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## Patent Fair Use 2.0

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1 **PATENT FAIR USE 2.0**  
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3 New York University School of Law  
4 (forthcoming U.C. Irvine L. Rev. 2011)  
5

6 I. INTRODUCTION

7 In their book, *The Patent Crisis and How the Courts Can Solve It*, Dan Burk and Mark  
8 Lemley argue that patent law should be tailored to industry characteristics.<sup>2</sup> They then explore  
9 doctrinal mechanisms by which courts can and should take up the laboring oar to accomplish the  
10 necessary tailoring. Burk and Lemley explore possibilities for industry-sensitive adjudication at  
11 numerous points throughout the patent lifecycle – from patent acquisition through claim  
12 interpretation to remedies.<sup>3</sup> Essentially absent (or present only in faint echoes) from their catalog  
13 of current and potential “policy levers” for the courts are infringement exemptions. The absence  
14 is striking in light of the fact that copyright law, which has been much more prone than patent  
15 law to legislative accommodation to particular industries,<sup>4</sup> nonetheless retains a robust judicial  
16 policy lever at the infringement stage – the fair use doctrine.<sup>5</sup> Though striking, the lack of  
17 discussion is not at all surprising. Patent law has no fair-use-type doctrine and the “research

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<sup>1</sup> Professor of Law, New York University School of Law. I am grateful to the participants in the Symposium “Bend or Break: Tailoring the Patent System to Promote Innovation,” which is the subject of this volume, and to participants at an NYU College of Law faculty workshop and Some Modest Proposals 4.0: A Conference About Pouring Academic Ideas into Legislative Bottles at Cardozo Law School, for helpful comments. I also gratefully acknowledge research support from The Filomen D'Agostino and Max E. Greenberg Research Fund.

<sup>2</sup> DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009).

<sup>3</sup> *Id.* at Chs. 9 and 10.

<sup>4</sup> See, e.g., Jessica Litman, *Digital Copyright* (2006). For an updated discussion of copyright legislative history, see Jessica Litman, *Real Copyright Reform*, 96 *Iowa L. Rev.* (forthcoming 2011).

<sup>5</sup> For an excellent recent overview and analysis of the fair use doctrine in copyright law, see Pamela Samuelson, *Unbundling Fair Uses*, 77 *Fordham L. Rev.* 2537 (2009).

18 exemptions” that exist are either very narrow<sup>6</sup> or available only in highly specific  
19 circumstances.<sup>7</sup>

20 In this Essay, I will argue that a fair-use-type infringement exemption should take its  
21 place in patent law’s toolbox of policy levers and propose specific factors that should govern  
22 such an exemption.<sup>8</sup>

### 23 A. The Non-Contextual Focus of Patent Doctrine

24 Particularly in the United States, policing the scope of patent rights has been, at least in  
25 principle, a highly front-loaded enterprise, in which the patent scope determination is  
26 intentionally divorced from the context of infringement. An extensive set of patent validity  
27 doctrines, including limits on patentable subject matter,<sup>9</sup> the requirements of utility,<sup>10</sup> novelty,<sup>11</sup>  
28 and nonobviousness,<sup>12</sup> the written description, enablement, and best mode requirements,<sup>13</sup> and  
29 the requirement of definite claims<sup>14</sup> have served as a series of “doors”<sup>15</sup> through which a  
30 prospective patentee must pass to obtain patent protection. The perspective of the “person  
31 having ordinary skill in the art,” or PHOSITA, has been the primary mechanism by which the  
32 hurdles to obtaining patent protection are adjusted to particular technological areas.<sup>16</sup> At least  
33 until recently, once a patent was obtained, patent exclusivity was unyielding: injunctions were

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<sup>6</sup> *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (university research did not qualify for the “very narrow and strictly limited” common law research exemption)

<sup>7</sup> See 35 U.S.C. 271(e)(1) (exemption for research related to FDA approval). See also KATHERINE J. STRANDBURG, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress, in Intellectual Property and Information Wealth* (Peter Yu ed. 2006)

<sup>8</sup> In this effort I will build on the seminal work on “patent fair use,” Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 Colum. L. Rev. 1177 (2000).

<sup>9</sup> 35 U.S.C. § 101

<sup>10</sup> 35 U.S.C. §§ 101, 112

<sup>11</sup> 35 U.S.C. § 102

<sup>12</sup> 35 U.S.C. § 103

<sup>13</sup> 35 U.S.C. § 112

<sup>14</sup> 35 U.S.C. § 112

<sup>15</sup> *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979)

<sup>16</sup> See, e.g., Rebecca Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of the PHOSITA*, 19 Berkeley Tech. L. J. 885 (2004); Cyril A. Soans, *Some Absurd Presumptions in Patent Cases*, 10 IDEA 433, 438 (1966) (coining the name “Mr. PHOSITA”).

34 virtually certain at the end of a successful patent infringement suit<sup>17</sup> and compulsory licenses  
35 were scorned.<sup>18</sup> An upfront-focused system has several purported advantages. Focusing the  
36 debate over patent rights at the front end is intended to bring certainty and, similarly to property  
37 rights in other contexts, to provide secure rewards to those who invest in technology and thus to  
38 facilitate a market.<sup>19</sup>

39 Of course, this system has never been as simple as the upfront doctrinal focus suggests.  
40 The validity of patent claims is commonly challenged at the point of enforcement during  
41 litigation.<sup>20</sup> Though supposedly independent of the context of infringement, claim interpretation  
42 is also a ubiquitous subject of dispute in litigation.<sup>21</sup> On the infringement side, the doctrine of  
43 equivalents developed to ensure that patentees were not deprived of their rewards by  
44 “unscrupulous copyists”<sup>22</sup> or, in more recent iterations, by unforeseeable and tangential

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<sup>17</sup> EBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393-94 (2006) (describing the Federal Circuit’s approach to injunctions in patent cases). The Supreme Court in eBay, id. at 394, softened this rule to some extent in some circumstances as discussed further *infra*.

<sup>18</sup> See, e.g., Colleen M. Chien, Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation, 18 Berkeley Tech. L. J. 853, 857-64 (2003); Joseph A. Yosick, Compulsory Patent Licensing for Efficient Use of Inventions, 2001 U. Ill. L. Rev. 1275 (discussing the history of compulsory licensing in the United States).

<sup>19</sup> Guido Calabresi & A. Douglas Melamed. Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092-93 (1972). For discussions of the debate over the merits of “property rules” and “liability rules” in intellectual property, see, e.g., ROBERT P. MERGES, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 Cal. L. Rev. 1293(1996) ; James Bessen & Michael J. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk (2008); Mark A. Lemley & Philip J. Weiser, Should Property or Liability Rules Govern Information?, 85 TEX. L. REV 783 (2007); Daniel A. Crane, Intellectual Liability, 88 Tex. L. Rev. 253 (2009). See also MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005) (“Because the ‘right to exclude recognized in a patent is but the essence of the concept of property,’ the general rule is that a permanent injunction will issue once infringement and validity have been adjudged.”), rev’d sub nom EBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393-94 (2006).

<sup>20</sup> Chisum on Patents 19.02. Indeed, it may soon be somewhat easier to challenge patent validity. The Supreme Court has recently granted certiorari in Microsoft Corp. v. I4I Ltd., 2010 U.S. Lexis 9311 (November 29, 2010 ) (granting petition for certiorari), to decide whether to reduce the burden of proving invalidity at trial, at least with respect to prior art not previously considered by a patent examiner.

<sup>21</sup> See, e.g., Dan L. Burk and Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743 (2009) and many references therein.

<sup>22</sup> Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607 (U.S. 1950)

45 technological developments.<sup>23</sup> Nonetheless, the basic conception of a system of upfront barriers  
46 followed by secure rights is well-ensconced.<sup>24</sup>

47         Around the turn of the twenty-first century, there began to be widespread dismay over the  
48 state of the patent system.<sup>25</sup> A number of factors contributed to the sense that something had  
49 gone wrong. Globalization of the system under the Agreement on Trade-Related Aspects of  
50 Intellectual Property Rights (TRIPS Agreement) pitted (or at least seemed to pit) patent rights  
51 against critical public health interests.<sup>26</sup> Patent protection expanded into subject areas, such as  
52 business methods, software, and biotechnology, in which it was more difficult to define rights  
53 than it had been in the paradigmatic chemical and mechanical fields.<sup>27</sup> These and other factors  
54 led to a burgeoning of the sheer number of patents the United States Patent and Trademark  
55 Office (PTO) was required to consider.<sup>28</sup> Technological changes increased the importance of

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<sup>23</sup> *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 304 F.3d 1289, 1290 (Fed. Cir. 2002)

<sup>24</sup> For discussions and critiques of the Federal Circuit's bright line "formalistic" approach, see, e.g., Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 *Berkeley Tech. L.J.* 1141, 1142-51 (2008) (describing the "new formalism of patent law" and the treatment of patent validity and infringement as conceptually separate and "binary" determinations); Timothy R. Holbrook, *The Supreme Court's Complicity in Federal Circuit Formalism*, 20 *Santa Clara Comp. & High Tech. L.J.* 1 (2003); John R. Thomas, *Formalism at the Federal Circuit*, 52 *Am. U. L. Rev.* 771 (2003); Rochelle C. Dreyfuss, 23 *Berkeley Tech. L.J.* 787 (2008);

<sup>25</sup> See, e.g., Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>, and references therein; A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY, NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES (Stephen A. Merrill, Richard C. Levin, & Mark B. Myers, eds., 2004), and references therein; Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCI.* 698 (1998); ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS AND WHAT TO DO ABOUT IT* (2004) and references therein; Rochelle C. Dreyfuss, *Pathological Patenting: The PTO As Cause or Cure*, 104 *MICH. L. REV.* 1559 (2006) (critiquing Jaffe and Lerner for its emphasis on patent invalidity and pointing out other potential sources of problems with the patent system).

<sup>26</sup> See generally Margaret Chon, *Intellectual Property and the Development Divide*, 27 *Cardozo L. Rev.* 2821 (2006); Rochelle C. Dreyfuss, *TRIPS-Round II: Should Users Strike Back?*, 71 *U. Chi. L. Rev.* 21 (2004); Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 *Fordham L. Rev.* 505 (2005); Peter Yu, *TRIPS and Its Discontents*, 10 *Marq. Intell. Prop. L. Rev.* 369 (2006). See also Thomas W. Pogge, *Human Rights and Global Health: A Research Program*, 36 *Metaphilosophy* 182 (2005) (discussing the impact of TRIPS on biotechnology and pharmaceuticals); Symposium, *Intellectual Property, Trade and Development: Accommodating and Reconciling Different National Levels of Protection*, 82 *Chi.-Kent L. Rev.* 1109 (2007) (collecting articles discussing the impact of intellectual property agreements on public health and agriculture); Symposium, *Traditional Knowledge, Intellectual Property, and Indigenous Culture*, 11 *Cardozo J. Int. & Comp. L.* 239 (2003) (collecting articles discussing the impacts of intellectual property agreements on indigenous cultures, plants, and medicines).

<sup>27</sup> See, e.g., BESSEN & MEURER, *supra* note 19 and references therein.

<sup>28</sup> See, e.g., Bronwyn Hall, *Exploring the Patent Explosion*, 30 *J. Tech. Transfer* 35 (2005)..

56 both cumulative innovation and complex products, lending greater salience to overlapping patent  
57 rights.<sup>29</sup> Innovation paradigms are also evolving, with user innovation, open innovation, and  
58 collaborative and open source approaches playing an increasingly important role.<sup>30</sup> Rather than  
59 purchasing products over which the patent rights are “exhausted” by the sale,<sup>31</sup> consumers  
60 increasingly are licensees (and hence potential infringers) with ongoing obligations to patent  
61 holders.

62 Besides leading to a sense, at least in many quarters, of a patent system run amok, these  
63 changes drove a wedge between industries, since the changes played out in technology-specific  
64 ways.<sup>32</sup> In response, proposals for reform abounded. Legislation has been introduced repeatedly  
65 in Congress and, as Burk and Lemley explain, for the most part become stymied by opposing  
66 pressures from different industry sectors.<sup>33</sup>

67 With the legislature at an impasse, the courts – particularly the Supreme Court<sup>34</sup> – and the  
68 USPTO have stepped in with attempts to rein in perceived over-patenting. Commentators have

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<sup>29</sup> There is a large and contentious literature on this topic, which is reviewed recently (and skeptically) in Jonathan Barnett, *Property as Process: How Innovation Markets Select Innovation Regimes*, 119 *Yale L.J.* 384 (2009).

<sup>30</sup> *See, e.g.*, Yochai Benkler, *The Wealth of Networks* (2006); Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 *U. Colo. L. Rev.* 467 (2008); Katherine J. Strandburg, *Evolving Innovation Paradigms and the Global Intellectual Property Regime*, 41 *Conn. L. Rev.* 861 (2009) and references therein.

<sup>31</sup> *See Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) (reaffirming that the patent exhaustion doctrine precludes a patent holder from asserting a claim against a third party purchaser).

<sup>32</sup> Burk & Lemley, *supra* note 2.

<sup>33</sup> *Id.* *See also* Jay P. Kesan and Andres A. Gallo, *The Political Economy of the Patent System*, 87 *N.C. L. Rev.* 1341 (2009). Note, however, that at this writing there is renewed optimism regarding the potential for passage of substantive patent reform legislation. *See Patent Reform Act of 2010*, S. 515. The current legislation would not provide the kind of ex post contextually sensitive enforcement advocated here, however.

<sup>34</sup> *See Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) (reaffirming that the patent exhaustion doctrine precludes a patent holder from asserting a claim against a third party purchaser); *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007) (rejecting a rigid requirement that obviousness be demonstrated by evidence of a “teaching, suggestion, or motivation to combine” prior art references); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 456 (2007) (rejecting an expansive interpretation of infringement provision involving component parts of a patented product manufactured domestically but assembled and sold abroad); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2006) (holding a party is not required to break a license agreement “before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed”); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006) (holding that standard principles of equity apply when granting injunctive relief in patent disputes); *Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45–46 (2006) (finding that a patent does not

69 also been prolific with suggestions for improving “patent quality.”<sup>35</sup> With important exceptions,  
70 to which I will return, the interventions and proposals have maintained the focus on better  
71 defining the ex ante scope of patent exclusive rights.<sup>36</sup>

72 One important example of this focus is the Supreme Court’s recent opinion in *KSR v.*  
73 *Teleflex*,<sup>37</sup> in which the Court arguably raised the bar to patentability by recognizing that at least  
74 some level of creativity is the province of the ordinary artisan.<sup>38</sup> Even more recently, the  
75 Supreme Court and Federal Circuit have moved to rein in the scope of patentable subject matter,  
76 particularly with regard to the interpretation of the ban on the patenting of “abstract ideas” which  
77 is crucial to determining the scope of patent rights in business methods and software.<sup>39</sup> The  
78 Federal Circuit had adopted a virtually unbounded “useful, concrete, and tangible result” test for  
79 patentable subject matter.<sup>40</sup> Heeding signals of discontent with such a broad approach to

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automatically confer market power); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 138 (2006) (Breyer, J., dissenting) (criticizing the Court for choosing not to decide this case and supporting a more restrictive view of patentable subject matter); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005) (holding “the use of patented compounds in preclinical studies is protected” and is not infringement in most circumstances). See also John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 Sup. Ct. Rev. 273 (2002).

<sup>35</sup> One rough measure of the interest in the topic is that a LEXIS search in the US Law Reviews and Journals database yields 402 hits for the phrase “patent quality,” (search conducted on 5/4/2010), while there were only 22 such hits prior to 2000.

<sup>36</sup> To be sure, commentators have debated when, as a matter of procedure and administrability, it is best to expend resources to determine the scope of patent rights definitively. See, e.g., Mark A. Lemley, *Rational Ignorance at the PTO*, 95 N.W. U. L. Rev. 1495 (2001); Jay P. Kesan, 17 *Berkeley Tech. L.J.* 763 (2002); F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 *B.C. L. Rev.* 55 (2003); Shubha Ghosh & Jay Kesan, *What do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*, 40 *Hous. L. Rev.* 1219 (2004). These discussions still generally presume a conceptual separation between the definition of patent scope and the context of infringement, however. See Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 *Berkeley Tech. L.J.* 1141, 1147 (2008) (describing the Federal Circuit’s “rigid conceptual separation” between infringement and validity determination). Perhaps closest in spirit to the approach I advocate here are recent proposals for a return to a central claiming regime. See, e.g., Jeanne C. Fromer, *Claiming Intellectual Property*, 76 *U. Chi. L. Rev.* 719 (2009); Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 *U. Pa. L. Rev. PENNumbra* 1743 (2009). These proposals still assume, however, that there is a proper scope of patent exclusivity, as against all comers, even if it is most desirable, as a practical and administrative matter to determine that scope in light of the accused product or process.

<sup>37</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

<sup>38</sup> *Id.* at 421.

<sup>39</sup> *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)..

<sup>40</sup> *State Street Bank & Trust Co v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373

80 patentable subject matter from at least some Supreme Court justices, the USPTO began to issue  
81 more patentable subject matter rejections and the Federal Circuit moved to narrow its approach.<sup>41</sup>  
82 The Supreme Court addressed the issue in 2010.<sup>42</sup> While rejecting the Federal Circuit’s attempt  
83 to enshrine a specific “machine or transformation of matter” test for unpatentable “abstract  
84 ideas,”<sup>43</sup> the Supreme Court, in a divided opinion, rejected the overly permissive “useful,  
85 concrete, and tangible result” test,” and reaffirmed its traditional concerns about the patenting of  
86 abstract ideas. While there was no majority for a categorical ban on business method patents,  
87 four justices would have banned them,<sup>44</sup> while another four expressed the point of view that  
88 business method patents “raise special problems in terms of vagueness and suspect validity” and  
89 suggested that it might be possible to craft a categorical rule against patenting some (as-yet-  
90 unspecified) category of business methods.<sup>45</sup> The PTO has also made efforts to improve upfront  
91 quality control of business method patenting through its “second pair of eyes” review of certain  
92 business method patents<sup>46</sup> and its experimental “peer-to-patent” program.<sup>47</sup>

93 The Federal Circuit’s claim construction jurisprudence reflects various attempts to  
94 establish an upfront clarity for the scope of patent rights, including the focus on the specification  
95 and prosecution history as sources of claim interpretation,<sup>48</sup> the ill-fated attempt to use  
96 dictionaries to establish claim term meanings,<sup>49</sup> the downplaying of “extrinsic evidence” and of

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<sup>41</sup> See, e.g., *In re Comiskey*, 554 F.3d 967 (Fed. Cir. 2009), *Bilski*, supra note \_\_, *In re Nuijten*, 515 F.3d 1361 (Fed. Cir. 2008).

<sup>42</sup> *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>43</sup> *Id.* at 3226-27.

<sup>44</sup> *Id.* at 3231 (Stevens, J., concurring).

<sup>45</sup> *Id.* at 3229.

<sup>46</sup> See, e.g., John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 *BERKELEY TECH. L.J.* 729, 734–35 (2006) (describing the PTO’s “second pair of eyes” review of business method patent applications).

<sup>47</sup> See [www.peertopatent.org](http://www.peertopatent.org).

<sup>48</sup> *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-17 (Fed. Cir. 2005) (en banc); *Vitronics Corp. v. Conceptronix*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996).

<sup>49</sup> *Phillips*, 415 F.3d at 1319-24; *Tex. Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002)

97 the factual underpinnings of claim interpretation,<sup>50</sup> and the insistence that claim meaning be  
98 established independently of the product or process that is accused of infringement.<sup>51</sup> Recent  
99 expansions in the written description<sup>52</sup> and utility<sup>53</sup> doctrines similarly focus on reining in over-  
100 patenting at the front end.

101 The long-running back-and-forth between the Federal Circuit and the Supreme Court  
102 concerning the contours of the doctrine of equivalents can also be seen largely as a colloquy over  
103 the extent to which claim scope can and should be set in stone at issuance.<sup>54</sup> While the doctrine  
104 eventually established recognizes the theoretical possibility of a need to encompass activity  
105 beyond the scope of the literal claims,<sup>55</sup> the foreseeability approach ensures that cases applying  
106 the doctrine will be few and far between.<sup>56</sup>

107 Unfortunately, the results of the focus on upfront clarity have not been encouraging.  
108 Claim construction, for example, remains a mess, with the Federal Circuit disagreeing with the

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<sup>50</sup> Phillips, 415 F.3d at 1317-19; *Cybor Corp. v. Fas Techs.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc). But see *Cybor*, 138 F.3d at 1473-78 (Rader, J., dissenting) (criticizing the Federal Circuit for adopting a de novo review standard for claim construction).

<sup>51</sup> *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). See Chisum on Patents 18.03[1][b].

<sup>52</sup> *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

<sup>53</sup> *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

<sup>54</sup> *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368 (Fed. Cir. 2007); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 72 F.3d 857 (Fed. Cir. 1995); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512 (Fed. Cir. 1995) (en banc). The doctrine of equivalents imposes infringement liability when an allegedly infringing product or process does not fit literally within a patent's claims but would be considered "insubstantially different" by a PHOSITA. For example, an older case considered seminal to the development of the modern doctrine of equivalents is *Winans v. Denmead*, 56 U.S. 330 (1853). In that case the Court held that a freight car with an octagonal cross-section infringed a patent claiming a car in the shape of a frustum of a cone. Essentially, the Court held that an octagonal cross-section was equivalent to the claimed circular cross-section in terms of its technological function. More recent cases largely confine the scope of the doctrine of equivalents to equivalents that would have been unforeseeable at the time of patenting, at least for claims that have been amended during patent prosecution. Since many, if not most, claims are amended, this is a significant cabining of the doctrine.

<sup>55</sup> *Festo*, 535 U.S. at 740.

<sup>56</sup> John R. Allison & Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 STAN. L. REV. 955, 977-78 (2007).

109 district courts in a large number of cases.<sup>57</sup> Validity is routinely disputed in litigation, though it  
110 is possible that proposals to permit early stage third party oppositions to patent rights might  
111 improve the situation.<sup>58</sup> In some industries, notably in information technology, the uncertainty of  
112 patent scope appears to limit their effectiveness in deterring infringement upfront, except in  
113 portfolios<sup>59</sup>

114 Thus, while there is much to be said for well-defined patent scope, experience  
115 demonstrates that there are important limitations, both theoretical and practical, to an entirely  
116 upfront approach. These limitations include the unpredictability of technology, and hence the  
117 inability to determine a priori how much downstream innovation a particular claim will be  
118 deemed to encompass<sup>60</sup> or how intertwined a particular patented invention will become with  
119 other “pieces” of technology;<sup>61</sup> the fact that patented technology, especially in some industries, is  
120 employed in contexts in which the spillover effects of exclusive rights vary widely;<sup>62</sup> and the

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<sup>57</sup> See, e.g., Christian A. Chu, Empirical Analysis of the Federal Circuit's Claim Construction Trends, 16 Berkeley Tech. L.J. 1075 (2001); Kimberly A. Moore, Are District Court Judges Equipped to Resolve Patent Cases?, 15 Harv. J.L. & Tech. 1 (2001); Kimberly A. Moore, Markman Eight Years Later: Is Claim Construction More Predictable?, 9 Lewis & Clark L. Rev. 231 (2005); Michael Saunders, A Survey of Post-Phillips Claim Construction Cases, 22 Berkeley Tech. L.J. 215 (2007); Lee Petherbridge, The Claim Construction Effect, 15 Mich. Telecomm. Tech. L. Rev. 215 (2008).

<sup>58</sup> See, e.g., Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763 (2002); Patent Reform Act of 2010.

<sup>59</sup> Bessen & Meurer, *supra* note 19; Mark A. Lemley, Ignoring Patents, 2008 Mich. St. L. Rev. 19 (2008); Christopher A. Cotropia and Mark A. Lemley, Copying in Patent Law, 87 N.C.L. Rev. 1421 (2009); Gideon Parchomovsky and R. Polk Wagner, Patent Portfolios, 154 U. Pa. L. Rev. 1 (2005); Ronald J. Mann & Thomas W. Sager, *Patents, Venture Capital, and Software Start-ups*, 36 RES. POL'Y 201, 203, 204 (2007), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=802806](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=802806). (software start-ups do not do patent searches); Stuart Graham, Robert Merges, Pam Samuelson & Ted Sichelman, *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L. REV. 1248 (2010) (less than one quarter of DB software start-up companies do patent searches, while about 30% of venture-backed software companies do so).

<sup>60</sup> Patent jurisprudence recognized this issue early on, particularly in discussions of the scope of patentable subject matter. See, e.g., *Gottschalk v. Benson*, 409 U.S. 63, 67-68 (U.S. 1972); *O'Reilly v. Morse*, 56 U.S. 62, 113 (U.S. 1854)

<sup>61</sup> See, e.g., *Heller & Eisenberg*, *supra* note 25 for a discussion of the potential for “anticommons” problems with upstream patenting.

<sup>62</sup> For example, an invention may serve both as a commercial product (e.g. a pharmaceutical or diagnostic test) and as a research tool. The implications of exclusive rights may be quite different in the two contexts. For a discussion of this distinction, see Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary between Academic and Industry Research*, 77 Fordham L. Rev. 2237 (2009).

121 inability to determine whether a particular invention might otherwise be independently invented  
122 and disseminated by another inventor before the expiration of the twenty-year patent term.<sup>63</sup>  
123 Commentators have also questioned the efficiency of investing in clearly determining property  
124 rights up front, in light of the very large fraction of patents that are never licensed, traded, or  
125 enforced (a clear distinction from real and personal property).<sup>64</sup> Some have even suggested  
126 reverting to a registration system for patents in light of the difficulties in examining patents at  
127 issuance.<sup>65</sup>

128         These limitations, which are very real, are in some respects the flipside of the frequently  
129 invoked concern with hindsight bias<sup>66</sup> (and the less frequently invoked, but equally important,  
130 countervailing attribution error<sup>67</sup>). While hindsight bias and the attribution error arise because of  
131 the difficulty in truly appreciating the past,<sup>68</sup> the failings of a focus on ex ante boundary-setting

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<sup>63</sup> The Federal Circuit has at times considered near-simultaneous invention to be indicative of obviousness and at other times declined to do so. See *Chisum on Patents*, 5.05[7]; *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 n.7 (Fed. Cir. 1983)

<sup>64</sup> Lemley, *supra* note 59.

<sup>65</sup> F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55 (2003).

<sup>66</sup> See, e.g., *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 Ohio St. L.J. 1391 (2006); Gregory Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue before the Supreme Court in KSR v. Teleflex*, 9 Yale J. L. & Tech. 1 (2006-07).

<sup>67</sup> See, e.g., Bradford S. Simon, *Intellectual Property and Traditional Knowledge: A Psychological Approach to Conflicting Claims of Creativity in International Law*, 20 Berkeley Tech. L.J. 1613 (2005); Joseph S. Miller, *Hoisting Originality*, 32 Cardozo L. Rev. 451, 485-86 (2009) (noting that “people respond to situations more uniformly than a typically personality-centered view of human behavior would suggest”)

<sup>68</sup> Well-recognized difficulties of this type in patent law include: i) the difficulty in determining, especially at the time of examination, whether a particular invention is nonobvious or whether it is simply part of an ongoing stream of routine advances, see, e.g., articles within 12 *Lewis & Clark L. Rev.*, *Business Law Forum: Nonobviousness—The Shape of Things to Come*; ii) the imprecision of language, and hence the inability to ensure that claim terms will be interpreted as conceived of by the patentee and examiner at the time of examination, see, e.g., *Festo*, 535 U.S. at 731-32 (discussing limitations of language as a rationale for the doctrine of equivalents). These difficulties are exacerbated by the inability of non-technically-trained judges and juries to capture accurately the perspective of the PHOSITA About this quandary, Learned Hand, writing in 1911, opined:

“I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these. The inordinate expense of time is the least of the resulting evils, for only a trained chemist is really capable of passing upon such facts, e.g., in this case the chemical character of Von Furth's so-called "zinc compound," or the presence of inactive organic substances. In Germany, where the national spirit eagerly seeks for all the assistance it can get from the whole range of human knowledge, they do quite differently. The court summons technical judges to whom technical

132 arise from the generally more severe difficulties in anticipating the future of technological  
133 evolution. The quest for ex ante certainty in intellectual property rights is doomed to failure.  
134 Nothing in our experience with real or personal property can really compare to the radical  
135 uncertainty that is endemic to patent law. While there may be occasional situations in which the  
136 value of a piece of real property drastically changes as a result of, say, a discovery of valuable  
137 minerals, a decision to build a shopping mall down the street (or even an economic recession),  
138 uncertainty moves from the periphery to the center when it comes to intellectual property.  
139 Moreover, the overlapping nature of patent rights dramatically increases the potential for  
140 windfalls and the extent to which windfalls spill over to implicate the future of innovation.

141         Given the important implications of technological unpredictability, one might expect  
142 patent law to have developed a robust set of ex post doctrines to deal with it.<sup>69</sup> This has not been  
143 the case. Where such doctrines have been developed in the past, for the most part mere vestiges  
144 of them remain today. Thus, as already discussed, the doctrine of equivalents plays very little  
145 role in today's infringement determinations.<sup>70</sup> Doctrines that might cabin the enforcement of  
146 patent rights have fared much worse. The exemption for experimental use of patented inventions,  
147 with the exception of a statutory exemption focused on dealing with regulatory delay in the  
148 pharmaceutical context, has shrunk arguably to the point of non-existence in Federal Circuit case

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questions are submitted and who can intelligently pass upon the issues without blindly groping among testimony upon matters wholly out of their ken. How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows; but all fair persons not conventionalized by provincial legal habits of mind ought, I should think, unite to effect some such advance.” Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 115 (C.C.D.N.Y. 1911).

<sup>69</sup> The unpredictability I focus on here is distinct from a form of unpredictability that is recognized in patent doctrine – the concept of “unpredictable arts.” See, e.g., Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 Nw. J. Tech. & Intell. Prop. 278 (2008) (describing the implications for “unpredictable arts” for patent disclosure doctrine). The doctrine of “unpredictable arts” recognizes the ex ante unpredictability of success for inventive efforts in some arenas, whereas I focus here on the unpredictability of how technology will progress after invention.

<sup>70</sup> Allison & Lemley, *supra* note 56.

149 law.<sup>71</sup> The so-called “reverse doctrine of equivalents,” which allows courts to find non-  
150 infringement in cases where an accused product or process fits within the claim scope despite  
151 radical change by the infringer, is occasionally acknowledged but never applied.<sup>72</sup> The Federal  
152 Circuit has clarified that there is no “de minimis” exception to patent infringement.<sup>73</sup> The  
153 doctrine of patent misuse is rarely successful at the Federal Circuit; moreover, what it reaches  
154 outside of antitrust violations is increasingly unclear.<sup>74</sup> Unlike some other jurisdictions, the  
155 United States has no recent history of working requirements<sup>75</sup> and makes very limited use of  
156 compulsory licensing.<sup>76</sup>

157         Of course, skeptics will respond to arguments in favor of contextual infringement  
158 exemptions with a number of critiques. First, one might argue that incorporating infringement  
159 exemptions and defenses into patent law will undermine the certainty of rights that is the aim of  
160 the emphasis on defined patent scope. Second, one might argue that exemptions and defenses  
161 will undermine incentives to invent, disclose and disseminate (through commercialization) new

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<sup>71</sup> For a review of both the general and specific exemptions, see Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress*, in *INTELLECTUAL PROPERTY AND INFORMATION Wealth* 107, 112-15 (Peter Yu ed., 2006)

<sup>72</sup> *Burk & Lemley*, supra note 2 at \_\_; *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1378 (Fed. Cir. 2008) (“The reverse doctrine of equivalents is rarely applied, and this court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents.”). In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (1991), the Federal Circuit considered a reverse doctrine of equivalents argument in a case involving “human Factor VIII:C, a complex protein that occurs naturally in normal blood and is essential to the clotting of blood.” The patentee had discovered a process for isolating factor VIII:C from blood plasma to a high level of purity. The product claims at issue encompassed factor VIII:C of a particular purity and potency. The accused infringer, Genentech, had produced factor VIII:C using a recombinant process that did not involve the purification of naturally occurring factor VIII:C. Genentech argued that its recombinantly produced factor VIII:C was noninfringing under the reverse doctrine of equivalents because it was “changed ‘in principle’” from the patented substance. It argued that “the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process.” The court reversed the district court’s grant of summary judgment on infringement, suggesting that the reverse doctrine of equivalents might apply in this circumstances, depending upon the facts. Unfortunately for those favoring revival of the doctrine, the case settled and the issue was never brought to trial.

<sup>73</sup> See, e.g., *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1299 (Fed. Cir. 2009).

<sup>74</sup> See Chisum on Patents 19.04; Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 *Hastings L.J.* 399, 425-31 (2003).

<sup>75</sup> Chisum on Patents 19.04

<sup>76</sup> Joshua D. Sarnoff and Christopher M. Holman, 23 *Berkeley Tech. L.J.* 1299, 1351-55 (2008).

162 technology.<sup>77</sup> Both of these arguments have some appeal, but neither is sufficient to outweigh  
163 the potential benefits of appropriately tailored post hoc policy levers.

164         Given the current state of things, it is not at all clear that much certainty would be lost by  
165 adopting a set of exemptions and defenses sensitive to the context of an alleged infringement. In  
166 practice, as already discussed, the validity and scope of a patent are not finally determined until  
167 the outcome of litigation is known. If an infringement exemption can do a reasonably  
168 predictable job of improving social welfare at the back end, it may be worth some additional  
169 blurring of the already muddy boundaries of patent rights. If we institute a fair-use-type  
170 infringement exemption, both inventors and users of patented technology will naturally  
171 incorporate the potential for such exemptions into their planning (including licensing  
172 negotiations). Indeed, the primary distinction between the present situation and one with a  
173 robust system of exemptions is not really between ex ante certainty and ex post adaptability, but  
174 between a system that recognizes the significance of the context in which patented technology is  
175 used and one that does not.

176         The potential effects of contextualized infringement determinations on incentives are also  
177 insufficient grounds to reject these potential policy levers outright. First, as the example of the  
178 doctrine of equivalents shows, it is possible to use ex post doctrines to enhance a patentee's  
179 position as well as to weaken it.<sup>78</sup> Moreover, any cabining of patent rights – whether through  
180 patentable subject matter, obviousness, utility, or any other doctrine – in principle “reduces”  
181 some kinds of incentives. On the flip side, any expansion of patent rights – via any doctrine – in

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<sup>77</sup> For discussions of the traditional incentive theories of patenting, see, e.g., Roger D. Blair & Thomas F. Cotter, Rethinking Patent Damages, 10 Tex. Intell. Prop. L.J. 1, 78-80 (2001); Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017, 1024-28 (1989); Katherine J. Strandburg, What Does the Public Get? Experimental Use and the Patent Bargain, 2004 Wis. L. Rev. 81 (2004).

<sup>78</sup> See Timothy R. Holbrook, Equivalency and Patent Law's Possession Paradox, 23 Harv. J. Law & Tech. 1, 17-18 (2009) (discussing implications of assessing equivalency at time of infringement).

182 principle adds to the deadweight loss of exclusivity. The point of using doctrines as policy  
183 levers,<sup>79</sup> however, is to get beyond this standoff to consider more specifically questions such as  
184 “Incentives to do what?” or “What specific decreased incentives in exchange for what particular  
185 social benefits?”<sup>80</sup>

186         Instituting ex post exemptions and defenses is one way to tailor patent rights to these  
187 more specific questions. So, for example, where the increase in incentives provided by enforcing  
188 patent rights in a particular context is small relative to the costs of exclusivity or the social cost  
189 of the additional incentives is particularly large, an exemption or defense can carve out specific  
190 types of uses, using a scalpel rather than a cleaver to shape a socially beneficial patent scope.

191         Allowing more flexibility at the time of infringement would also take the pressure off of  
192 doctrines such as patentable subject matter and claim construction. For example, I have argued  
193 elsewhere for a “business method use” exemption, which would avoid the difficulties inherent in  
194 determining, from abstract claim language, whether a particular claimed invention “is” a  
195 business method.<sup>81</sup> Similarly, I have argued that a research use exemption can avoid the need to  
196 determine whether a particular invention “is” a research tool in the abstract.<sup>82</sup> Such ex ante (and  
197 unavoidably abstract) determinations would be necessary to implement patentable subject matter  
198 exclusions, but are not necessary to implement use exemptions. Almost by definition, an  
199 infringement exemption can account for the fact that different uses of patented technology have

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<sup>79</sup> Dan L. Burk and Mark A. Lemley, 89 Va. L. Rev. 1575 (2003)./

<sup>80</sup> A similar argument responds to any concerns about the effects of implementing a “fair-use-type” exemption on ex ante licensing transactions. The value of patent rights directly affects the outcome of licensing negotiations. Uncertainty in the scope of rights affects transaction costs. To the extent that a fair-use-type exemption increases uncertainty it will increase transaction costs. But a carefully designed exemption may not lead to a large increase in transaction costs overall. This is because an exemption will clarify rights in some instances (i.e. it will be possible to predict with reasonable certainty that there is no liability even if the scope of the patent claims is uncertain), have no effect in many cases (where there is clearly infringement and clearly no exemption), and have only a minor effect in many other circumstances (where there is already a high degree of uncertainty as to the scope of the rights).

<sup>81</sup> Katherine J. Strandburg, *What If There Were a Business Method User Exemption to Patent Infringement?*, 2008 Mich. St. L. Rev. 245.

<sup>82</sup> Strandburg, *Users as Innovators*, supra note 30 at 500.

200 different social costs and benefits. Neither social nor private costs and benefits are all-or-nothing  
201 quantities.

202 One important exception to the present dearth of ex post policy levers in patent law arises  
203 out of the Supreme Court’s 2006 decision in *eBay v. MercExchange*.<sup>83</sup> There, a unanimous  
204 Supreme Court overturned a Federal Circuit rule that virtually guaranteed an injunctive remedy  
205 for infringement.<sup>84</sup> The Court ruled instead that the grant of an injunction is a discretionary  
206 measure decided after considering a “well-established” four-factor test, taking into account  
207 whether the plaintiff can establish “(1) that it has suffered an irreparable injury; (2) that remedies  
208 available at law, such as monetary damages, are inadequate to compensate for that injury; (3)  
209 that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity  
210 is warranted; and (4) that the public interest would not be disserved by a permanent  
211 injunction.”<sup>85</sup> The justices differed as to the extent to which this test aimed to take account of  
212 changes in the innovation environment,<sup>86</sup> but lower courts have relied on the case to provide  
213 leeway to take account of the effects that patent injunctions can have on complex, inter-related  
214 technologies, particularly in dealing with non-practicing entities.<sup>87</sup> Besides exercising discretion  
215 with respect to the granting of injunctions, courts have begun to award ongoing royalties – which  
216 have many of the same effects as compulsory licenses.<sup>88</sup>

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<sup>83</sup> 547 U.S. 388 (2006).

<sup>84</sup> *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005) (“Because the ‘right to exclude recognized in a patent is but the essence of the concept of property,’ the general rule is that a permanent injunction will issue once infringement and validity have been adjudged.”), rev’d sub nom *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006).

<sup>85</sup> 547 U.S. at 391.

<sup>86</sup> Compare 547 U.S. at 394-95 (Roberts, J., concurring) with 547 U.S. at 395-97 (Kennedy, J., concurring).

<sup>87</sup> See, e.g. Stacy Streur, *The eBay Effect: Tougher Standards but Courts Return to the Prior Practice of Granting Injunctions for Patent Infringement*, 8 *Nw. J. Tech. & Intell. Prop.* 67 (2009).

<sup>88</sup> See, e.g., *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1316 (Fed. Cir. 2007) (majority and concurrence debating whether ongoing royalties constitute a compulsory license). See also H. Tomas Gomez-Arostegui, *Prospective Compensation in Lieu of a Final Injunction in Patent and Copyright Cases*, 78 *Fordham L. Rev.* 1661 (2010).

217           Of course, after *eBay v. MercExchange*, one must ask whether more is needed. Is the  
218 discretion now afforded to courts at the remedies stage sufficient to provide ex post contextual  
219 policy levers where they are desirable? There are three basic reasons why the answer to this  
220 question is no. First, as mentioned above, the *eBay* factors are not tailored to promote  
221 innovation. There is no particular reason to think that courts applying them will make the most  
222 socially beneficial choices about when to grant (or not to grant) injunctive relief. Thus, at the  
223 very least, it would be desirable to explore factors that courts should consider in making the  
224 decision. Second, there are reasons to anticipate specific types of market failures in patent  
225 licensing that are not illuminated by the *eBay* test. Many of these parallel those that have been  
226 advanced to justify fair use in copyright law. Third, there are situations in which the social costs  
227 of exclusivity in a particular context simply outweigh the social benefits of the additional patent  
228 incentive provided by infringement liability in that context. The ex ante doctrines of patentable  
229 subject matter, nonobviousness, and so on cannot identify these situations.

230           The lower courts' responses to the *eBay* ruling demonstrate that district court judges, at  
231 least, find it useful to have some mechanism for ex post tailoring at their disposal. The extent to  
232 which courts have grasped at this slim reed of ex post tailoring power begs the question whether  
233 there might be other and better ways to design a set of "policy levers" to be applied at the time of  
234 infringement. The rest of this Article considers that question. Part II reviews a previous  
235 proposal for "patent fair use" and discusses how social and technological changes since that  
236 proposal was made have bolstered the case for a fair-use-type exemption and provided insights  
237 into how it should be designed. Part III discusses proposals to deal with some of the issues  
238 discussed in Part II either by beefing up existing doctrine or by some form of an independent  
239 inventor defense and concludes that those proposals are less desirable than a general fair-use-

240 type defense. Part IV provides the justification for the “patent fair use 2.0” proposal, sets it out  
241 in some detail, and then illustrates how it might be applied to the cases of open source software  
242 and essential medicines. Part V concludes.

## 243 II. WHY PATENT FAIR USE NOW?

### 244 A. Professor O’Rourke’s Patent Fair Use Proposal

245 This Article is certainly not the first to recognize many of these justifications for  
246 infringement exemptions. In particular, a groundbreaking article by Maureen O’Rourke ten  
247 years ago proposed a version of “patent fair use” based on many of the considerations that will  
248 be discussed here.<sup>89</sup> Reasoning by analogy to fair use in copyright law and expanding on  
249 existing patent doctrines, O’Rourke identified a list of five factors, which she argued should form  
250 the basis of a patent fair use doctrine: “i) the nature of the advance represented by the  
251 infringement; ii) the purpose of the infringing use; iii) the nature and strength of the market  
252 failure that prevents a license from being concluded; iv) the impact of the use on the patentee’s  
253 incentives and overall social welfare; and v) the nature of the patented work.”<sup>90</sup>

254 O’Rourke’s explication of these factors focused on the potential for market failure in the  
255 patent system and on the implications of a fair use finding for patentee incentives to invent.  
256 Thus, for instance, she notes that “commercial use is much more likely to harm the patentee’s  
257 incentives without a corresponding increase in social welfare,”<sup>91</sup> points to the statutory  
258 exemption for use of patented inventions to prepare for Food and Drug Administration (FDA)  
259 approval as an example of a situation in which the social value of certain types of infringement  
260 has been deemed to outweigh any corresponding depression of incentives,<sup>92</sup> and discusses a

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<sup>89</sup> Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

<sup>90</sup> *Id.* at 1205.

<sup>91</sup> *Id.* at 1206.

<sup>92</sup> *Id.* at 1197-98.

261 number of situations in which fair use could be used to ensure that patentees do not have overly  
262 broad ability to hamper follow-on innovation. For example, her first factor is included for  
263 reasons similar to those justifying the reverse doctrine of equivalents – to protect radical  
264 improvers from hold-up by earlier patentees.<sup>93</sup>

265 O’Rourke focuses heavily on the need for fair use in circumstances in which network  
266 effects give patentees overly broad control over markets extending beyond the market for the  
267 patented invention itself,<sup>94</sup> discussing the case of software application programming interfaces  
268 (APIs) in detail.<sup>95</sup> She recognizes the potential for licensing breakdown in situations involving  
269 complex products that implicate many patents (the “anticommons” problem) and the related  
270 possibility that licensing breakdown might undermine the “blocking patents” doctrine.<sup>96</sup> The  
271 blocking patents doctrine assumes that those who improve significantly upon patented inventions  
272 will be able to coordinate exploitation of the improvement with the initial patentee because both  
273 parties will be motivated to cross-license.<sup>97</sup>

274 Importantly, O’Rourke suggests that a fee should sometimes be charged for patent “fair  
275 use.”<sup>98</sup> In this respect her proposal foreshadows the practices of those district courts that have  
276 ordered ongoing royalties while denying injunctions in the wake of *eBay v. MercExchange*.<sup>99</sup>

#### 277 B. Signs of the Times: O’Rourke’s Concerns Remain Valid Today

278 Most of the arguments O’Rourke made in her 2000 article remain compelling today.  
279 Indeed, in many respects, O’Rourke’s article was ahead of its time. Many of the justifications  
280 she advanced for some form of patent fair use have become considerably stronger in recent

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<sup>93</sup> Id. at 1228-30.

<sup>94</sup> Id. at 1233-34.

<sup>95</sup> Id. at 1211-35.

<sup>96</sup> Id. at 1236-39. See also, Robert Merges, Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents, 62 Tenn. L. Rev. 75 (1994).

<sup>97</sup> O’Rourke, supra note 89 at 1194.

<sup>98</sup> Id. at 1234 – 35.

<sup>99</sup> See discussion, supra.

281 years. While the anticommons problem was recognized at the turn of this century, the particular  
282 issues raised by non-practicing entities (so-called “patent trolls”) in relation to complex  
283 technology were not yet widely recognized.<sup>100</sup> By 2006, however, Justice Kennedy’s  
284 concurrence in *eBay v. MercExchange* responded explicitly to concerns about non-practicing  
285 entities and the problem of hold-up for complex technologies.<sup>101</sup> Similarly, while the research  
286 exemption was a topic of concern in 2000, the Federal Circuit’s 2002 *Madey v. Duke* opinion  
287 heightened concerns about the diminishing scope of the common law exemption.<sup>102</sup> The issue of  
288 unauthorized research tool use remains much discussed and unresolved.<sup>103</sup> Longstanding  
289 concerns about the applicability of patent infringement doctrine to reverse engineering of  
290 software, a central focus of O’Rourke’s analysis, also remain.<sup>104</sup>

### 291 C. Signs of the Times: Evolving Reasons for Patent Fair Use

292 Not only have developments over the past ten years heightened some of the concerns  
293 motivating O’Rourke’s fair use proposal, but also new issues have come to the fore that both  
294 provide additional rationales for a fair-use-type infringement exemption and help us to flesh out  
295 relevant factors for such an exemption.

296 Traditionally, one could divide the world of potential patent infringers into several  
297 categories: commercial users of industrial processes, commercial manufacturers of patented

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<sup>100</sup> The first use of the term “patent troll” in a law review article, for example, was in 2003. Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509 (2003).

<sup>101</sup> 547 U.S. at 396 (“An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees. . . . For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent.”) (Kennedy, J., concurring).

<sup>102</sup> *Madey v. Duke Univ.*, 307 F.3d 1351, 1362–63 (Fed. Cir. 2002) (experimental use defense persists in a “very narrow form”). Though the Supreme Court did preserve a broad reading of the statutory FDA exemption. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

<sup>103</sup> See *id.* at n. 7 (explicitly leaving open the status of research tools under the statutory research exemption); *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008) (device used in development of FDA submissions but not itself subject to FDA approval was not covered by statutory research exemption). See also Strandburg, *Users as Innovators*, *supra* note 30 at 502-03.

<sup>104</sup> Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539 (2009)

298 products, innovators building upon patented products or processes, and consumers of patented  
299 products. Commercial users of industrial processes and manufacturers of patented products  
300 could be expected to negotiate patent licenses. Follow-on innovators were protected by a  
301 complex of patent doctrines: the reverse doctrine of equivalents (or its predecessors) in principle  
302 protected radical innovators from hold-up by earlier inventors; the experimental use exemption  
303 permitted inventors to build upon the patent disclosures of earlier inventors; and the doctrine of  
304 blocking patents, which allows the patenting of improvements without the permission of earlier  
305 inventors (in contrast to the situation in copyright law),<sup>105</sup> encouraged inventors of  
306 complementary inventions to negotiate cross-licenses. In a world dominated by manufacturer  
307 innovation, there was little need to worry about infringement by what we would now call end  
308 users of technology. Consumers of patented products were protected by the doctrine of patent  
309 exhaustion (which holds that a patentee’s rights in a particular artifact are “exhausted” when the  
310 artifact is sold to a consumer by an authorized manufacturer).<sup>106</sup>

311         Recent changes in law and technology have changed the landscape. Traditional  
312 approaches may no longer suffice to induce the optimal level of invention, disclosure, and  
313 dissemination of new technology. Here I discuss five important developments, which provide  
314 reasons for concern about the balance among patent exclusivity, access, and follow-on  
315 innovation: i) the increasing importance (and recognition of) non-traditional paradigms of  
316 innovation, including open source approaches and user innovation, especially within  
317 communities of users; ii) a breakdown of the effectiveness of patent exhaustion and repair and  
318 reconstruction as means to take consumers out of the patent infringement loop; iii) growing

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<sup>105</sup> See Julie Cohen and Mark Lemley, Patent Scope and Innovation in the Software Industry, 89 Cal. L. Rev. 1, 23-25 (2001)

<sup>106</sup> The Supreme Court recently reaffirmed this doctrine in *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109, 2117 (2008). See also Chisum on Patents, 16.03[2][a].

319 evidence of the ineffectiveness of patent notice and search, especially in some technological  
320 arenas; iv) increasing recognition of the prevalence of independent invention among potential  
321 infringers; and v) the increasing ubiquity of software in technology, which is accompanied by a  
322 growing separation of design from manufacture and a movement toward mass customization.  
323 Each of these developments upsets assumptions underlying the traditional patent regime,  
324 changing the balance of costs and benefits of patenting in ways that may justify broader  
325 infringement exemptions.

### 326 1. Alternative Paradigms of Innovation

327 Numerous patent doctrines reflect an assumption of an industrial seller innovator. Yet, as  
328 others and I have discussed in more detail elsewhere, that paradigm is increasingly out of date.<sup>107</sup>  
329 The success of the open source software movement, with its increasingly important role in  
330 commercial ventures, is itself a game changer.<sup>108</sup> Moreover, that success has spawned a number  
331 of attempts to introduce similar collaborative models into other arenas, including  
332 biotechnology,<sup>109</sup> agriculture,<sup>110</sup> and traditional tangible products.<sup>111</sup> Alongside the growing  
333 importance of this particular model of collaborative innovation is increasing recognition of the  
334 importance of users as technology innovators and of the extent to which groups of users of  
335 similar technology often share their inventions freely with one another, even in commercial

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<sup>107</sup> See, e.g., Strandburg, Users as Innovators, supra note 30; Benkler, supra note 30; von Hippel, supra note **Error!**  
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<sup>108</sup> See STEVEN WEBER, THE SUCCESS OF OPEN SOURCE (2004); Siobhan O'Mahony & Beth Bechky, *Boundary Organizations: Enabling Collaboration Among Unexpected Allies*, 53 ADMIN. SCI. Q. 422 (2008).

<sup>109</sup> For a recent review of these efforts, see Emily Marden, Health Care & Pharmaceuticals: Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?, 11 Minn. J.L. Sci. & Tech. 217 (2010). See also Strandburg, *Evolving Innovation Paradigms*, supra note 30 and references cited therein.

<sup>110</sup> See, e.g., Keith Aoki, "Free Seeds, Not Free Beer": Participatory Plant Breeding, Open Source Seeds, and Acknowledging User Innovation in Agriculture, 77 Fordham L. Rev. 2275 (2009).

<sup>111</sup> For an interesting example of such a project see [www.quirky.com](http://www.quirky.com). Of course, community innovation of tangible products is not at all new. See, for example, Nikolas Franke and Sonali Shah, How Communities Support Innovative Activities: An Exploration of Assistance and Sharing among End-Users, 32 Res. Pol'y 157 (2003) (studying community innovation among users of sports equipment).

336 contexts.<sup>112</sup> Technological shifts, especially the increasing importance of software as a  
337 component of technology and of computers as means for facilitating collaboration, suggest that  
338 the contribution of these non-traditional paradigms is likely to grow.<sup>113</sup>

339         Where user, open, and collaborative innovation predominate, a number of basic  
340 assumptions of patent doctrine are undercut.<sup>114</sup> Incentives to invent, disclose, and disseminate  
341 technology may be provided by use, by reciprocal exchange, or by other non-patent mechanisms,  
342 decreasing the importance of patent incentives and correspondingly tilting the cost-benefit  
343 balance away from exclusivity. Such approaches sometime target markets under-served by or  
344 outside of the scope of the markets that are important to the patentee, thus decreasing the impact  
345 of infringement on the patentee's profits and increasing the potential positive social externalities  
346 of unauthorized use. Moreover, user, open, and collaborative innovations are often either  
347 unpatentable because of issues of inventorship due to their incremental and emergent origins or  
348 unpatented because their inventors do not wish to patent them or lack the funds to do so.  
349 Because these innovations are not patent protected, the blocking patent doctrine -- patent law's  
350 mechanism for balancing rights between initial and follow-on inventors -- breaks down.<sup>115</sup>

351         2.         The Declining Relevance of Patent Exhaustion and the Repair/Reconstruction  
352 Distinction

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<sup>112</sup> See von Hippel, *Democratizing Innovation*, supra note **Error! Bookmark not defined.**; Eric von Hippel & Georg von Krogh, *Free Revealing and the Private Collective Model for Innovation Incentives*, 36 R&D Mgmt. 295(2006); Joachim Henkel, *Selective Revealing in Open Innovation Processes: The Case of Embedded Linux*, 35 Res. Pol'y 953(2006); Dietmar Harhoff, et al., *Profiting from Voluntary Information Spillovers: How Users Benefit by Freely Revealing Their Innovations*, 32 Res. Pol'y 1752(2003).

<sup>113</sup> See, e.g., Benkler, supra note 30; Carliss Baldwin and Eric von Hippel, *Modeling a Paradigm Shift: From Producer Innovation to User and Open Collaborative Innovation*, Working Paper, available at <http://hbswk.hbs.edu/item/6325.html>.

<sup>114</sup> Strandburg, *Users as Innovators*, supra note 30.

<sup>115</sup> Ex ante licensing approaches, such as the General Public License ("GPL") often used in open source software, are of only limited use in the patent context, since infringers need not be copiers and thus need have no pre-existing relationship with a patentee in order to infringe. For an extensive recent discussion of the GPL, see Greg R. Vetter, *Commercial Free and Open Source Software: Knowledge Production, Hybrid Appropriability, and Patents*, 77 Fordham L. Rev. 2087 (2009).

353 Under the traditional seller innovator paradigm, the doctrines of patent exhaustion  
354 (corresponding to copyright's "first sale" doctrine<sup>116</sup>) and repair/reconstruction<sup>117</sup> provided  
355 significant protection for consumers against liability for patent infringement while making  
356 ordinary use and repair of their purchases. The protection provided by these doctrines is  
357 shrinking, however.

358 First, the position of users of patented products and processes has shifted drastically due  
359 to the increasing dominance of software and business method claims. More and more often,  
360 ordinary consumers find themselves in the position, not of purchasers of products about which  
361 patent rights have been exhausted, but of users of patented processes or "systems" to which  
362 patent exhaustion may not apply.<sup>118</sup> For example, ordinary consumers use most software  
363 products as licensees. These licenses may contain both copyright- and patent-based limitations.  
364 While in most situations to date commercial entities mediate consumers' access to patented  
365 technology and provide any necessary licenses, those same licenses often purport to restrict  
366 significantly what purchasers can do with the technology.<sup>119</sup> While the Supreme Court in  
367 *Quanta Computer, Inc. v. LG Elecs., Inc.*, reaffirmed the doctrine of patent exhaustion, the Court

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<sup>116</sup> 17 U.S.C. 109.

<sup>117</sup> Chisum on Patents, 16.03[3]

<sup>118</sup> The Supreme Court held in *Quanta Computer, Inc. v. LG Elecs., Inc.*, 533 U.S. 617 (2008), that method patents may be exhausted by the sale of an item that "substantially embodies" the method. The scope of situations in which exhaustion applies to methods is not at all clear, however. The district court in *Katz Interactive Call Processing Patent Litig. v. DirecTV Group, Inc.*, 2009 U.S. Dist. LEXIS 72134 (C.D. Cal. May 1, 2009), determined that exhaustion applied to sale of a service, for example, but the question was one of first impression and similar questions have not yet been addressed by other courts.

<sup>119</sup> There are reasons to be concerned about the permissible scope and terms of these licenses. Others have discussed this issue, primarily in the context of software copyright licenses. See, e.g., Anthony Reese, *The First Sale Doctrine in the Era of Digital Networks*, 44 B.C.L. Rev. 577 (2003); Glen O. Robinson, *Personal Property Servitudes*, 71 U. Chi. L. Rev. 1449 (2004); Elizabeth I. Winston, *Why Sell What You Can License? Contracting Around Statutory Protection of Intellectual Property*, 14 Geo. Mason L. Rev. 93 (2006).; Molly Shaffer van Houweling, *The New Servitudes*, 96 Geo. L.J. 885 (2008); Saami Zain, *Quanta Leap or Much Ado about Nothing*, 20 Alb. L.J. Sci. & Tech. 67 (2010). I do not discuss it here.

368 specifically declined to address what limits (if any) apply to adhesion contract restrictions on  
369 consumer use.<sup>120</sup> Lower courts have generally enforced such restrictions.<sup>121</sup>

370         Moreover, patents are increasingly likely to cover things that users and small  
371 entrepreneurs can do and make for themselves, without a manufacturer or other commercial  
372 intermediary.<sup>122</sup> These types of actors generally have neither the sophistication nor the funds to  
373 engage in patent clearance searches (indeed, many have argued that even sophisticated players  
374 cannot effectively clear patent rights in the software and business method arenas<sup>123</sup>) or the  
375 wherewithal to engage effectively in case-by-case licensing transactions even if they do learn of  
376 a potentially relevant patent.

377         Similarly, in the past, the repair/reconstruction doctrine generally protected consumers  
378 when they engaged in intuitively reasonable manipulations of their patented purchases. Thus, in  
379 the “old” days, consumers found it unreasonable to be precluded from repairing things they had  
380 purchased, even if those items were patented. Patent doctrine recognized this expectation as  
381 legitimate.<sup>124</sup> Reconstruction of patented inventions, however, was much more likely to be the  
382 province of commercial players.<sup>125</sup> The repair/reconstruction doctrine evolved to separate these  
383 two types of behavior, broadly privileging repair, even when it involved using after-market parts,  
384 while counting wholesale reconstruction of patented products as infringement (and thus  
385 protecting patentees from attempts by competitors to undermine patent exclusivity through the

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<sup>120</sup> *Quanta*, 533 U.S. at n. 7. See also *McFarling v. Monsanto Co.*, 545 U.S. 1139 (2005), denying cert in *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004), which enforced a contractual restriction on use of second generation patented seeds.

<sup>121</sup> See discussion of the case law in *Zain*, supra note 119.

<sup>122</sup> This is the case for business method and software patents and increasingly may be the case for tangible goods as technology for “mass customization” through “toolkits” and for “3D printing” improves. See e.g., Eric von Hippel, *Perspective: User Toolkits for Innovation*, 18 *J. Prod. Innovation Mgmt.*, 247 (2001); Simon Bradshaw et al., *The Intellectual Property Implications of Low-Cost 3D Printing*, 7 *Scripted* 5 (2010) (discussing the issue in the context of UK law).

<sup>123</sup> *Bessen & Meurer*, supra note 19; *Burk & Lemley*, supra note 2.

<sup>124</sup> *Chisum on Patents*, 16.03[3].

<sup>125</sup> *Id.*

386 sale of “parts”).<sup>126</sup> Nowadays, in contrast, consumers are increasingly “prosumers,” who expect  
387 to interact with the products they purchase in creative and innovative ways.<sup>127</sup> The applicability  
388 of the repair/reconstruction distinction either to the increasing number of products that are  
389 licensed rather than purchased or to significant consumer customization is unclear at best.

### 390 3. Breakdown of Patent Notice and Search

391 Much has been written lately about the breakdown of the patent notice function in  
392 certain technological areas. As discussed in detail by Bessen and Meurer, this breakdown is due  
393 in part to inherent difficulties in describing software and business method inventions, in part to  
394 low standards for enablement and description in these areas, which permit broad and vaguely  
395 bounded claims, and in part to the unpredictability of claim construction, which can lead to  
396 patent coverage of inventions that were completely unforeseeable at the time of patenting.<sup>128</sup>  
397 The import of these problems is to increase the cost of patent search and decrease its  
398 effectiveness (to the point where, in software for instance, even sophisticated commercial players  
399 reportedly often opt out of patent clearance and hope for the best<sup>129</sup>).

400 Patent search problems will be even greater for those engaged in the new innovation  
401 paradigms. Consumer innovators lack the sophistication and funds to embark on searches.

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<sup>126</sup> Id.

<sup>127</sup> The term “prosumer” has taken on a variety of meanings. Here I adopt the meaning originated by Alvin Toffler, who coined the term in 1980, Alvin Toffler, *The Third Wave* (1980), and discussed in a recent book co-authored with his wife. Alvin Toffler and Heidi Toffler, *Revolutionary Wealth* (2006) (prosumer is “One who create goods, services or experiences for his own satisfaction, rather than for sale or exchange.”) The Tofflers’ predictions of “revolutionary wealth” are sadly pre-2008, but their predictions of a rise in “prosumption” are reflected in widespread Web 2.0 phenomena and perhaps in an incipient wave of mass customization of tangible goods. See also, e.g., Michael Weinberg, *It Will Be Awesome If They Don’t Screw It Up: 3d Printing, Intellectual Property, and the Fight over the Next Great Disruptive Technology* (Public Knowledge White Paper, November 2010), available at <http://www.publicknowledge.org/it-will-be-awesome-if-they-dont-screw-it-up> (describing the emerging technology of 3D printing and its potential to empower users to customize and create products).

<sup>128</sup> See Bessen & Meurer, *supra* note 19.

<sup>129</sup> Lemley, *Ignoring Patents*, *supra* note 59.

402 Moreover, emergent innovations such as open source software lack a central “blueprint” which  
403 even could be compared with patent claims.<sup>130</sup>

#### 404 4. The Importance of Independent Invention

405 Though copying has never been a requirement of patent infringement (as it is for  
406 copyright infringement), much of traditional patent doctrine and rhetoric assumes implicitly that  
407 infringers are generally copyists.<sup>131</sup> While independent, nearly simultaneous invention has  
408 undoubtedly always been common, the extent to which infringement suits involve independent  
409 inventors as defendants is newly recognized and probably increasing as a result of the patent  
410 notice problems described in the previous section. Empirical studies at least suggest that a large  
411 fraction of accused infringers, if not most, are independent inventors (or at least are not  
412 copyists).<sup>132</sup>

413 Independent invention (at least if it is close to the time of patenting) diminishes the force  
414 of the free rider justification for patenting, suggesting that the patent incentive may not have  
415 been needed to induce a given invention.<sup>133</sup> Even if we need the prospect of a patent to induce a  
416 race to produce a particular innovation, economic arguments suggest that there is no need for a  
417 winner-take-all regime.<sup>134</sup>

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<sup>130</sup> While most open source software projects seem to have some kind of hierarchical structure for vetting “official” versions, see Weber, *supra* note 108, it seems unlikely, at least for a complex piece of software such as an operating system, that even the vetters have a complete view of the detailed implementation of algorithms in the various modules and all of the their interactions. Moreover, one of the values of open source software is its customizability by users. Customizers are even less likely to be able to perform a proper patent clearing search.

<sup>131</sup> See, e.g., *Festo*, 535 U.S. at 727; *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950) (explaining the doctrine of equivalents as a defense against “unscrupulous copyists”).

<sup>132</sup> See, e.g., Christopher A. Cotropia and Mark A. Lemley, *Copying in Patent Law*, 87 N.C. L. Rev. 1421 (2009).

<sup>133</sup> For this reason, nearly simultaneous invention is sometimes treated as a “secondary consideration” suggesting obviousness. See Chisum on Patents 5.05[7].

<sup>134</sup> See, e.g., Stephen M. Maurer and Suzanne Scotchmer, *The Independent-Invention Defense in Intellectual Property*, 69 *Economica* 535 (2002); Carl Shapiro, *Patent Reform: Aligning Reward and Contribution*, in 8 *INNOVATION POLICY AND THE ECONOMY*, Adam Jaffe, Josh Lerner, and Scott Stern, eds. (2007) at 111; Samson Vermont, *Independent Invention as a Defense to Patent Infringement*, 105 *Mich. L. Rev.* 475 (2006).

418           Moreover, fairness concerns weigh against imposing infringement liability on  
419 independent inventors; those concerns are enhanced when the preferred alternative – patent  
420 search – is expensive or infeasible. For all of these reasons, commentators have increasingly  
421 suggested either an independent inventor defense or other means to decrease the burden of patent  
422 liability for independent inventors.<sup>135</sup>

423           One justification for nonetheless deeming independent inventors to be infringers relies on  
424 the idea that duplicative research is wasteful, a justification which is at least controversial.<sup>136</sup>  
425 Moreover, this justification makes sense only if the patent notice function is effective so that  
426 search costs are not too high. This does not seem to be the case in many arenas, as just  
427 discussed.

428           Another justification for holding independent inventors liable for infringement applies to  
429 those who keep their inventions as trade secrets. Potential infringement liability might induce  
430 some inventors to opt for patenting rather than trade secrecy.<sup>137</sup> It is not at all clear that trade  
431 secrecy is worse for society than patenting in situations where independent invention occurs,  
432 however. Independent inventors operating in secret are still presumably in competition with one  
433 another (at least if they are commercial inventors), so the public gets the benefit of lower prices,  
434 even if disclosure is delayed. Moreover, only one of these inventors need make the choice to  
435 freely reveal the invention to undermine the secrecy of the others. In any event, prior user

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<sup>135</sup> See, e.g., Oskar Liivak, Rethinking the Concept of Exclusion in Intellectual Property, *Geo. L. J.* (forthcoming 2010); Shapiro, *supra* note 134; Samson Vermont, Independent Invention as a Defense to Patent Infringement, 105 *Mich. L. Rev.* 475 (2006); Mark A. Lemley, Should Patent Infringement Require Proof of Copying?, 105 *Mich. L. Rev.* 1525 (2007); Samson Vermont, The Angel is in the Big Picture: A Response to Lemley, 105 *Mich. L. Rev.* 1537 (2007).

<sup>136</sup> See, e.g., Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 *Colum. L. Rev.* 839, 870-79 (1990)

<sup>137</sup> This theory is reflected in patent case law, which treats an inventor's own trade secret exploitation of an invention as "public use", but allows patenting in the face of a third party's secret use. See, e.g., *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) ("Early public disclosure is a linchpin of the patent system. As between a prior inventor who benefits from a process by selling its product but suppresses, conceals, or otherwise keeps the process from the public, and a later inventor who promptly files a patent application from which the public will gain a disclosure of the process, the law favors the latter.")

436 defenses, which excuse infringement by independent inventors who do not make it to the patent  
437 office first, are common in other patent systems.<sup>138</sup> The United States has implemented such a  
438 defense in the business method patent arena<sup>139</sup> without apparent ill effect.

#### 439 5. Mass Customization and the Separation Between Manufacture and Design

440 Much has been made in the copyright literature about the changing structure of the  
441 entertainment industry, from a system of centralized production aimed at mass markets to an  
442 increasingly decentralized and individualized marketplace, in which users play important roles in  
443 disseminating and creating content.<sup>140</sup> Similar changes in the production of goods are under  
444 discussion in the management literature, but have been little noted in the legal literature.<sup>141</sup>

445 Just as computer technology and the Internet have lessened (or even undermined) the  
446 need for identical mass-produced entertainment products, the increasing role of computerized  
447 design, manufacture, and operation with respect to tangible goods makes it easier to customize  
448 products and to design user-friendly “toolkits” for customization.<sup>142</sup> The line between user and  
449 manufacturer is beginning to blur. Moreover, some experts predict an increasing availability of  
450 custom fabrication plants and even of home equipment for “3D printing,” which will even more

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<sup>138</sup> See Christopher Garrison, Exceptions to Patent Rights in Developing Countries, International Centre for Trade and Sustainable Development, Issue Paper No. 17 (October 2006) at 5-6, 49-50 (discussing prior user rights in various countries).

<sup>139</sup> 35 U.S.C. 273(b).

<sup>140</sup> See, e.g., Edward Lee, Warming up to User-Generated Content, 2008 U. Ill. L. Rev. 1459; Steven A. Hetcher, Using Social Norms to Regulate Fan Fiction and Remix Culture, 157 U. Pa. L. Rev. 1869 (2009); Daniel Gervais, The Tangled Web of UGC: Making Copyright Sense of User-Generated Content, 11 Vand. J. Ent. & Tech. L. 841 (2009); Debora Halbert, Mass Culture and the Culture of the Masses: A Manifesto for User-Generated Rights, 11 Vand. J. Ent. & Tech. L. 921 (2009); Steven Hetcher, Hume’s Penguin, or, Yochai Benkler and the Nature of Peer Production, 11 Vand. J. Ent. & Tech. L. 963 (2009); Mary W.S. Wong, “Transformative” User-Generated Content in Copyright Law: Infringing Derivative Works or Fair Use?, 11 Vand. J. Ent. & Tech. L. 1075 (2009); Jane C. Ginsburg, Separating the Sony Sheep from the Grokster Goats: Reckoning the Future Business Plans of Copyright-Dependent Technology Entrepreneurs, 50 Ariz. L. Rev. 577 (2008).

<sup>141</sup> See, e.g., von Hippel, Democratizing Innovation, supra note **Error! Bookmark not defined.**

<sup>142</sup> See, e.g., Nikolas Franke & Frank Piller, *Value Creation by Toolkits for User Innovation and Design: The Case of the Watch Market*, 21 J. Prod. Innovation Mgmt. 401(2004); Nikolas Franke & Eric A. von Hippel, *Satisfying Heterogeneous User Needs via Innovation Toolkits: The Case of Apache Security Software*, 32 Res. Pol’y 1199(2003); Lars Bo Jeppesen, *User Toolkits for Innovation: Consumers Support Each Other* (Copenhagen Bus. Sch. Dep’t Econ. & Strategy 2005); Eric A. von Hippel & Ralph Katz, *Shifting Innovation to Users via Toolkits* (2002), available at <http://ssrn.com/abstract=309740>.

451 significantly blur the distinction between user and manufacturer and between designing and  
452 producing tangible goods.<sup>143</sup> If these predictions are realized, not only will consumers be more  
453 able to design their own products, but also there will likely be a growing number of “designer  
454 innovator” entrepreneurs who, rather than contracting with a manufacturer to produce products  
455 using their designs, will seek to market designs directly to consumers. Patents may or may not  
456 play an important role in such new business models.<sup>144</sup> In this brave new world, ordinary  
457 consumers may be able to make more extensive modifications of patented technology than was  
458 possible with earlier tangible goods. They may also be more likely to stumble upon patented  
459 technology through independent invention, to be able to make copies of patented technology for  
460 their own use, and to be “innocent purchasers” of infringing technology made by others. All of  
461 these developments taken together mean that it will become more and more likely that small  
462 entities (consumers or “designer innovators”), for whom the transaction costs involved in  
463 clearing patent rights would be prohibitive, will be patent infringers not protected by patent  
464 exhaustion or the repair/reconstruction doctrine.

### 465 III. EXISTING EX POST DOCTRINES AND RECENT PROPOSALS

466 While there is no general defense to patent infringement analogous to copyright’s fair use  
467 doctrine, there are, as already discussed in passing, various ex post doctrines in patent law that  
468 seek to address the issues of transaction failures, the balance between initial and follow-on  
469 innovators, and the potential that overriding societal costs may outweigh the benefits of  
470 patenting. These doctrines are inadequate to the task of serving as effective policy levers for

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<sup>143</sup> See, e.g., Eric von Hippel, Perspective: User Toolkits for Innovation, 18 J. Prod. Innovation Mgmt., 247 (2001); Simon Bradshaw et al., The Intellectual Property Implications of Low-Cost 3D Printing, 7 Scripted 5 (2010) (discussing the issue in the context of UK law). See also, Public Knowledge White Paper, supra note \_\_\_ at 2 (“The machines can download plans for a wrench from the Internet and print out a real, working wrench. Users design their own jewelry, gears, brackets, and toys with a computer program, and use their machines to create real jewelry, gears, brackets, and toys.”)

<sup>144</sup> This issue is worthy of more extensive consideration, which I do not attempt here.

471 various reasons. As discussed above, some, such as the experimental use exemption<sup>145</sup> and prior  
472 user defense for business methods,<sup>146</sup> are too narrowly targeted or interpreted to serve the  
473 purpose. Others, such as the reverse doctrine of equivalents<sup>147</sup> and patent misuse,<sup>148</sup> are never or  
474 increasingly rarely applied. Still others, such as the doctrines of patent exhaustion and  
475 repair/reconstruction, are no longer adequate in light of social and technical changes.<sup>149</sup> The  
476 most recent addition to the list – the discretion given to district court judges as a result of the  
477 Supreme Court’s *eBay v. MercExchange* decision – is promising but at least to date inadequately  
478 tailored to the innovation issues motivating the patent system.<sup>150</sup>

479 In light of the slim ex post options available under existing law, commentators have made  
480 a number of suggestions for reform. These suggestions fall primarily into two categories:  
481 proposals to beef up existing doctrines and proposals to deal with independent invention.

#### 482 A. Proposals to Beef Up Existing Doctrines

483 A number of scholars (including this one) have argued for a more expansive research exemption,  
484 while others have disputed the wisdom of such an exemption.<sup>151</sup> The Supreme Court has in fact  
485 taken an expansive approach to the statutory exemption for experimentation related to FDA  
486 approval.<sup>152</sup> While I continue to believe an expansive research exemption is a good idea, there  
487 are limits to what a piecemeal approach can accomplish (particularly if implemented by statute).

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<sup>145</sup> See discussion, *supra*, at \_\_\_. See also Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance Between Current and Future Technical Progress*, in *Intellectual Property and Information Wealth*, Peter Yu, ed. (2006) for a review; Burk & Lemley, *supra* note 2.

<sup>146</sup> See discussion, *supra*, at \_\_\_. See also Burk & Lemley, *supra* note 2.

<sup>147</sup> See discussion, *supra*, at \_\_\_. See also Burk & Lemley, *supra* note 2.

<sup>148</sup> See discussion, *supra*, at \_\_\_. See also Burk & Lemley, *supra* note 2.

<sup>149</sup> See discussion, *supra*, at \_\_\_.

<sup>150</sup> See discussion, *supra*, at \_\_\_.

<sup>151</sup> For reviews of the literatures see Joshua D. Sarnoff and Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents*, 23 *Berkeley Tech. L.J.* 1299 (2008) (relating to research tools); Strandburg, *supra* note 7 (relating to both common law and statutory exemptions).

<sup>152</sup> See e.g., *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

488 For example, I have argued elsewhere that a business method use exemption would be  
489 justified by arguments based on user innovation very similar to those I offered for expanding the  
490 research exemption.<sup>153</sup> Despite the similar justifications, these proposals raise entirely separate  
491 questions under existing law. Similarly, the statutory exemption from imposition of remedies  
492 (but not from infringement liability) for a medical practitioner’s “performance of a medical or  
493 surgical procedure on a body”<sup>154</sup> is ill-equipped to deal with issues raised by the outsourcing of  
494 diagnostic testing to independent laboratories, despite the fact that similar questions about  
495 doctors as user innovators and the importance of non-commercial motivations arise.<sup>155</sup> If we can  
496 identify common factors underlying various scenarios in which an infringement exemption  
497 would be desirable it is sensible to consider the merits of a more general fair-use-like doctrine.

498 The reverse doctrine of equivalents is, of course, a general approach and several authors  
499 (including Burk and Lemley in the book that is the impetus for this symposium) have suggested  
500 revitalizing it.<sup>156</sup> The doctrine, which the Federal Circuit recently described as “rarely invoked  
501 and virtually never sustained,”<sup>157</sup> might in principle have the potential to play a role similar to  
502 the role that “transformative use” plays in copyright’s fair use doctrine.<sup>158</sup> It could be employed  
503 to deal with “blocking patent failure,” in which bargaining between initial and follow-on  
504 inventors with overlapping patent rights breaks down or there is independent invention of a  
505 significant advance over a patented technology.

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<sup>153</sup> Strandburg, *supra* note 81.

<sup>154</sup> 35 USC 287(c)

<sup>155</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (U.S. 2006) (Writ of certiorari dismissed as improvidently granted in case involving patentability of broad claims to medical diagnostic tests); *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009) (finding broad claims to medical diagnostic tests patentable) (petition for cert pending).

<sup>156</sup> See, e.g., Burk & Lemley, *supra* note 2; Timothy R. Holbrook, *Equivalency and Patent Law’s Possession Paradox*, 23 *Harv. J. Law & Tech.* 1, 12-15 (2009); Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 *DUKE L.J.* 1, 118-23 (2004); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 *TEX. L. REV.* 989, 1010-13 (1997); Merges & Nelson, *supra* note 136 at 856-66.

<sup>157</sup> *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009)

<sup>158</sup> See Samuelson, *supra* note 5.

506           The reverse doctrine of equivalents is unlikely to rise to the occasion, however. The  
507 doctrine applies, according to the Supreme Court, “where a device is so far changed in principle  
508 from a patented article that it performs the same or similar function in a substantially different  
509 way, but nevertheless falls within the literal words of the claim.”<sup>159</sup> Simply reading this  
510 description within the context of modern patent law is enough to explain why the defense is  
511 never successful. It has the ring of a remnant of a historical central claiming regime in which it  
512 made sense to invoke the “principle” of an invention.<sup>160</sup> In its current form it makes little sense  
513 in a peripheral claiming regime. Moreover, the doctrine is described in terms that are unmoored  
514 from any innovation policy goal and will certainly seem obscure to any jury tasked with applying  
515 it (the “unreversed” doctrine of equivalents is bad enough in that respect).<sup>161</sup>

516           Finally, depending on how an expanded reverse doctrine of equivalents was defined, even  
517 a beefed up form of this defense could be substantially under and over inclusive: Why apply it  
518 only when the accused infringing product or process “performs the same or similar function” or  
519 when there is a “fundamental change in the basic principle by which the device operates”<sup>162</sup>?  
520 And do we really want to exempt infringement even in cases in which the infringer copied and  
521 there was no reason to expect bargaining breakdown? Suppose, for example, that the initial  
522 patentee offers a standard non-exclusive license to all comers. These cases may warrant  
523 exemption if the new invention is a big enough advance, but, in its present form, the reverse  
524 doctrine of equivalents does not account for these factors at all.

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<sup>159</sup> *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09, 70 S. Ct. 854, 94 L. Ed. 1097, 1950 Dec. Comm'r Pat. 597 (1950) (emphasis added)

<sup>160</sup> Burk & Lemley, *supra* note 21 at 1773-74 (describing how the reverse doctrine of equivalents originated in a central claiming regime).

<sup>161</sup> See Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 *Berkeley Tech. L.J.* 1141, n. 23 (2008) (making a similar point).

<sup>162</sup> *Depuy Spine*, 567 F.3d at 1338.

525 In sum, while the impetus to revive the reverse doctrine of equivalents is a sound one,  
526 accounting for the size of an improvement in a multi-factored fair-use-type test is likely both to  
527 reflect the underlying policy goals more accurately and to be more palatable to decision makers.  
528 Similar problems arise when considering the potential for patent misuse to play an important role  
529 as an ex post policy lever, as Burk and Lemley acknowledge.<sup>163</sup>

530 B. Proposals to Deal with Independent Invention

531 A number of legal commentators have proposed exempting independent inventors from  
532 infringement liability.<sup>164</sup> As discussed above, there are several policy reasons to favor such a  
533 proposal, given the importance of independent invention and the growing difficulty, at least in  
534 some technological arenas, of performing cost-effective patent clearances.

535 In a response to a thoughtful analysis and proposal by Samson Vermont,<sup>165</sup> however,  
536 Mark Lemley has argued that an independent inventor defense might be very strong medicine  
537 indeed, given the historical prevalence of nearly simultaneous invention.<sup>166</sup> Though this is not  
538 necessarily reason not to enact such a defense (if the defense is warranted, the prevalence of  
539 independent invention also suggests a very large social payoff from enacting it), it does give one  
540 pause. Moreover, as Lemley also argues, there may be special concerns about an independent  
541 inventor defense in particular arenas (Lemley mentions pharmaceuticals) involving high costs  
542 and high expected payoffs.<sup>167</sup> Lemley suggests four approaches, short of an independent  
543 invention defense, to address some of the problems posed by infringement liability for

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<sup>163</sup> Supra note 2.

<sup>164</sup> See, e.g., references supra note 134.

<sup>165</sup> Vermont, supra note 134.

<sup>166</sup> Lemley, supra note 134 at 1528.

<sup>167</sup><sup>167</sup> Lemley, supra note 134 at 1529. He also argues that an independent inventor defense might make it more difficult to have a workable market for patent rights. *Id.* at 1531-32. This argument applies to virtually any ex post policy lever. However, like Vermont in his reply to Lemley's critique, supra note 134 at 1539-40, I think this argument is not particularly strong, given the many degrees of uncertainty already plaguing the definition of patent rights. Moreover, if the copyright context is at all analogous, it gives cause for hope since the market for copyrighted works seems to have survived the ex ante uncertainties of the fair use defense.

544 independent inventors: i) requiring copying as an element of willful infringement; ii) expanding  
545 prior user rights beyond business methods; iii) using nearly simultaneous invention as a  
546 secondary indication of obviousness; and iv) taking account of independent invention in  
547 evaluating whether to award injunctive relief.<sup>168</sup>

548         These are all sensible suggestions for stopping short of a bright line independent inventor  
549 defense. Incorporating the questions of copying and independent invention into a fair-use-like  
550 exemption from infringement liability similarly would add flexibility and be less drastic than an  
551 across-the-board independent invention defense (and, if fair use can be accompanied by an  
552 obligation to pay royalties, might be very similar indeed to the suggestion regarding injunctive  
553 relief). A fair-use-type exemption has at least two types of advantages over Lemley's proposals.

554         First, rather than simply scaling back liability when there is independent invention, it  
555 permits courts to tailor the exemption in light of the technology involved and other relevant  
556 factors. Second, and I think importantly, a fair-use-type defense could handle a point that is not  
557 much discussed in the independent invention analyses. The world of potential infringers is not  
558 simply divided into copyists and independent inventors. There are degrees of copying and  
559 independent invention. There are those who copy from an unmarked (but patented) product and  
560 those who copy slavishly from the patent itself. There are those who are "inspired" by the  
561 patent, but produce radical improvements. There are independent inventors who willfully turn  
562 their eyes away from clearly relevant patent literature and those who would have to make large  
563 investments to determine whether they are infringing another's patent. Further, there is a whole  
564 gray area of other potential infringers: those who copy from an independent inventor, those who  
565 copy from a copyist, and so forth. Taking copying and independent invention into account as  
566 factors in a fair-use-type analysis permits a more nuanced (and less difficult to implement)

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<sup>168</sup> Lemley, *supra* note 134 at 1532-35.

567 response to these various factual scenarios, providing policy levers that can take into account  
568 differences between technologies and other contextual factors.

569 IV. PATENT FAIR USE 2.0: A PROPOSAL

570 Given the reasons to favor a fair-use-like patent infringement exemption, what should it  
571 look like? As with copyright's fair use, there is a tension between providing flexibility and  
572 giving patentees, potential fair users, and courts sufficient clarity of implementation. While  
573 O'Rourke's proposal is an excellent jumping-off point, I have argued elsewhere that it may be  
574 quite difficult for courts to implement.<sup>169</sup> In particular, factors iii) ("the nature and strength of  
575 the market failure that prevents a license from being concluded") and iv) ("the impact of the use  
576 on the patentee's incentives and overall social welfare")<sup>170</sup> are little more than directions to grant  
577 fair use where it would be socially desirable to do so. Necessarily, O'Rourke's proposal also  
578 fails to incorporate factors whose relevance has only become apparent during the past ten years.  
579 Can we do better? Though it is an inherently difficult task, I think so. In particular,  
580 developments over the past ten years may allow us to be more specific about some of the factors  
581 that should be considered.

582 To come up with a list of relevant factors, it is helpful to back up and categorize the  
583 circumstances under which exemption from infringement may be appropriate. Because of the  
584 strength of the arguments for exempting independent inventors from liability, I begin by dividing  
585 the analysis between factors that should be relevant whether or not the infringer has copied from  
586 the patentee and factors that are relevant only when there is no copying. This is also a useful  
587 division because the analogy to copyright fair use is most relevant in situations involving  
588 copying. Since independent inventors (and others who have not copied from the patentee) have a

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<sup>169</sup> See Strandburg, *supra* note 77.

<sup>170</sup> O'Rourke, *supra* note 8 at 1206-07.

589 stronger case for exemption than copyists do, any factors that might weigh in favor of exempting  
590 a copyist should weigh in favor of exempting an independent inventor as well. The next section  
591 discusses such factors. After considering factors that would be relevant even when there has  
592 been copying, I turn to consider factors that will be relevant only when an alleged infringer has  
593 not copied from the patentee.

#### 594 A. Fair Use Even for Knowing Copyists

595 There are three types of analytically distinct (though possibly overlapping) situations in  
596 which an infringement exemption might be socially desirable even when an infringer has copied  
597 from the patentee. First, there are situations involving excusable licensing failure. Second, there  
598 are situations involving large improvements (analogous to “transformative uses” in copyright fair  
599 use). Third, there are situations in which patent incentives are not needed (or, more precisely,  
600 where the boost to invention resulting from patent incentives is not worth the tradeoff in  
601 exclusivity). Each type of situation suggests factors to consider in a fair-use-type approach.

##### 602 1. Excusable Licensing Failures

603 The category of excusable licensing failures has a large overlap with the types of  
604 concerns motivating at least some understandings of copyright fair use.<sup>171</sup> Three sub-categories  
605 are useful in the analysis: under-served markets, what O’Rourke calls “anti-patent” refusals to  
606 license,<sup>172</sup> and “anticommons”-type hold-up in relation to complex products or processes.<sup>173</sup>

##### 607 a. Under-Served Markets

608 Under-served markets can arise either because potential users are unable to pay the  
609 patented price or because the transaction costs of licensing exceed the value of use. The most

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<sup>171</sup> See Wendy J. Gordon, Fair Use as Market Failure, A Structural and Economic Analysis of the Betamax Case and Its Predecessors, 82 Colum. L. Rev. 1600, 1601-02 (1982).

<sup>172</sup> O’Rourke, *supra* note 8 at 1199.

<sup>173</sup> See Heller & Eisenberg, *supra* note 25.

610 noted example of under-served markets in patent law involves patented pharmaceuticals.<sup>174</sup> It is  
611 evident that there are large numbers of individuals in developing countries who would benefit  
612 from life-saving drugs yet are unable to pay the going rate. Arguably, generic companies could  
613 manufacture and sell inexpensive drugs to these under-served markets without undercutting the  
614 pharmaceutical companies' profits from patented medicines in developed countries. In  
615 considering whether a fair use exemption should apply, courts should look for situations  
616 involving high social value and low ability to pay. In some cases the distinction between  
617 commercial and non-commercial use is a reasonable proxy for ability to pay (and would weigh in  
618 favor of exempting educational and non-profit research uses, for example).

619         The pharmaceutical example points up a dilemma often posed by the possibility of fair-  
620 use-type exemptions for under-served markets, however. While the social value of providing  
621 life-saving medicines to those who cannot afford them is extremely high, the potential for  
622 arbitrage – leakage of cheap goods back into the market for those who can pay – weighs against  
623 the benefit of providing lower-priced drugs only to those who cannot afford the going rate.<sup>175</sup> If  
624 such gray market goods undermine drug inventors' ability to recoup their investment, future  
625 innovation might be in danger. This possibility clearly must play a role in weighing whether to  
626 allow an exemption for the purpose of serving those who lack ability to pay.

627         In the pharmaceutical example, a generic manufacturer is needed to give those in  
628 developing countries access to the patented technology. In this respect it differs from the  
629 personal use paradigm which commonly dominates thinking about fair use as a response to

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<sup>174</sup> See, e.g., Kevin Outterson, Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries, 32 Am. J. L. and Med. 159 (2006); Graham Dutfield, Delivering Drugs to the Poor: Will the TRIPS Amendment Help?, 34 Am. J. L. and Med. 107 (2008);

<sup>175</sup> See, e.g., Michael Ilg, Market Competition in Aid of Humanitarian Concern: Reconsidering Pharmaceutical Drug Patents, 9 Chi-Kent J. Intell. Prop. 149 (2010); Peter Lee, Toward a Distributive Commons in Patent Law, 2009 Wis. L. Rev. 917.

630 under-served markets in copyright.<sup>176</sup> For personal use, the concern is less about ability to pay  
631 than about prohibitive transaction costs associated with licensing. Increasingly, as discussed  
632 above, consumers have the potential to infringe patents directly, without the mediation of a  
633 manufacturer. In situations where there is no easy way to purchase an embodiment or a standard  
634 license to a patented invention, transaction costs may make licensing ineffective. Such situations  
635 weigh in favor of a fair use exemption. Exempting personal use would even be in line with the  
636 Federal Circuit’s recent narrow reading of the experimental use exemption as extending to uses  
637 “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”<sup>177</sup> and could be  
638 quite effective in protecting user innovators whose customizations might stray beyond “repair”  
639 and into “reconstruction.”

640 Factors to consider in determining whether an exemption should be made for an under-  
641 served market should thus include whether the use was commercial or non-commercial, the  
642 likely danger to the patentee’s markets due to arbitrage, and the availability of low-transaction  
643 cost means to obtain embodiments of or licenses to the patented technology that would obviate  
644 the need for unauthorized activity.

645 b. “Anti-Patent” Refusals to License

646 In the copyright context, fair use is often employed to facilitate criticism, parody, and  
647 other uses of copyrighted material to which a copyright owner objects not out of a desire to  
648 control the market for the patented invention but out of a desire to suppress a socially desirable  
649 activity that might undermine (rather than compete in) the patentee’s market.<sup>178</sup> These fair uses

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<sup>176</sup> A similar concern does arise with respect to potential fair use of copyrighted textbooks in developing countries. Margaret Chon, Intellectual Property “From Below”: Copyright and Capability for Education, 40 U.C. Davis L. Rev. 803 (2007).

<sup>177</sup> *Madey*, at 1362, citing *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349, 55 U.S.P.Q.2D (BNA) 1161, 1163 (Fed. Cir. 2000).

<sup>178</sup> See, e.g., Samuelson, *supra* note 5; Gordon, *supra* note 171; O’Rourke, *supra* note 8 at 1207.

650 often implicate First Amendment concerns which generally are not salient in the patent  
651 context.<sup>179</sup> Nonetheless, similar concerns underlie arguments for a research exemption applied to  
652 “experimenting on” a patented invention to understand, design around, or improve upon it.<sup>180</sup>  
653 O’Rourke also identifies refusals to permit reverse engineering to develop compatible products  
654 as similarly intended to subvert the limitations of the patent right by extending a patentee’s  
655 control to markets for complementary goods.<sup>181</sup> Refusals to license substantial improvements as  
656 a means to hold up the improver for higher royalties also fit into a category of “anti-patent”  
657 refusals to license.

658 c. Hold-up Due to “Anticommons”-Type Issues

659 As O’Rourke and many others have pointed out, patent licensing may fail because of  
660 “anticommons” issues, in which negotiations over licensing are complicated by a need to  
661 assemble large number of licenses to produce a particular product or implement a particular  
662 process.<sup>182</sup> At the time of O’Rourke’s writing, concern about the anticommons problem focused  
663 on biotechnology and gene patenting.<sup>183</sup> In the past ten years, however, it has become evident  
664 that major anticommons issues arise in the information technology arena.<sup>184</sup> While these issues  
665 can sometimes be resolved by forming patent pools (in which a number of industry players are  
666 granted cross-licenses to one another’s patented technology),<sup>185</sup> patent pools are actually rather

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<sup>179</sup> See, e.g., Samuelson, *supra* note 5 at 2546-2568.

<sup>180</sup> See, e.g., Eisenberg, *supra* note 77; Strandburg, *supra* note 77.

<sup>181</sup> O’Rourke, *supra* note 8 at 1227-30.

<sup>182</sup> *Id.* at 1179-80. See also, e.g., Heller and Eisenberg, *supra* note 25; Mark A. Lemley and Carl Shapiro, Patent Holdup and Royalty Stacking, 85 *Tex. L. Rev.* 1991 (2007).

<sup>183</sup> Heller and Eisenberg, *supra* note 25

<sup>184</sup> See, e.g., Lemley and Shapiro, *supra* note 182; Sapna Kumar and Arti Rai, 85 *Tex. L. Rev.* 1745, 1756-57 (2007)

<sup>185</sup> See, e.g., Ed Levy et al., Patent Pools and Genomics: Navigating a Course to Open Science?, 16 *B.U. J. Sci. & Tech. L.* 75 (2010); Carl Shapiro, Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Setting, in 1 *Innovation Policy & the Economy* 118, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern, eds., 2001), available at <http://faculty.haas.berkeley.edu/shapiro/thicket.pdf>

667 rare.<sup>186</sup> Moreover, these problems are exacerbated where, as is often the case in the information  
668 technology sector, some patents are held by non-practicing entities that have no interest in cross-  
669 licensing.<sup>187</sup>

670 At least some Supreme Court justices recognized this issue when deciding the *EBay* case,  
671 discussed above.<sup>188</sup> While the factors set out in *eBay* to guide courts' discretion in awarding  
672 injunctive are not tailored to innovation concerns, courts have in fact employed them to deny  
673 injunctions and impose ongoing royalties primarily in cases involving non-practicing entities, as  
674 discussed by Burk and Lemley.<sup>189</sup>

675 Though *eBay v. MercExchange* has alleviated concerns about hold-up from “patent  
676 trolls,” the danger that courts may not have their eyes on innovation policy and may simply turn  
677 the “injunction always” rule into a “no injunctions for non-practicing entities” rule remains.  
678 Thus, for example, whether the infringer is a copyist or an independent inventor and the extent of  
679 the inventive contributions of patentee and infringer arguably should play a role in determining  
680 whether injunctive relief is warranted and whether a royalty should be imposed in a potential  
681 anticommons scenario. An independent inventor will be particularly subject to hold-up if he or  
682 she has made a substantial investment in producing a complex product incorporating a patented  
683 invention. Such an inventor may have been unable, as a practical matter, to have negotiated a  
684 license before making the investment. Conversely, a company that knowingly copies highly  
685 innovative technology from a non-practicing entity is probably not a victim of licensing failure.  
686 These considerations might be squeezed into the “balance of hardships” and “public interest”

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<sup>186</sup> See David Serafino, Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures, Knowledge Ecology Int'l, June 4, 2007, <http://www.keionline.org/misc-docs/ds-patentpools.pdf> for a recent survey of patent pools; Merges, supra note 19 at 1355.

<sup>187</sup> See, e.g., Lemley & Shapiro, supra note 182 at 2015.

<sup>188</sup> 547 U.S. at 395-97 (Kennedy, J., concurring).

<sup>189</sup> Burk & Lemley, supra note 2. See also, Streur, supra note 87, at 67.

687 prongs of the *eBay* analysis,<sup>190</sup> but a fair-use-type analysis would accommodate innovation-  
688 related concerns much more cleanly.

689 2. Substantial Improvements

690 Copyright fair use doctrine relies heavily on the extent to which a particular use is  
691 “transformative.”<sup>191</sup> The motivation behind this reliance is the intuition that the public should  
692 not be deprived of a major advance because the initial author refuses to “play along.” The  
693 argument is similar in the patent law context and is the basis for the reverse doctrine of  
694 equivalents already discussed at length. In the patent context, the evaluation of the substantiality  
695 of the improvement should also take into account the size of the technological contribution of the  
696 initial innovator. It is longstanding patent doctrine that a “pioneer” inventor should be afforded a  
697 broad scope of equivalents in assessing infringement.<sup>192</sup> That doctrine, like the reverse doctrine  
698 of equivalents, had its roots in central claiming and is somewhat difficult to apply under the  
699 present peripheral claiming system.<sup>193</sup> It can be quite sensibly taken into account in a fair-use-  
700 type analysis, however, where the relative sizes of the initial invention and improvement are  
701 relevant to how the returns from the invention should be divided and indicative of whether there  
702 is likely to be a hold-up problem or licensing breakdown.

703 There is one major difference between patent law and copyright law that would seem to  
704 obviate the need for a fair-use-type exemption for improvers except in the most extreme  
705 circumstances (where one might suspect a bargaining breakdown due to holdup). Unlike authors  
706 (who are not permitted *ex ante* to obtain copyright in unauthorized transformative works),<sup>194</sup>  
707 improvers on patented technology can proceed without authorization and are specifically

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<sup>190</sup> 547 U.S. at 393-94.

<sup>191</sup> See, e.g., Samuelson, *supra* note 5 at 2619.

<sup>192</sup> See, e.g., Burk & Lemley, *supra* note 21 at 1772-73, n. 13.

<sup>193</sup> *Id.*

<sup>194</sup> 17 U.S.C. 103(a).

708 permitted to obtain patents on their improvements.<sup>195</sup> This “blocking patent” doctrine is assumed  
709 to result in the salutary situation in which it is in both parties’ interests to come to terms, cross  
710 license their patents, and proceed to make use of the improved technology.<sup>196</sup> The expectation  
711 that this will ordinarily occur is probably behind the present, rather dusty, status of the reverse  
712 doctrine of equivalents.<sup>197</sup> Unless there is some reason to think that initial and follow-on  
713 inventors cannot come to terms, why confer a fair use defense on the improver? Thus, a  
714 likelihood of “blocking patent failure” would strongly increase the force of an argument for an  
715 exemption for a substantial improver.

716         While O’Rourke argues that fair use analysis should consider the possibility of blocking  
717 patent failure due to difficulties of valuation, especially where there is potential for hold-up due  
718 to large disparities in the values of the contributions made by initial and follow-on inventors,<sup>198</sup>  
719 recent developments provide much stronger reasons to anticipate that the blocking patent  
720 doctrine may not be sufficient to protect the substantial improver. First, the blocking patent  
721 doctrine assumes that the improver is able and willing to patent the improvement. As discussed  
722 above, this may not be the case for many of those involved in new innovation paradigms. User  
723 innovators may not have the resources to patent their improvements or may belong to  
724 communities in which free revealing rather than patenting is the norm.<sup>199</sup> Open source software  
725 developers may have non-pecuniary motivations that preclude (and would be dampened by)  
726 applying for patents.<sup>200</sup> In many cases in which a widespread group of contributors undertakes

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<sup>195</sup> 35 U.S.C. 101.

<sup>196</sup> See discussion, *supra*.

<sup>197</sup> See discussion, *supra*.

<sup>198</sup> O’Rourke, *supra* note 8 at 1204.

<sup>199</sup> See sources *supra* note 112.

<sup>200</sup> See, e.g., Karim Lakhani & Robert G. Wolf, *Why Hackers Do What They Do: Understanding Motivation and Effort in Free/Open Source Software Projects* (MIT Sloan Sch. of Mgmt., Working Paper No. 4425-03, 2003), available at <http://ssrn.com/abstract=443040>.

727 highly cumulative innovation, patent protection is simply unavailable either in principle or as a  
728 practical matter.

729         If patenting is inconsistent with the innovation paradigm that produces the improvement,  
730 the blocking patent doctrine breaks down. Assuming the improvement is disclosed, as it often  
731 will be under new innovation paradigms, the initial inventor can freely use the improvement,  
732 while retaining the right to sue the improver for patent infringement. In such circumstances, the  
733 initial inventor has no reason to come to terms – even if the improvement is a major advance.  
734 Fair use for the improver may be a socially desirable means to solve this breakdown.

735         Second, the blocking patent doctrine is less effective where the “improver” is an  
736 independent inventor and/or the initial inventor is a non-practicing entity. Having invested  
737 heavily in marketing a product or using a process that is only later determined to infringe an  
738 earlier patent, the substantial improver may be subject to holdup issues similar to those discussed  
739 in section 1.c above. Additionally, if the initial patentee is not locked by upfront investment into  
740 using the improvement (or never intends to practice either patent), the improver again may be  
741 subject to holdup.

### 742         3. Alternative Innovation Paradigms

743         As I have argued elsewhere in the context of user innovation,<sup>201</sup> the availability of non-  
744 patent-motivated innovation paradigms for a particular technology weakens the argument for  
745 patent exclusivity because it changes the cost-benefit tradeoffs. Thus, if user innovation (or  
746 some other non-patent-based paradigm) predominates either in a particular case or in the field of  
747 the invention that fact should weigh in favor of an infringement exemption. The extent to which  
748 an exemption should be favored also depends on the extent to which the alternative innovation  
749 paradigm leads to disclosure and dissemination of inventions. Open source software, for

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<sup>201</sup> Strandburg, Users as Innovators, supra note 30.

750 example, is non-patent-motivated, widely disclosed, and widely disseminated. The prevalence of  
751 open source approaches in a particular technological area weighs in favor of an infringement  
752 exemption. User innovation is frequently non-patent-motivated, but whether it is widely  
753 disclosed and disseminated will depend on whether the invention is self-disclosing or could be  
754 kept as a trade secret, whether it can be easily “picked up” by other users once disclosed,  
755 whether there are norms of free revealing among a particular group of users and so forth. In a  
756 fair-use-type approach, the availability and nature of alternative innovation paradigms should  
757 factor into determining whether an infringement exemption is appropriate.

758 B. Fair Use For Independent Inventors, Other Non-Copyists, and “Innocent” Copyists

759 When an accused infringer is an independent inventor or other non-copyist, there are  
760 additional factors that could weigh in favor of an infringement exemption. First, as already  
761 discussed,<sup>202</sup> the fact of independent invention itself weighs in favor of an exemption. As noted,  
762 however, non-copyists are not all alike and neither are copyists. To avoid some of the potential  
763 for over-reaching of a strict independent inventor defense (and to deal with other non-copyists  
764 and with “innocent” copyists who copy without knowledge of the patent), one should consider  
765 the circumstances of any infringement that occurs without knowledge of the patent.

766 Besides considering whether the infringer is an independent inventor, it is also sensible to  
767 consider to what extent the infringer’s ignorance of the patent was reasonable under the  
768 circumstances. Relevant circumstances would include patent search costs (which will depend  
769 upon the technological area, as discussed above), custom within a particular industry (which may  
770 be evidence of search costs or of norms of reciprocal forbearance), the extent to which the  
771 infringer should have been able to foresee the possibility of infringing the patent at issue (which  
772 may be related to the fuzziness of claim boundaries) and the extent to which a particular infringer

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<sup>202</sup> See discussion, *supra*.

773 could reasonably be expected to have the sophistication and funds to undertake the necessary  
774 patent search (which may be related to whether the infringer is a commercial or nonprofit entity  
775 or a small entity or individual). Consideration of context is important to avoid encouraging  
776 “head in the sand” behavior by potential infringers and to determine whether an infringement  
777 exemption is appropriate for those who are neither knowing copyists nor true independent  
778 inventors.

779 C. Summary of Patent Fair Use 2.0 Proposal

780 The above analysis leads to the following proposed factors for courts to consider in  
781 determining whether to award an infringement exemption (or alternatively to refrain from  
782 awarding an injunction and impose an ongoing royalty):

- 783 1) Is there a justifiable failure to purchase or license due to:
- 784 a. The social value of making the invention available to a market that the  
785 patentee will not be able to serve, such as those who are unable to pay or those  
786 for whom the transaction costs of licensing are prohibitive (taking into  
787 account the potential damage to the patentee’s interests by arbitrage);
  - 788 b. An “anti-patent” license failure due to the patentee’s attempt to squelch  
789 further innovation or to exert control over markets beyond the scope of the  
790 claims; or
  - 791 c. A failure to license due to anticommons-type hold-up?
- 792 2) Did the infringer make a substantial improvement over the patentee’s invention and  
793 was there some reason for blocking patent failure?
- 794 3) Does the availability of alternative innovation paradigms in the technological arena  
795 provide evidence of reduced importance of patent incentives?

796 4) Was the infringer a knowing copyist, independent inventor, or something in between?  
797 If the infringer was not a knowing copyist was her failure to locate the patent through  
798 search reasonable in light of patent search costs in the particular technology, custom  
799 in the industry, the foreseeability of infringement, and the infringer's commercial,  
800 non-commercial, or small entity status?

801 D. Applications

802 To breathe some life into the proposed fair use 2.0 analysis, this section briefly discusses  
803 two possible applications: open source software and essential medicines.

804 1. Open Source Software

805 There has been considerable concern about the vulnerability of open source software to  
806 patent infringement liability, which could arise either as a result of independent invention or  
807 because one of one of a myriad of widely distributed contributors inserts infringing code into an  
808 open source project.<sup>203</sup> Under current law, there is no likely defense to such a claim<sup>204</sup> and while  
809 the *eBay v. MercExchange* approach might undercut a request for injunctive relief from a non-  
810 practicing entity, it is not at all clear that courts would refuse to enjoin an open source program if  
811 a software company marketing a competing product were to sue. On the other hand, applying  
812 the fair-use-type factors proposed here would exempt open source software in most cases, as  
813 follows:

814 1) Is there a justifiable failure to purchase or license?

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<sup>203</sup> See, e.g., Ronald J. Mann, Commercializing Open Source Software: Do Property Rights Still Matter?, 20 Harv. J. Law & Tech. 1, 37 (2006) (raising this question and discussing it in the context of litigation in which SCO group sued IBM, contending that Linux contained some lines of proprietary code); Greg Vetter, The Collaborative Integrity of Open-Source Software, 2004 Utah L. Rev 563, 593; Joe Mutschelknaus, Spillover Effect: Investigating Patent Implications to Open-Source Software Copyright Licenseing, 19 Fed. Cir. B.J. 409 (2009-10) (discussing how the GPL attempts to deal with patent issues); John Tsai, For Better or Worse: Introducing the GNU General Public License Version 3, 23 Berkeley Tech. L.J. 547 (2008) (same).

<sup>204</sup> Though some have suggested that an infringement exemption for open source software be considered. See, e.g., Garrison, supra note 138.

815 This factor may not weigh strongly in favor of open source software that infringes patents held  
816 by companies marketing competing products, though the fact that open source software is  
817 available to everyone at no charge is somewhat favorable. Of course, in particular cases, this  
818 factor may have more weight.

819           2) Did the infringer make a substantial improvement over the patentee's invention  
820           and was there some reason for blocking patent failure?

821 The analysis of this factor will depend upon the extent to which the open source software is  
822 innovative beyond the patentee's claims. If there is a substantial improvement, this factor is  
823 strongly in favor of an exemption for the open source software since the inability of the open  
824 source community to patent its improvements leads to a complete blocking patent failure.

825           3) Does the availability of alternative innovation paradigms in the technological  
826           arena provide evidence of reduced importance of patent incentives?

827 This factor will generally weigh strongly in favor of exempting the open source software unless  
828 there is evidence that open source is not playing an important role in innovation in the particular  
829 arena.

830           4) Was the infringer a knowing copyist, independent inventor, or something in  
831           between? If the infringer was not a knowing copyist was her failure to locate the  
832           patent through search reasonable?

833 This factor will probably favor exemption since the open source community likely invented  
834 independently. Even if a contributor knowingly contributed patented code, it may be  
835 unreasonable to expect the core developers to police such infringement.<sup>205</sup> Moreover, it would in  
836 most cases be unreasonable to expect participants in an emergent and modular innovation

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<sup>205</sup> The issues here would be comparable to those that arise in considering the liability of internet service providers for infringement, an issue dealt with in the copyright context by "safe harbor" provisions. 17 U.S.C. 512.

837 paradigm such as open source software to conduct patent searches and attempt patent clearance.  
838 As already discussed, the information technology arena is one in which even commercial players  
839 have found it prohibitively difficult to conduct patent searches.

840 The proposed fair use-type exemption thus would probably apply to most open source  
841 projects. Adopting such an exemption would therefore remove the shadow of potential  
842 infringement liability from such projects. Note, however, that the exemption would not be  
843 automatic. If an open source project blatantly and knowingly copied patented code, encouraged  
844 its contributors to ignore patents when making their contributions, and so forth, it would not be  
845 eligible for the exemption. The proposal thus has advantages over a bright line “open source”  
846 defense.<sup>206</sup>

847 2. Essential Medicines

848 The problem of access to medicine is hugely important in the international arena and has  
849 inspired a correspondingly vast literature.<sup>207</sup> Here I do not attempt to engage that literature  
850 seriously. This analysis simply illustrates how the proposed factors would apply in the context  
851 of a domestic patent infringement case against a very low cost provider of essential medicines to  
852 those with very low incomes. I will assume in this discussion that the infringer is a nonprofit  
853 entity and consider whether there might be workable models for tailoring provision of essential  
854 medicines so as to qualify for a “patent fair use” exemption.

855 1) Is there a justifiable failure to purchase or license?

856 Where patients are in need of essential medicines and unable to afford them, there is a very  
857 strong social benefit to providing those medicines. The rub, of course, is the arbitrage problem,

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<sup>206</sup> See Garrison, *supra* note 138.

<sup>207</sup> See, for a small taste, Symposium, *Global Access to Health: Legal, Business, and Policy Obstacles*, 34 *Am. J. L. and Med.* 97 (Erik Iverson and Regina Rabinovich, eds. April 2008); James Love and Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 *Ann. Health L.* 155 (2009); Cynthia Ho, *Competing Patent Perspectives*, 46 *Hous. L. Rev.* 1047 (2009).



881 investment, at least under the current regulatory system. This might conceivably change in the  
882 future, since various experiments with “open source drug development” are underway.<sup>208</sup>  
883 However, the costs of clinical trials for approval of new drugs are likely to constrain the potential  
884 for such open source approaches, at least within the United States.<sup>209</sup> Once again, though, the  
885 situation might be different at some point with respect to the development of new uses of  
886 existing drugs.<sup>210</sup>

887 4) Was the infringer a knowing copyist, independent inventor, or something in  
888 between? If the infringer was not a knowing copyist was her failure to locate the  
889 patent through search reasonable?

890 This factor will typically weigh against an exemption, since we are postulating the use of a  
891 known, patented drug. At least with respect to patents on the chemical entity, search is generally  
892 not a serious problem for pharmaceuticals.<sup>211</sup>

893 The bottom line of such an analysis will probably favor the patentee most of the time.  
894 But the analysis suggests room for creativity on the part of organizations seeking to serve those  
895 who are unable to pay for essential medicines because the analysis is sensitive to the facts on the

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<sup>208</sup> See, e.g., Emily Marden, *Health Care & Pharmaceuticals: Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?*, 11 *Minn. J. L. Sci. & Tech.* 217 (2010). See also [www.bioendeavor.net](http://www.bioendeavor.net) (Reviewing projects and providing information and links for the expressed goal of “enabling innovation in the life sciences”) (visited December 17, 2010).

<sup>209</sup> See, e.g., Marden, *supra* note \_\_ at 234 (discussing the high costs of drug development). Some have also proposed shifting responsibility for clinical trials away from the private sector, see, e.g., Amy Kapczynski, *Innovation Policy for a New Era*, 37 *J.L. Med. & Ethics* 264 (2009); T. R. Lewis, J. H. Reichman and A. D. So, “The Case for Public Funding and Public Oversight of Clinical Trials,” *Economists' Voice* 4, no. 1 (2007):1-4; D. Baker, *The Benefits and Savings of Publicly-Funded Clinical Trials of Prescription Drugs* (2008), available at <<http://www.cepr.net/index.php/publications/reports/the-benefits-and-savings-of-publicly-funded-clinical-trials-of-prescription-drugs/>> (last visited April 16, 2009); A. Jayadev and J. Stiglitz, “Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices,” *Health Affairs* 28, Web Exclusive (2008): w165-w168, available at <<http://content.healthaffairs.org/cgi/reprint/hlthaff.28.1.w165v1.pdf>> (last visited April 24, 2009). Any major changes in the regulatory paradigm could affect the viability of open and collaborative innovation approaches to pharmaceutical innovation, as could major scientific or technical advances that reduced the costs.

<sup>210</sup> See, e.g., C.R. Chong and D.J. Sullivan, *New Uses for Old Drug*, 448 *Nature* 645 (2007) (describing the Johns Hopkins Clinical Compound Screening Initiative); H.J. Demonaco, A. Ali and E. von Hippel, *The major role of clinicians in the discovery of off-label drug therapies*, 26 *Pharmacotherapy* 323 (2006); Stephen M. Maurer, *Open Source Drug Discovery: Finding a Niche (Or Maybe Several)*, 76 *UMKC L. Rev.* 405).

<sup>211</sup> Bessen & Meurer, *supra* note \_\_.

896 ground with respect to the issue of gray market goods. A fair use approach thus might provide a  
897 path out of the stalemate caused by attempts to balance the value of essential medicines to those  
898 who cannot afford them against the value of as-yet-uninvented future medicines.

899 V. CONCLUSIONS

900 This Essay has attempted to update the inquiry into the wisdom of “patent fair use” to  
901 account for the evolution of technology and of inventive paradigms in the years since  
902 O’Rourke’s seminal treatment of the issue in 2000. I have argued that a fair-use-type ex post  
903 approach to cabining patent exclusivity is even more attractive as a theoretical matter now than it  
904 was in 2000. I have also suggested a set of “patent fair use 2.0” factors that would be relevant to  
905 such an exemption: 1) Is there a justifiable failure to purchase or license due to the social value  
906 of serving an under-served market (taking into account the potential damage to the patentee’s  
907 interests by arbitrage), “anti-patent” license failure due to the patentee’s attempt to squelch  
908 further innovation or to exert control over markets beyond the scope of the patent, or failure to  
909 license due to anticommons-type hold-up? 2) Did the infringer make a substantial improvement  
910 over the patentee’s invention and was there some reason for blocking patent failure? 3) Does the  
911 availability of alternative innovation paradigms in the technological arena provide evidence of  
912 reduced importance of patent incentives? 4) Was the infringer a knowing copyist, independent  
913 inventor, or something in between? If the infringer was not a knowing copyist was her failure to  
914 locate the patent through search reasonable in light of patent search costs in the particular  
915 technology, custom in the industry, the foreseeability of infringement, and the infringer’s  
916 commercial, non-commercial, or small entity status?

917 While this Essay has been primarily in the nature of a thought experiment about optimal  
918 doctrine, it is obviously important to consider whether any of this is at all practical. Could the

919 judiciary implement a fair-use-type exemption? The fair use exemption in copyright, though  
920 later codified, began in just that way,<sup>212</sup> as did the limits on patentable subject matter in patent  
921 law,<sup>213</sup> which arise from similar policy concerns. So it might be possible in principle for judges  
922 to make such a move. At this point, however, a wholesale move to a fair-use-type exemption by  
923 the judiciary seems highly unlikely. A statutory fair-use-type exemption is perhaps more likely,  
924 but only just so. Failing that, what can we hope to obtain from a discussion such as this one?  
925 First, the law regarding the award of injunctions under the *eBay* decision is only beginning to  
926 develop. The analysis here could inform how courts interpret the “balance of hardships” and  
927 “public interest” prongs of the test. Second, there will continue to be proposals for, and  
928 occasional enactment of, more limited exemptions in various contexts. While limited  
929 exemptions may not be optimal, the factors here can provide guidance both in evaluating the  
930 need for a particular limited exemption and in designing its implementation. For example, the  
931 analysis suggests how one might design an independent inventor-type exemption that might  
932 avoid some of the over- and under- coverage of a bright line rule. Finally, a conversation about  
933 the analytical basis for infringement exemptions can help to illuminate commonalities among  
934 proposals for specific exemptions, as in the example of business methods and research tools  
935 discussed above.

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<sup>212</sup> See, e.g., *Harper & Row, Inc. v. Nation Enterp.*, 471 U.S. 539, 547 (1985) (17 U.S.C. 107 codifies the traditional “fair use” privilege).

<sup>213</sup> See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303(1980) (citing the history of the ban on patent “laws of nature, physical phenomena, and abstract ideas”).