1_700.pdf [<https://perma.cc/X8GC-QVZA>]; Robinson, *supra* note 274, at 384–85.

328. See Tran, *Expediting Innovation*, *supra* note 30, at 140–42.

329. Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 119, 125 (2013).

330. Cf. Jerry Cohen, *Functions, Costs and Fees of the U.S. Patent Office*, 15 PAT. TRADEMARK & COPY. J. RES. & ED. 595, 607 (1972). To affirmatively encourage the USPTO to process applications from small and micro entities, Congress could even choose to provide additional subsidies above normal patent fees for such applicants.

331. Graham et al., *supra* note 180, at 1262.

332. McDowell & Vishnubhakat, *supra* note 184, at 53.

333. See *supra* notes 268–283 and accompanying text.

Finally, the USPTO should increase investments in reaching out to underrepresented inventors. The AIA's charge for the USPTO to establish methods for studying diversity in the patent system explicitly stated that "[t]he Director shall not use the results of such study to provide any preferential treatment to patent applicants."³³⁴ However, Representative Moore's proposal of this amendment clearly contemplated ultimately using this information to conduct outreach to underrepresented inventors.³³⁵ The USPTO has already demonstrated a commitment to serving local inventive communities by creating satellite offices in Dallas, Denver, Detroit, and Silicon Valley. Now that the USPTO has established methods for studying diversity, it should utilize those methods to determine relative levels of representation of women, minorities, veterans, small enterprises, and other groups in the patent system. And once the agency has developed this insight, it should expand efforts to reach out via "road shows," community engagement, and technical assistance to expand participation and diversity in the patent system.

VI. CONCLUSION

Contrary to common perception, widely distributing access to technologies and the patent system itself are central to the normative foundations of U.S. patent law. As traditionally perceived, the patent system creates a neutral regime of strict exclusive rights that allows the market to coordinate the development and dissemination of new technologies. In important ways, the rhetoric of private property rights and market value seems to crowd out other values that could reasonably inform a system to promote technological progress. While the U.S. patent system seems unconcerned with equity, access, and distributive justice, this Article has shown that distributive mechanisms are already part and parcel of the existing system. A variety of statutes, doctrines, and regulations both within and related to the patent system enhance access to patented technologies of great need, deviate from market allocation to promote the development of socially valuable technologies, and selectively favor low-income and underrepresented inventive entities.

This Article has argued that these distributive mechanisms are not only consistent with the broader normative objectives of

334. Pub. L. No. 112-29 § 29, 125 Stat. 339 (Sept. 16, 2011).

335. 157 CONG. REC. H4484 (daily ed. June 23, 2011) (statement of Rep. Moore).

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the U.S. patent system but also affirmatively support them. Wide distribution of the fruits of the patent system advances intuitive meanings of progress, maximizes social utility, and increases efficiency over a system based purely on market allocation. Furthermore, invoking the notion that patents are property only underscores the appropriateness of subjecting them to distributive safeguards, and such safeguards bolster the patent system's political legitimacy. Accordingly, this Article has sketched the contours of a distributive agenda for U.S. patent law. Congress, courts, and executive agencies—most notably the USPTO—have important roles to play in enhancing access to patented technologies, encouraging the creation of technologies of high social value, and broadening participation in the patent system. As stakeholders cultivate a more nuanced understanding of what the patent system is and should be, they can better orient it toward achieving its diverse and lofty objectives.