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## ARTICLE

THE GROWING PUBLIC DOMAIN IN MEDICINE<sup>†</sup>

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*This Article describes the growing public domain of inventions associated with drugs and medicine, and geographies associated with identifiable shifts in the balance of innovation that may be especially favorable for promoting wider access to socially useful technologies. To do so, it departs from the largely ex ante perspective that currently informs the intersectional debate regarding human rights and patent rights and, instead, looks backward to inquire what innovations from past patents have already become publicly available in service of the human rights objective of greater access to technology. Ex post analysis of this kind may help public and private institutions alike in identifying cycles of innovation that sustainably deprioritize socially valuable technologies and leave them free for public use.*

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## I. INTRODUCTION

Current scholarly discussions of what the balance is, and ought to be, between patent systems and human rights take a largely *ex ante* view of whether, to what extent, and how these regimes can and should be reconciled with each other. This is particularly true in the context of health and medicine where debates persist, for example, as to whether human rights principles require the complete or partial abrogation of patent rights or the two are compatible,<sup>1</sup> whether the appropriate forum for such balancing is in domestic law or international law,<sup>2</sup> and what the scope of patent-eligible subject matter should be in order to ensure the upstream integrity of basic research.<sup>3</sup>

This Article diverges from such debates and examines, not *ex ante* how patent rights can sufficiently foster future innovation in accordance with principles of human rights, but *ex post* what innovations from past patent bargains have already become publicly available in service of the human rights objective of greater access, particularly to health-related technologies.<sup>4</sup> Related empirical research by the author has recently described comprehensively the public domain of technologies that have recently passed out of U.S. patent protection, and has examined the technological, geographical, and procedural traits of these newly public inventions as a basis for exploring the social value

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1. See *infra* § Three Views of the Relationship.  
 2. See *infra* § The Proper Intersectional Forum.  
 3. See *infra* § The Reach of Eligible Subject Matter.  
 4. See *infra* § The Expired Patent Dataset.

associated with their unfettered use.<sup>5</sup> Further comparison of these inventions to those newly patented during the same period reveals ongoing changes in the balance of innovation in the United States and abroad.<sup>6</sup>

Proceeding from this general empirical framework, more detailed analysis of particular technology areas such as drugs and medicine and of particular geographies shows patterns of patent expiration and issuance and may help identify sources of innovation that reliably produce new inventions and sufficiently deprioritize recent inventions to lapse into the public domain.<sup>7</sup>

Part II of this Article surveys current scholarship at the interface of human rights and patent rights and explains the *ex ante* character of three illustrative debates at that interface. Part III describes the Expired Patents dataset and examines in detail the case of drugs and medical inventions as an *ex post* benefit of past patent bargains. Part IV concludes with a discussion of follow-on research.

## II. HUMAN RIGHTS AND PATENT RIGHTS: AN *EX ANTE* DEBATE

At the intersection of human rights and patent rights lies a literature rich in debate and persistent in calls for reform. Three salient threads of debate within this literature address different aspects of the intersection itself: the nature of the relationship between human rights and patent law; the legal sphere in which that relationship operates; and the practical boundaries of patent doctrine that appropriately account for this relationship. Importantly, all three proceed from an *ex ante* perspective.

### A. *Intersection of Human Rights and Patent Rights*

First, to understand the nature of the relationship between human rights and patent rights, it is helpful to consider the tripartite typology proposed in a recent essay by Richard Gold.<sup>8</sup> Professor Gold identifies three dominant conceptions of the relationship, which he calls the “subjugation” approach, the “integrated” approach, and the “coexistence” approach.<sup>9</sup>

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5. Saurabh Vishnubhakat, *Expired Patents* (forthcoming 2014).

6. *Id.*

7. *See infra* § The Case of Drugs and Medical Inventions.

8. E. Richard Gold, *Patents and Human Rights: A Heterodox Analysis*, 41 J.L. MED. & ETHICS 185 (2013).

9. *Id.* at 186.

### 1. Three Views of the Relationship

The subjugation approach holds human rights law as mutually exclusive—and superior in any conflict—to patent law.<sup>10</sup> Literature subscribing to this view, especially where public health is concerned, has often employed the rhetoric of balance and symmetry in curbing the scope of patent protections through explicit means such as compulsory licensing<sup>11</sup> as well as curbing the exercise of patent rights through implicit means such as self-regulatory best practices in university licensing.<sup>12</sup>

By comparison, the integrated approach holds patent law and other intellectual property regimes as themselves being species of human rights.<sup>13</sup> Given the orientation of human rights toward natural law,<sup>14</sup> literature subscribing to this view has tended to

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10. *Id.* at 187; see also Benjamin Mason Meier, *Employing Health Rights for Global Justice: The Promise of Public Health in Response to the Insalubrious Ramifications of Globalization*, 39 CORNELL INT'L L.J. 711, 727-31 (2006) (arguing that it is international intellectual property regimes “that often prevent states from easily providing medications and treatments to their peoples.”); cf. Ruth L. Gana, *The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development*, 18 LAW & POL'Y 315 (1996) (arguing that the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) reverses only through economic coercion the otherwise subordinate value of intellectual property to the priorities of developing economies).

11. Pier DeRoo, “Public Non-Commercial Use” Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs, 32 MICH. J. INT'L L. 347 (2011) (defending compulsory licensing as striking an “appropriate balance” within the TRIPS framework); Siddartha Rao, *Closing the Global Drug Gap: A Pragmatic Approach to the Access to Medicines Problem*, 3 J. LEGAL TECH. RISK MGMT. 1 (2008) (defending compulsory licensing under a framework of adequate remuneration that preserves the “delicate balance” between innovation and access).

12. Amy Kapczynski, et. al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005) (proposing a commons-based model of production and coordination “that treat[s] all actors symmetrically vis-à-vis the resource in question.”).

13. Gold, *supra* note 8, at 187-88. The human rights charter often cited as being amenable to incorporating intellectual property rights is the International Convention on Economic, Social and Cultural Rights, whose Article 15(1) entitles a person to “the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” A comparable entitlement arises from Article 27 of the Universal Declaration of Human Rights.

14. See, e.g., Smita Narula, *The Global Land Rush: Markets, Rights, and the Politics of Food*, 49 STAN. J. INT'L L. 101, 140 (rejecting the creation of markets for land as a commodity due to the tolerance in such markets for violations of human rights that are—by definition, the author argues—

define patent rights, not as a utilitarian balance between present innovation and future access upon which human rights may act as a supervening force,<sup>15</sup> but rather *a priori* in terms of human rights principles such as human dignity and personhood<sup>16</sup> as well as morality.<sup>17</sup>

Not least, the coexistence approach holds more divergently still that patent rights are neither inferior to, nor a species of, human rights, but rather that the two are separate and distinct bodies of law that advance the same foundational goal:<sup>18</sup> “defining the appropriate scope of private monopoly power that gives authors and inventors a sufficient incentive to create and innovate, while ensuring that the consuming public has adequate access to the fruits of their efforts.”<sup>19</sup>

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deontologically inviolable); Frank Garcia, *Trading Away the Human Rights Principle*, 29 BROOK. J. INT’L L. 51, 87 (1999) (equating international trade with a utilitarian approach and human rights with a deontological approach to forming value judgments about globalization).

15. Cf. Rochelle C. Dreyfuss, *Patents and Human Rights: Where is the Paradox?*, in INTELLECTUAL PROPERTY AND HUMAN RIGHTS: A PARADOX 72, 74 (Willem Grosheide, ed., 2010) (characterizing the traditional conception of intellectual property as utilitarian and the modern human rights conception as being capable of thwarting that utilitarian mechanism for impeding free riders in order to foster innovation).

16. See, e.g., Elizabeth L. Rosenblatt, *Intellectual Property’s Negative Space: Beyond the Utilitarian*, 40 FLA. ST. U. L. REV. 441, 456–57 (2013) (defining and defending intellectual property under personality theory as a means for exercising “a fundamental right to oneself” inasmuch as the products of one’s creative labor are “a manifestation of that self”); see also Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 330–65 (1988) (discussing more generally the personhood theory of intellectual property law).

17. See Laura A. Keay, *Morality’s Move Within U.S. Patent Law: From Moral Utility to Subject Matter*, 40 AIPLA Q.J. 409 (2012) (describing a recent reemergence in U.S. patent law of the moral utility doctrine as a result of ethical debates surrounding biotechnologies such as human-animal chimeras and genetic diagnostics); Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003) (arguing for just such a revival of the moral utility doctrine); see also Eur. Pat. Convention [EPC], *Convention on the Grant of European Patents* Art. 53(a), Oct. 5, 1973, as amended by EPC, *Decision of the Administration Council of the European Patent Organization*, 13 I.L.M. 268, 286 (Dec. 21, 1978) (excluding from patent protection those inventions “the publication or exploitation of which would be contrary to ‘ordre public’ or morality”).

18. Gold, *supra* note 8, at 188-89.

19. Laurence R. Helfer, *Human Rights And Intellectual Property: Conflict Or Coexistence?*, 5 MINN. INTELL. PROP. REV. 47, 48 (2003).

Notably, whereas the subjugation approach and integrated approach both regard human rights as a deontological privilege while differing on that legal regime's superiority over quintessentially utilitarian patent rights, Professor Helfer's articulation of the coexistence approach appears to view human rights law itself as a utilitarian balance between incentivization of innovation and surety of access.

## 2. The Proper Intersectional Forum

Second, the mutual orientation of human rights and patent rights thus understood, there is also debate regarding whether the appropriate forum for such balancing is in international law<sup>20</sup> or domestic law,<sup>21</sup> though the weight of the literature rests largely with the former. Professor Gold's framework points cogently to the latter, arguing that the subjugation and integrated approaches require comparing two incommensurable normative frameworks—human rights being a moral and deontological legal order, and patent rights being an instrumental and utilitarian one.<sup>22</sup>

Accordingly, only the coexistence approach may “respect the different [normative] spheres in which human rights and patents operate,” and it is only through domestic law that patent rights may sufficiently mediate the nation-specific complexities of innovation and economic welfare.<sup>23</sup> To be sure, it is not a failing of the coexistence approach that international law is an inappropriate forum for evaluating patent doctrine. To the contrary, patent law

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20. See, e.g., Laura Pedraza-Fariña, *Conceptions of Civil Society in International Lawmaking and Implementation: A Theoretical Framework*, 34 MICH. J. INT'L L. 605, 660-61 n.242, 667-68 n.271 (2013) (describing as “robust” the law of human rights *qua* international law because it seeks to supplant the role of sovereign governments in regulating state conduct); see also Holger Hestermeyer, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 76-136 (2007) (characterizing access to medicine *ab initio* as a human right under international law).

21. See, e.g., Chuan-feng Wu, *Raising the Right to Health Concerns Within the Framework of International Intellectual Property Law*, 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141, 163 (2010) (arguing that States must still consider human rights concerns while drafting and implementing domestic patent laws); cf. Robert Danay, *Copyright vs. Free Expression: The Case of Peer-to-Peer File-Sharing of Music in the United Kingdom*, 8 YALE J. L. & TECH. 2 (2006) (discussing the domestically incorporated international guarantee of free expression set forth in Article 10 of the European Convention on Human Rights and its protection under British copyright law).

22. Gold, *supra* note 8, at 189-90.

23. *Id.* at 193.

currently suffers from “artificial constraints imposed by the internationalization of the discourse”<sup>24</sup>—a problem quite independent of the approaches involved. The coexistence approach merely has the distinct virtue of being able to accommodate a desirable return to “domestic dialogues, within and proper to patent law.”<sup>25</sup>

### 3. The Reach of Eligible Subject Matter

Third, as to what the scope of patent-eligible subject matter should be, Gold argues that the desirability of a domestic-law conception for defining the reach of patents requires a coexistence approach.<sup>26</sup> Certainly to the extent that current literature casts the incentive of patent rights largely in utilitarian terms, Gold argues persuasively that recasting patent law to accommodate broader normative principles—deontological principles—is consistent with treating human rights as international law. However, it is only the *a priori* definition of human rights as international<sup>27</sup> that drives its supposed inconsistency with patent rights under an integrated approach. The development of a robust domestic dimension in human rights may equally enable a reconception of patent law as a species of human rights, building on the existing deontological discourse in patent doctrine and intellectual property doctrine more generally.<sup>28</sup>

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24. *Id.*

25. *Id.*

26. *Id.* (advocating that general distributional norms embodied in the law should be considered when determining the scope of patent rights).

27. *Id.* at 191–92 (“While domestic human rights laws—whether constitutionalized or otherwise—may have something to say about domestic patent laws, these have not been central to the debate.”).

28. *Supra* notes 16–17 and accompanying text; see also Wendy J. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J. 1533, 1540–83 (1993) (proceeding from a Lockean labor-desert theory that patents should reward the labor expended or the value added to society); Tom G. Palmer, *Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects*, 13 HARV. J.L. & PUB. POL’Y 817 (1990) (proceeding from a Hegelian actualization theory that a creative work is an extension of the creator’s personality and thus may properly be protected from appropriation); Margaret Jane Radin, *Property and Personhood*, 34 STAN. L. REV. 957 (1982) (similarly arguing from a Hegelian perspective that achieving self-development as a person requires a measure of control over external resources and that property rights assure such control). *But see* William W. Fisher III, *The Implications for Law of User Innovation*, 94 MINN. L. REV. 1417, 1446–55 (critiquing various

*B. Implications of an Ex Ante Perspective*

For all that these debates reflect a diverse literature on the relationship between human rights and patent rights, they are all nevertheless alike in that they take a largely *ex ante* view of how that relationship should be operationalized.

As forward-looking proposals for reform, all three approaches—subjugation, integrated, and coexistence—by their own terms make *ex ante* assessments of how best to reconcile human rights principles with patent law principles. More than any other, however, the coexistence approach with its utilitarian balance takes an *ex ante* orientation. As with the three approaches for balancing human rights with patent rights, the choice of domestic or international law is an *ex ante* debate about the most effective forum in which to do the balancing and achieve the greatest economic welfare rewards going forward. Finally, the debate over eligible subject matter is cast almost entirely in terms of utilitarian, *ex ante* incentives for innovation.

One important dimension of these relationships is the view of human rights principles as a dispositive check on the reach of patent rights through the use of mechanisms such as compulsory licensing. In this interaction, a common opposing argument is that, despite the relatively immediate potential for wider access, compulsory licensing will harm research and development,<sup>29</sup> foreign direct investment,<sup>30</sup> and technology commercialization<sup>31</sup> in

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deontological rationales for intellectual property protection, traditionally invoked in defense of producers, as applied to user-innovators).

29. DeRoo, *supra* note 11, at 393–94 (favoring compulsory licensing “despite the damaging impact it may have on the economic returns of pharmaceutical R&D”); see also Susan Vastano Vaughan, *Compulsory Licensing of Pharmaceuticals Under Trips: What Standard of Compensation?*, 25 HASTINGS INT’L & COMP. L. REV. 87, 101 (finding persuasive, though not categorically unassailable, arguments “that the availability of compulsory licensing impedes local research and development”).

30. See, e.g., Aileen M. McGill, *Compulsory Licensing of Patented Pharmaceuticals: Why A WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under The Doha Declaration*, 10 WAKE FOREST INTELL. PROP. L.J. 69, 90-92 (2009) (recounting significant declines in foreign direct investment in response to the issuance of compulsory licenses for pharmaceuticals in Thailand and Egypt).

31. Cf. Lori Pressman, *DNA Patent Licensing Under Two Policy Frameworks: Implications for Patient Access to Clinical Diagnostic Genomic Tests and Licensing Practice in the Not-for-Profit Sector*, 6 LIFE SCI. & INDUSTRY REP. 329 (2012) (finding across some 2600 academic institution-owned “DNA patents” and some 700 NIH-administered “DNA patents”—patents referring to



the medium to long term. To each of these points, scholars have also counter-argued that the perceived harm is less severe than *a priori* beliefs suggest, as in the case of research and development<sup>32</sup> and foreign direct investment,<sup>33</sup> and even that the actual effect of compulsory licensing may be salutary, as in the case of commercialization.<sup>34</sup> Beyond public health, similar debate has proceeded in the context of climate change and green technology.<sup>35</sup>

Thus framed as a consequentialist discussion of the negative and positive impacts upon incentives of various human rights-driven proposals, this debate is concerned very much *ex ante* with how best to balance the competing interests at work in

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nucleotides in the claim language—that exclusivity in licensing tended to operate as a greater incentive for faster commercialization).

32. See Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 885-92 (2003) (illustrating through six case studies that compulsory licenses issued predictably in significant pharmaceutical markets are likely to harm innovation, but that compulsory licensing is not *per se* harmful to innovation).

33. See Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 285-96, 297-317 (2008) (discussing the general inverse correlation between the use of compulsory licensing to weaken intellectual property rights and the magnitude of foreign direct investment, specifically in the context of public health—but clarifying sector-specific traits of firms and macroeconomic traits of nations that are correlated with meaningful changes in FDI).

34. See Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 380-88 (2010) (advocating compulsory licensing, together with a stricter standard of patent enablement, a shorter patent term, and the use of innovation prizes, as a means to “significantly diminish incentives to engage in costly and risky ex post commercialization efforts”). Indeed, it is frequently a *failure* by the patentee to commercialize its invention that provokes calls for compulsory licensing. See Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest As a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389, 434-49 (2002) (discussing the problem of patent nonuse and advocating compulsory licensing as a remedy to foster greater commercialization in the public interest).

35. Compare Robert Fair, *Does Climate Change Justify Compulsory Licensing of Green Technology*, 6 B.Y.U. INT’L L. & MGMT. REV. 21, 26-29, 37 (2009) (expressing concern for loss of FDI from compulsory licensing), with Joshua D. Sarnoff, *The Patent System and Climate Change*, 16 VA. J.L. & TECH. 301, 354-56 (2011) (expressing optimism for the more tailored use of march-in rights rather than compulsory licenses notwithstanding the effect of normative policy signals regarding the general desirability of expropriating technology for public use).

order to foster further innovation, if only as a future source of expropriable assets.

The same is true for debates over which forum is better suited for resolving conflicts between human rights and patents, conflicts in which localized economic and social interests may be oversimplified at the international level and so may be better mediated through domestic patent laws<sup>36</sup> or, conversely, conflicts in which domestic patent laws may be too narrow and inadequate in scope to support a desirable vindication of human rights objectives.<sup>37</sup>

So also for determining the normatively appropriate boundaries of patent subject matter eligibility, where the threat of an anticommons characterized by overly fragmented, mutually blocking private rights may result in the under-utilization of socially valuable resources.<sup>38</sup> Conversely, the anticommons argument for diminished patent protection has been disputed as being based on a threat that is overstated both theoretically<sup>39</sup> and empirically.<sup>40</sup>

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36. Gold, *supra* note 8, at 192; Wu, *supra* note 21 and accompanying text; see also HOLGER HESTERMAYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 158 (2007) (noting the ability of pharmaceutical firms and other patent owners to vindicate their rights in national and regional courts even though such rights be derived from regional human rights treaties, some of which identify intellectual property as a generally protected right), cited in Aaron Scheinwald, *Who Could Possibly Be Against a Treaty for the Blind?*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 445, 494 n.209 (2012).

37. See, e.g., Kelley A. Friedgen, *Rethinking the Struggle Between Health & Intellectual Property: A Proposed Framework for Dynamic, Rather Than Absolute, Patent Protection of Essential Medicines*, 16 EMORY INT'L L. REV. 689 (2002) (arguing for limited, so-called "dynamic patent protections" that are undefined in their diminished expectation of reward, but explicitly international in their origin and implementation).

38. The seminal critique of intellectual property protection through an anticommons lens is Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698-99 (1998). For a conceptual discussion of the so-called "tragedy of the anticommons" in property rights, see generally Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L.J. 1163, 1166-67 (1999). A related debate has also arisen as to the tension between respecting indigenous knowledge as a form of intellectual property and respecting biodiversity as a human rights objective. See, e.g., Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59 (1998).

39. See, e.g., Richard A. Epstein & Bruce N. Kuhlik, *Is There a Biomedical Anticommons?*, 27 REGULATION 54 (2004) (disputing Professors

Both debates, again framed as consequentialist discourses of the negative and positive impacts upon future economic welfare, are concerned *ex ante* with how best to design systems for reconciling human rights and patent rights concerns in the proper forum and therein to set the proper doctrinal boundaries of patent law. Indeed, the very framing of human rights as a claim of present access in opposition to patent rights as an incentive for future innovation leads naturally to a forward-looking discourse.

These *ex ante* debates about how to shape the patent system going forward are both appropriate and useful for informing public policy, particularly as academic and government research takes an increasingly empirical focus. They are ultimately incomplete, however, without evaluating in some detail the results of past policies, evaluation that requires an *ex post* view.

### III. LOOKING BACKWARD INSTEAD

Specifically, taking an *ex post* view of the patent bargain inquires what society has gained with respect to technologies that were previously accorded exclusionary protection in exchange for the expectation that access to such technologies would eventually flow into the public domain. The *ex post* perspective is analytically consonant with concerns of fairness and a deontological approach to evaluating outcomes,<sup>41</sup> just as human rights principles are.<sup>42</sup>

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Heller and Eisenberg's comparison of patents to government permits and of patent-enabled thickets to individual blockades of different segments along a river); Edmund W. Kitch, *Comment on the Tragedy of the Anticommons in Biomedical Research*, 50 *ADVANCES IN GENETICS* 271 (2003) (criticizing Professors Heller and Eisenberg's expectation that over issuance of patents on basic research technologies should hamper upstream innovation).

40. See, e.g., Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, in *INNOVATION POLICY AND THE ECONOMY* 1–31 (Adam P. Jaffe, Josh Lerner & Scott Stern, eds., 2007) (finding that biomedical research and development projects are interrupted for a variety of reasons such as competitive concerns (29%), lack of time (60%), and, most of all, lack of funding (62%)—but rarely because of patent concerns (1%).

41. See generally Louis Kaplow & Steven Shavell, *Fairness Versus Welfare*, 114 *HARV. L. REV.* 961, 1005–11 (2001) (articulating—in critique—the “meaning, nonconsequentialist nature, and *ex post* character” of fairness concerns).

42. See, e.g., Benoît Mayer, *Climate Change and International Law in the Grim Days*, 24 *EUR. J. INT'L L.* 947, 961–62 (2013) (referring to “human rights’ deontological roots.”); Timothy K. Kuhner, *The Democracy to Which We Are Entitled: Human Rights and the Problem of Money in Politics*, 26 *HARV. HUM.*

Accordingly, looking backward at patents that have expired into public use is a potentially powerful and analytically consistent means for determining what once-privately valuable inventions may now be placed in service of the human rights objective of greater access, particularly to health-related technologies. Empirical analysis of this kind is possible using the forthcoming Expired Patents Dataset.

#### A. *The Expired Patent Dataset*

More fully described elsewhere,<sup>43</sup> the Expired Patents Dataset describes lapses of patents into the public domain, for failure to pay statutory patent maintenance fees,<sup>44</sup> during the recent five-year period beginning January 1, 2008, and ending December 31, 2012. By merging patent maintenance fee data with patent bibliographic information and further matching patent class information with the familiar Hall-Jaffe-Trajtenberg aggregate technology category and subcategory system,<sup>45</sup> the full dataset comprises the following original and constructed variables:

##### Original Variables

- patent number;
- patent application filing date;
- patent issuance date;
- patent technology class;
- patent technology subclass;
- inventor name;
- inventor city (for domestic inventors);
- inventor state (for domestic inventors);

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RTS. J. 39, 88 (2013) (similarly referring to “human rights law’s deontological emphasis on human dignity”).

43. See Vishnubhakat, *supra* note 5.

44. 35 U.S.C. § 41(b) (2013). All patents that issue from applications filed on or after December 12, 1980, are subject to three maintenance fees respectively payable 3.5 years, 7.5 years, and 11.5 years from the date of issuance and each with a 6-month grace period. Failure to pay these maintenance fees results in the expiration of the patent at the end of the grace period: 4, 8, or 12 years from issuance, respectively.

45. See generally Bronwyn H. Hall et al., *The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools* (Nat’l Bureau of Econ. Research, Working Paper No. 8498, 2001). The category and subcategory definitions as well as the concordance are available at [www.nber.org/patents](http://www.nber.org/patents).

- inventor zip code (for domestic inventors, if available);
- country code<sup>46</sup> (for foreign inventors);
- dates of all maintenance events; and
- event codes describing all maintenance events.<sup>47</sup>

#### Constructed Variables

- patent age at expiration;
- Hall-Jaffe-Trajtenberg technology category; and
- Hall-Jaffe-Trajtenberg technology subcategory.

#### *B. The Case of Drugs and Medical Inventions*

In addition to the rich economic and legal literature on innovation in the pharmaceutical and medical fields generally, the present study relies in particular on the economic assumptions of the “Drugs and Medical” category of inventions as formally defined.<sup>48</sup> Thus, for example, the Hall-Jaffe-Trajtenberg analysis found that patents on “Drugs and Medical” inventions together with those on “Computers and Communications” and “Electrical and Electronic” inventions have risen in their share of total patents, and the traditional fields of “Chemical,” “Mechanical,” and “Other” inventions have declined in relative share—reflecting a shift toward high technology in economic importance.<sup>49</sup> Moreover, “Drugs and Medical” patents have tended to receive far more subsequent citations than they have made to their own prior art, though it is not clear whether this trend reflects greater technological originality or is simply artifactual.<sup>50</sup> Related trends in self-citation—the practice of a firm citing in one patent to another, earlier patent that it also holds—show much greater self-citation among “Drugs and Medical” patents, consistent with the tendency of innovation in that field to be more concentrated in large firms

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46. For documentation explaining the country codes, see *Patent Full-Text and Image Database*, USPTO, <http://patft.uspto.gov/netahtml/PTO/help/helpctry.htm> (last updated Dec. 6, 2005).

47. For documentation explaining the maintenance event codes, see UNITED STATES PATENT AND TRADEMARK OFFICE, U.S. PATENT GRANT MAINTENANCE FEE EVENTS FILE 5 tbl. 2 (2009), available at [storage.googleapis.com/patents/maint\\_fee\\_events/current/MaintFeeEventsFileDocumentation.doc](http://storage.googleapis.com/patents/maint_fee_events/current/MaintFeeEventsFileDocumentation.doc).

48. See Hall et al., *supra* note 45.

49. *Id.* at 13-14.

50. *Id.* at 16.

with a greater likelihood of internal citation.<sup>51</sup> Finally, these and other trends across technology categories and subcategories are markedly heterogeneous for patents within the “Drugs and Medical” category,<sup>52</sup> suggesting that inventions within the “Drugs,” “Surgery and Medical Instruments,” “Biotechnology,” and “Miscellaneous” subcategories reflect economically meaningful differences in how they are developed, protected, commercialized, and disseminated.

By way of context for the case study of “Drugs and Medical” patents, then, descriptive statistics for the Expired Patents Dataset focused on two dimensions: technologies of inventions and geographies of inventors.<sup>53</sup> Segmented by technology, the mean expiration age of patents ranged from 7.5 years to 9 years as shown in Figure 1. Among expiring cohorts, “Chemical” and “Drugs and Medical” patents were the oldest at expiration. Figure 2 revisualizes these trends using the mean patent age of each monthly expiration cohort to estimate the mean month in which that cohort of patents issued.

Segmentation by geography revealed that, across U.S. states, the mean expiration age of patents ranged from 6.5 years to 9.5 years as shown in Figure 3. Patents from Idaho and Vermont were consistently the youngest; those from Iowa and New Hampshire, largely the oldest. Figure 4 revisualizes these trends using the mean patent age of each monthly expiration cohort to estimate the mean month in which that cohort of patents issued.

Similarly, across foreign countries,<sup>54</sup> the mean expiration age of patents ranged from 4 years to 10 years as shown in Figure 5, and Figure 6 revisualizes these trends using the mean patent age of each monthly expiration cohort to estimate the mean month in which that cohort of patents issued. Cross-segmentation by both geography and technology shows in Figure 7 the number of expired patents per Hall-Jaffe-Trajtenberg technology category in each foreign country, and Figure 8 shows the percentage share of

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51. *Id.* at 19–20.

52. *Id.* at 23.

53. Vishnubhakat, *supra* note 5. Inventor “geographies” refer to the city, state, country, or other geographic unit of record associated with inventors named on a given patent. The present study looks at the first-named inventor, as is common practice in the relevant economic literature. Thus, for example, the analysis may attribute U.S. patents to Japan as shorthand for U.S. patents whose first-named inventors list Japan as their country of record.

54. This analysis looked at all foreign countries with U.S. patents expiring during the 2008-2012 period.

each foreign country's patent expirations across the Hall-Jaffe-Trajtenberg technology categories. Figures 9 and 10 likewise show, respectively, the number of granted patents per Hall-Jaffe-Trajtenberg technology category in each foreign country and the percentage share of each foreign country's patent grants across the Hall-Jaffe-Trajtenberg technology categories.

These findings enable direct comparison, therefore, of inventions entering the domain of patent protection and those leaving it for the public domain. Figures 11 and 12 show this comparison for foreign countries in decreasing order by expirations and grants, respectively. The descending order of patent expirations across foreign countries in Figure 11 would suggest that commensurate rates of patent grant would reveal a monotonically decreasing distribution from left to right across the same countries.<sup>55</sup> This is not the case, however, as a number of countries accounted for patent grants markedly higher than their incidences of patent expiration. So also in Figure 12, ordered descending by patent grants, where a number of countries conversely accounted for patent expirations markedly higher than their incidences of patent granting.

These findings also show in particular that patents on "Drugs and Medical" inventions both expire and issue at a higher and more variable proportion as the total count of patent expirations and grants decreases across foreign countries. Put another way, among countries whose inventors patent extensively in the United States, "Drugs and Medical" inventions are consistently a small minority—indeed, they are far eclipsed by patented inventions in the "Electrical" and "Computer and Communications" arts. This inverse relationship, between total patent expirations and grants on the one hand and "Drugs and Medical" patent expirations and grants on the other, suggests that an optimal middle ground may exist that balances the scale of overall patenting activity with the particular proportion of "Drugs and Medical" patenting. Because each diminishes as the other rises, the middle ground of interest is characterized by sufficiently high overall patenting activity as well as sufficiently high proportional importance given to the development, knowledge dissemination by patenting, and expiration into public use of "Drugs and Medical" technologies.

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55. In simple terms, a monotonic function is one that is everywhere increasing or everywhere decreasing, i.e., where  $a \leq b$ ,  $f(a) \leq f(b)$ , and vice-versa.

To determine this optimal middle, one may consider a country's throughput of patented technology into the public domain by its expired patents as a proportion of its newly granted patents over the same time period. By comparing this throughput statistic against the total patent grant activity for that country, it is possible to optimize both quantities independently.

Thus, as Figure 13 shows in a log-log<sup>56</sup> comparison, approximately half of the countries examined received fewer than 100 total patent grants during the entire period of 2008-2012, falling to the left of 2 on the logarithmic abscissa axis.<sup>57</sup> Moreover, a significant majority of countries also experienced more total expirations than total grants during the entire period of 2008-2012, falling below 0 on the logarithmic ordinate axis.<sup>58</sup> By comparison to total expirations and grants, however, throughput ratios for "Drugs and Medical" patents represent a slightly more clustered range of grant activity over the entire period of 2008-2012. More importantly, these patents all fall on or below 0 on the ordinate axis, meaning that expirations never outpaced new grants among such inventions in any country during 2008-2012.

Taking from this distribution those countries which, during 2008-2012, received approximately 1000 patents or more (thus having abscissa values of approximately 3 or higher) and expired approximately half or more of their existing patents (thus having ordinate values of approximately -0.3 or higher) reveals four countries of particular interest: the United Kingdom, France, Sweden, and Canada. By the patent throughput analysis described, these countries are potentially sustainable sources both of ongoing innovation as measured by total U.S. patenting activity and of public domain technology as measured by a high fraction of patent expiration.

The identification of these countries and their characterization and comparison in terms of an *ex post* analysis, however, are instrumental conclusions rather than causal or

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56. A log-log analysis transforms both axes into their logarithmic equivalents in order to compare exponential phenomena in a linear fashion.

57. An abscissa value of 2 corresponds to  $10^2$ , or 100, patent grants. This analysis refers to "abscissa" and "ordinate" axes rather than independent and dependent axes, respectively, to avoid suggesting causal relationships that are beyond the scope of this descriptive analysis.

58. An ordinate value of 0 corresponds to an expiration/grant ratio of  $10^0$ , or 1, indicating a steady state of patent turnover. Positive ordinate values indicate that more patents expired than were granted, and negative ordinate values indicate that fewer patents expired than were granted.



mechanistic ones and invite further study of two issues. One line of inquiry is into the economic drivers that impel inventors from these countries both to continue investing, inventing, and patenting in the United States and to allow a substantial portion of their patents to expire for non-maintenance. The other line of inquiry is into whether and how the drugs and medical technologies taught by expired patents are actually being practiced more widely to the benefit of the public.

#### IV. NEXT STEPS

More broadly, the analytical and empirical *ex post* inquiry set forth in this Article has described the value of looking backward to assess the public inheritance of technologies for which U.S. patent protection was previously granted, and has identified a geographic cluster of countries that may exhibit a cycle of innovation that sustainably deprioritizes socially valuable pharmaceutical and medical inventions and leaves them free for public use.

As a proof of principle, this Article therefore invites more detailed analysis along a number of dimensions. One such dimension is the technology sector itself, *viz.*, disaggregating the “Drug and Medical” category into subcategories to characterize with more precision the inventions that have become publicly available in recent years. Another, more sophisticated thread for follow-on research is not to select the threshold parameters of patent grant activity and expiration proportion *ab initio*, but to estimate them econometrically. Ultimately, it is hoped that these and other empirical inputs will encourage a greater understanding—and, if appropriate, deliberate development—of innovation equilibria with a sustainable output of socially valuable technologies available for public use.

V. TABLES AND FIGURES

Figure 1. Mean Age of Expiring Patents by Technology Category  
(2008–2012) (six-month moving average)

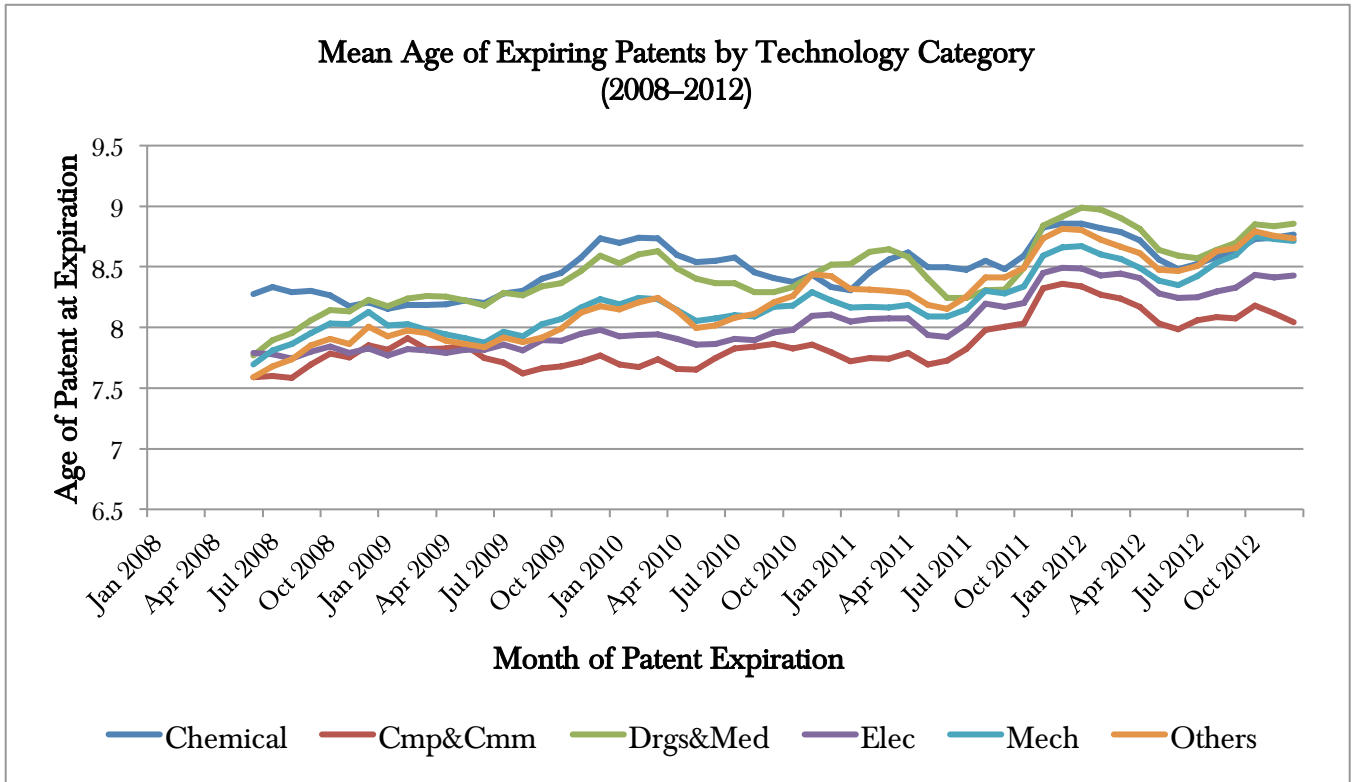


Figure 2. Mean Issue Month of Expiring Patents by Technology Category (2008–2012) (six-month moving average)

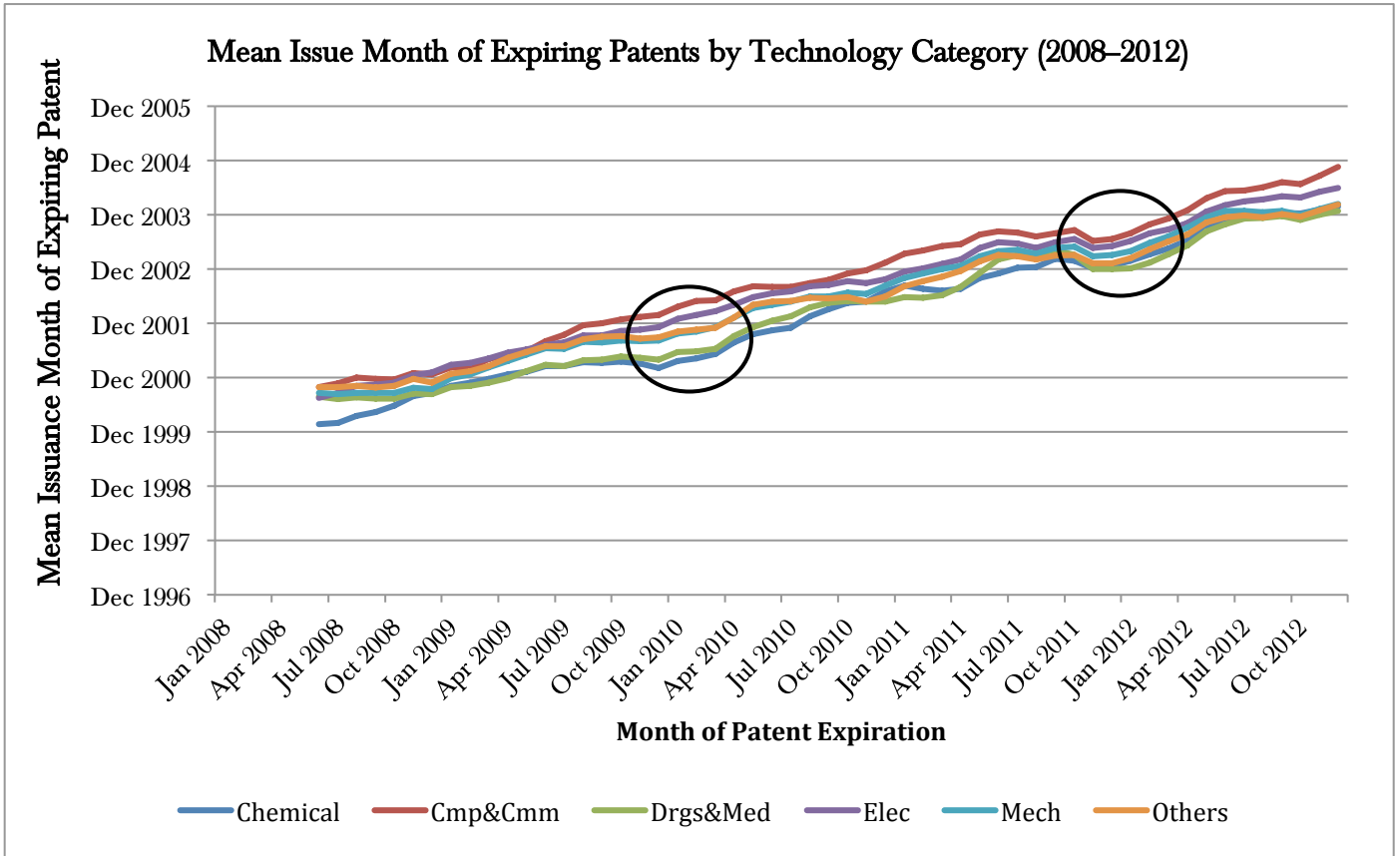


Figure 3. Mean Age of Expiring Patents by U.S. State  
(2008–2012) (six-month moving average)

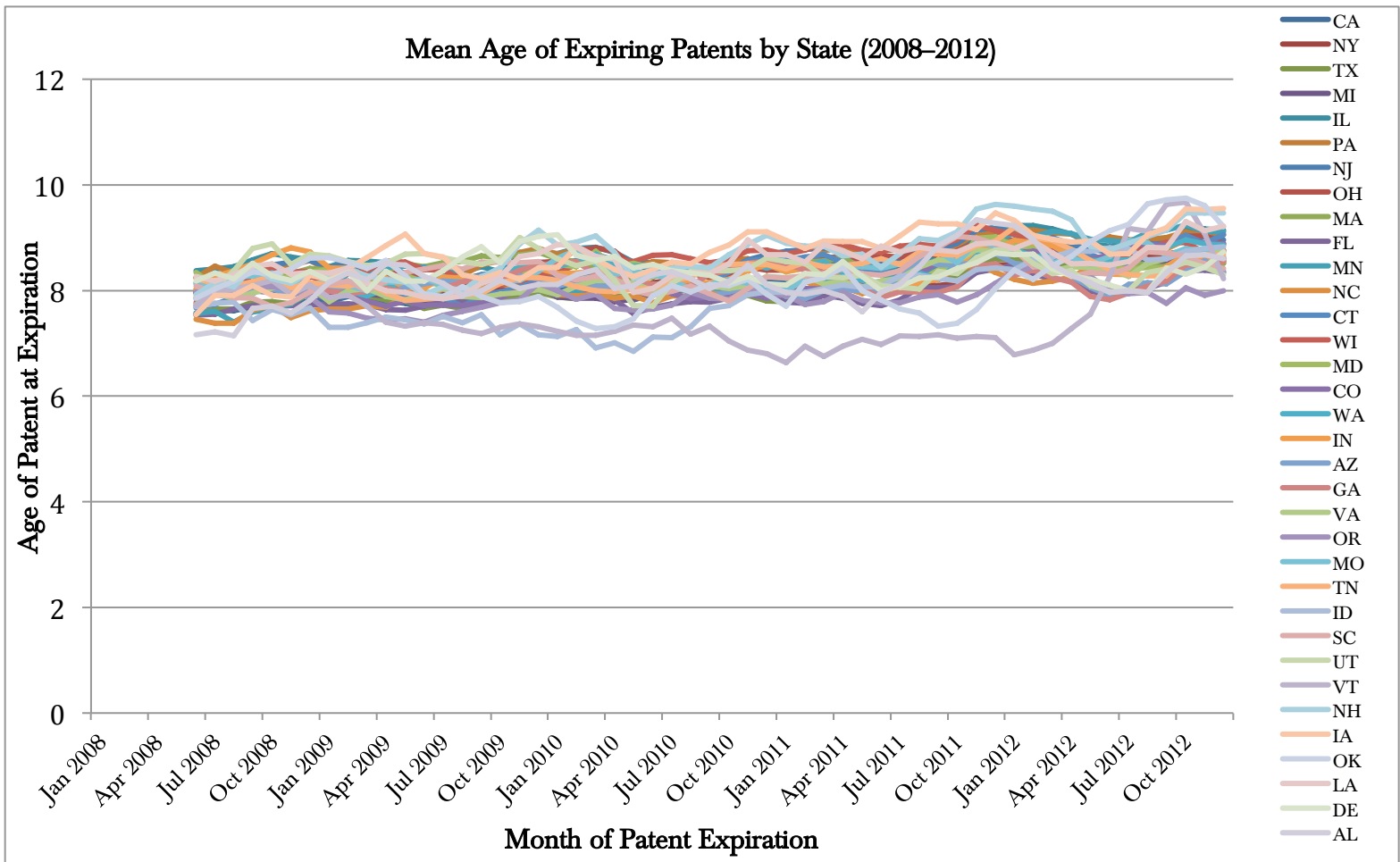


Figure 4. Mean Issue Month of Expiring Patents by U.S. State (2008–2012) (six-month moving average)

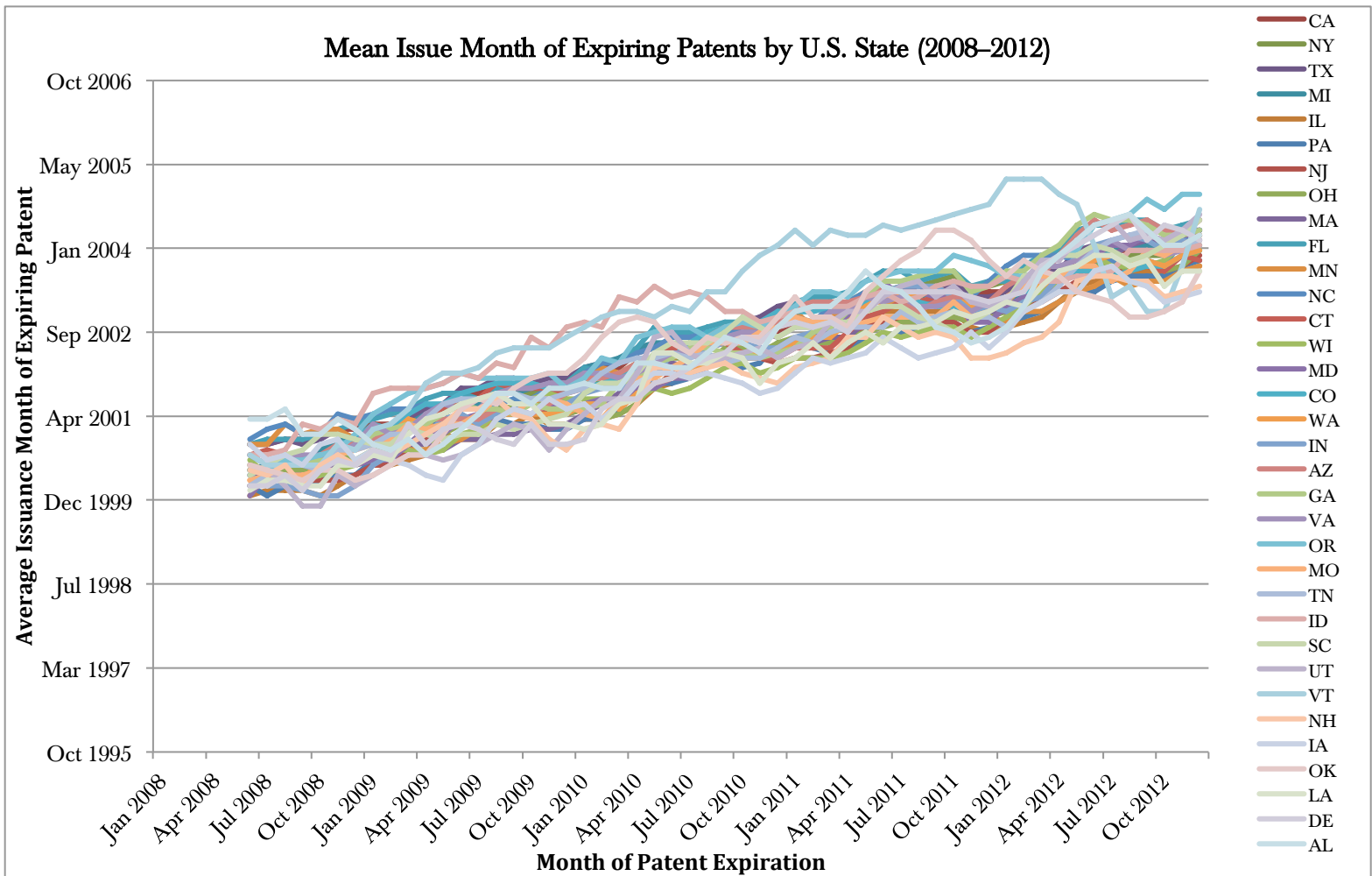


Figure 5. Mean Age of Expiring Patents by Foreign Country  
(2008–2012) (six-month moving average)

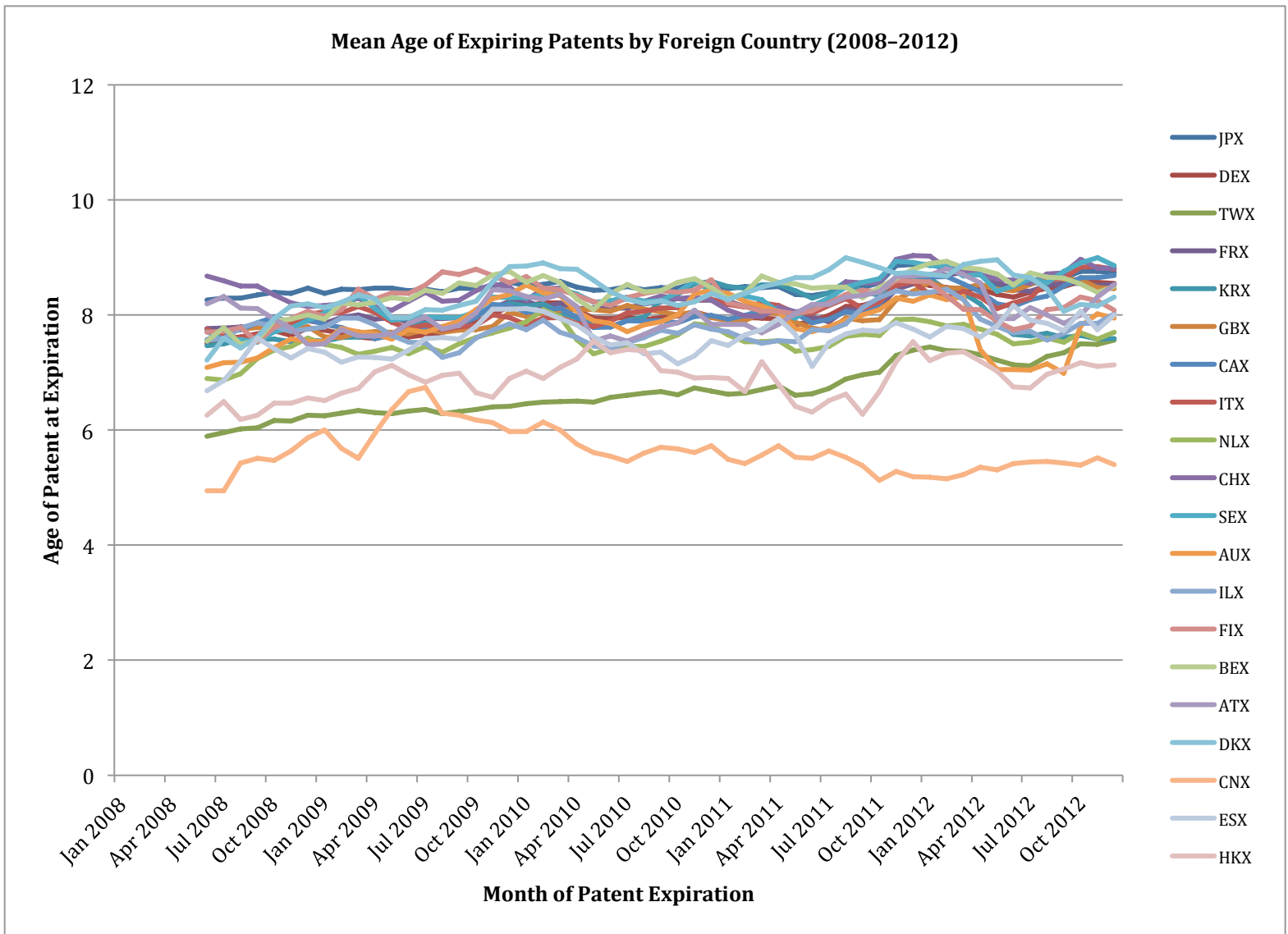




Figure 7. Patent Expirations by Foreign Country Across  
Technology Categories (2008–2012)  
(six-month moving average)

Patent Expirations by Foreign Country Across Technology Categories (2008–2012)

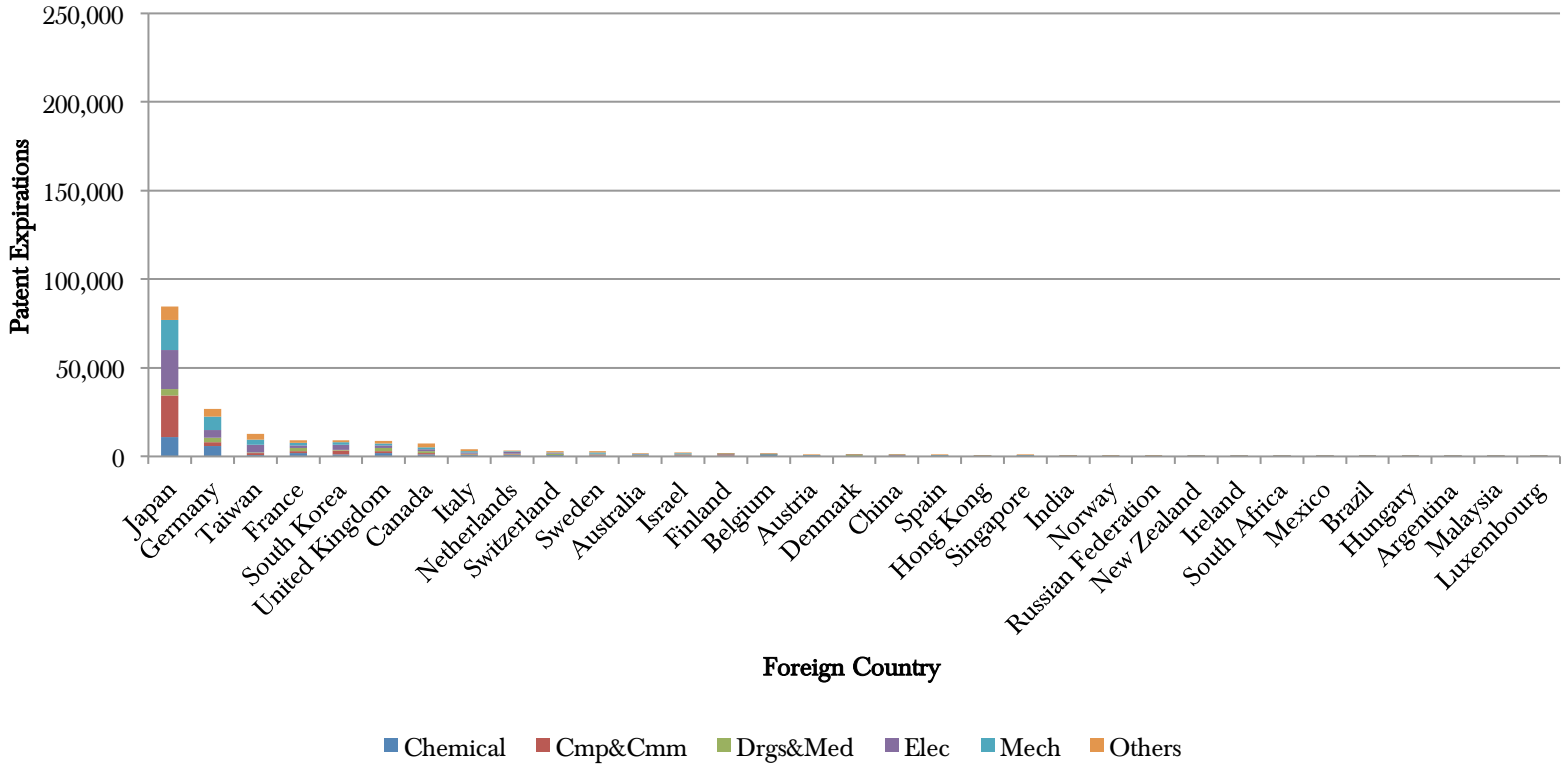




Figure 8. Patent Expirations by Foreign Country Across Technology Categories (2008–2012)  
(six-month moving average)

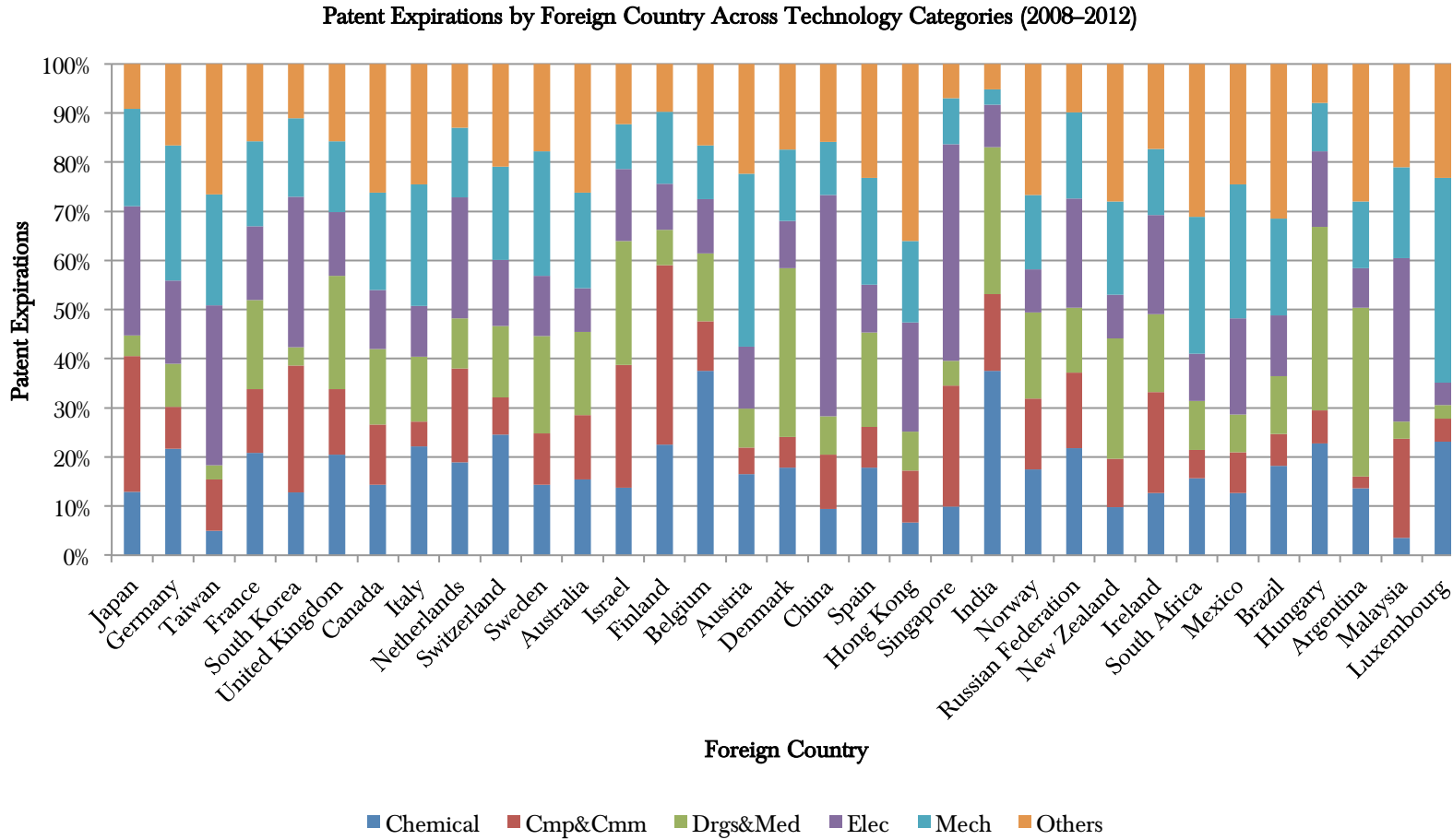


Figure 9. Patent Grants by Foreign Country Across Technology Categories (2008–2012) (six-month moving average)

Patent Grants by Foreign Country Across Technology Categories (2008–2012)

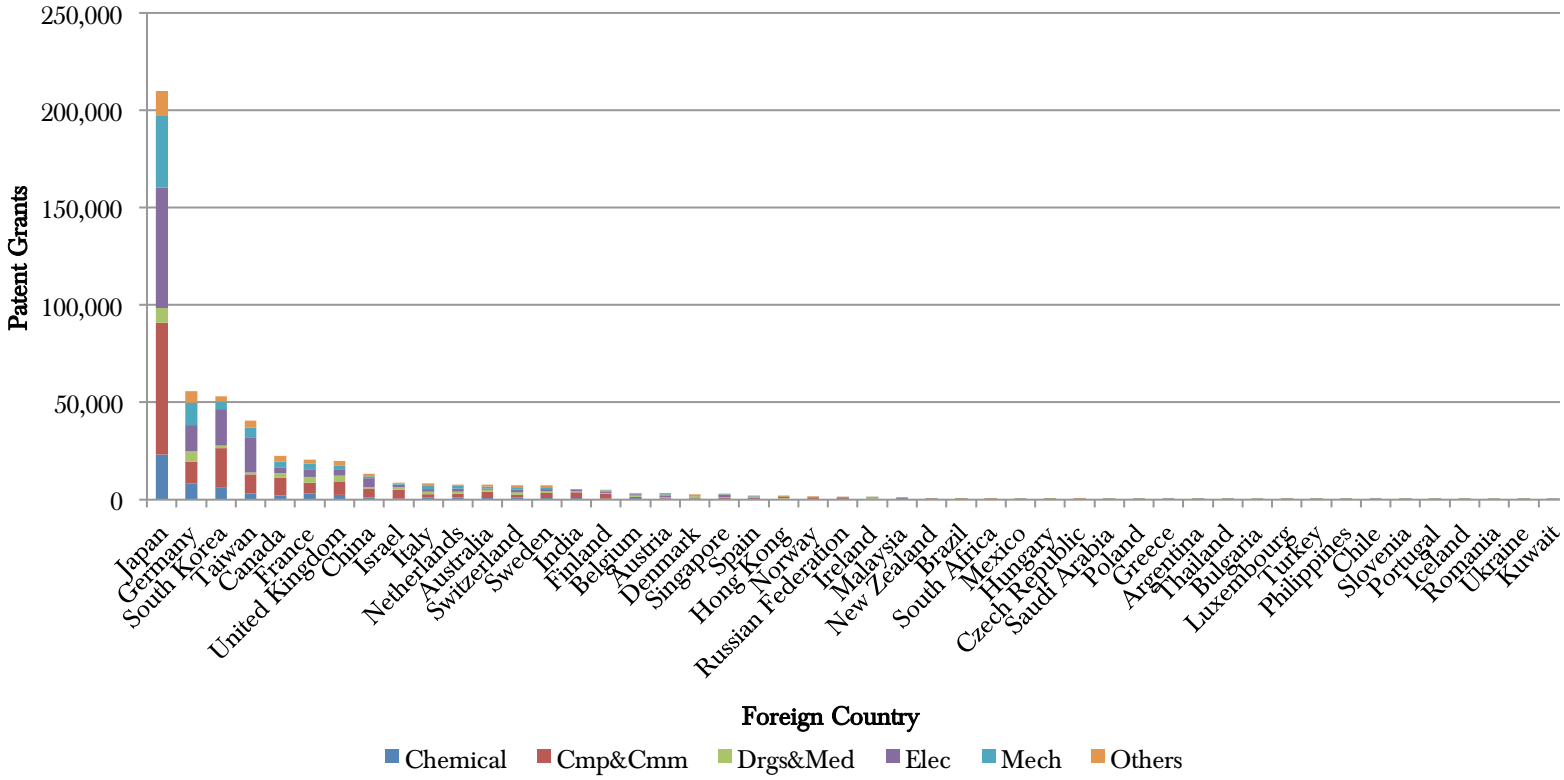


Figure 10. Patent Grants by Foreign Country Across Technology Categories (2008–2012)  
 Categories (2008–2012)  
 (six-month moving average)

Patent Grants by Foreign Country Across Technology Categories (2008–2012)

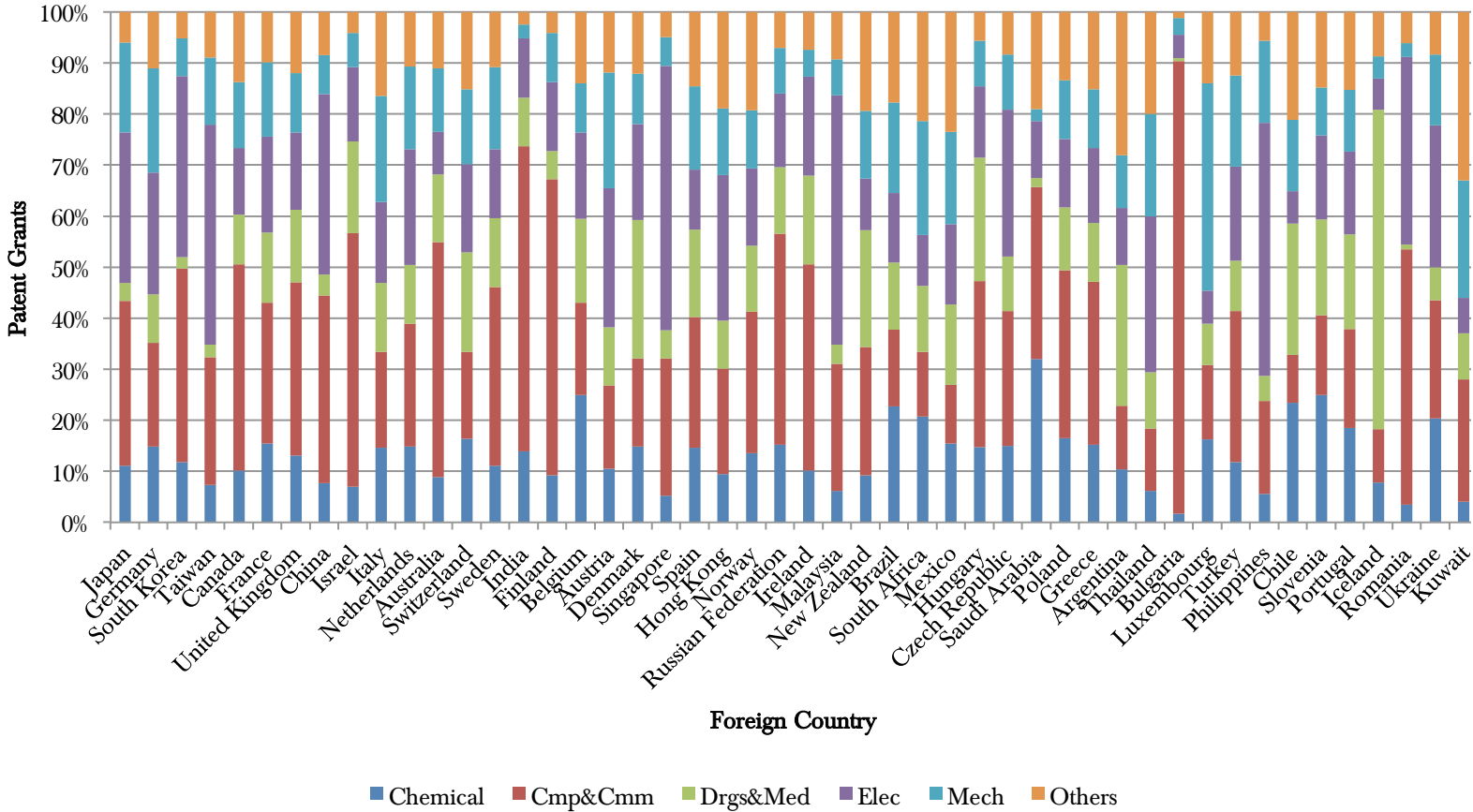


Figure 11. Patent Grants and Expirations Across Foreign Countries (2008–2012)

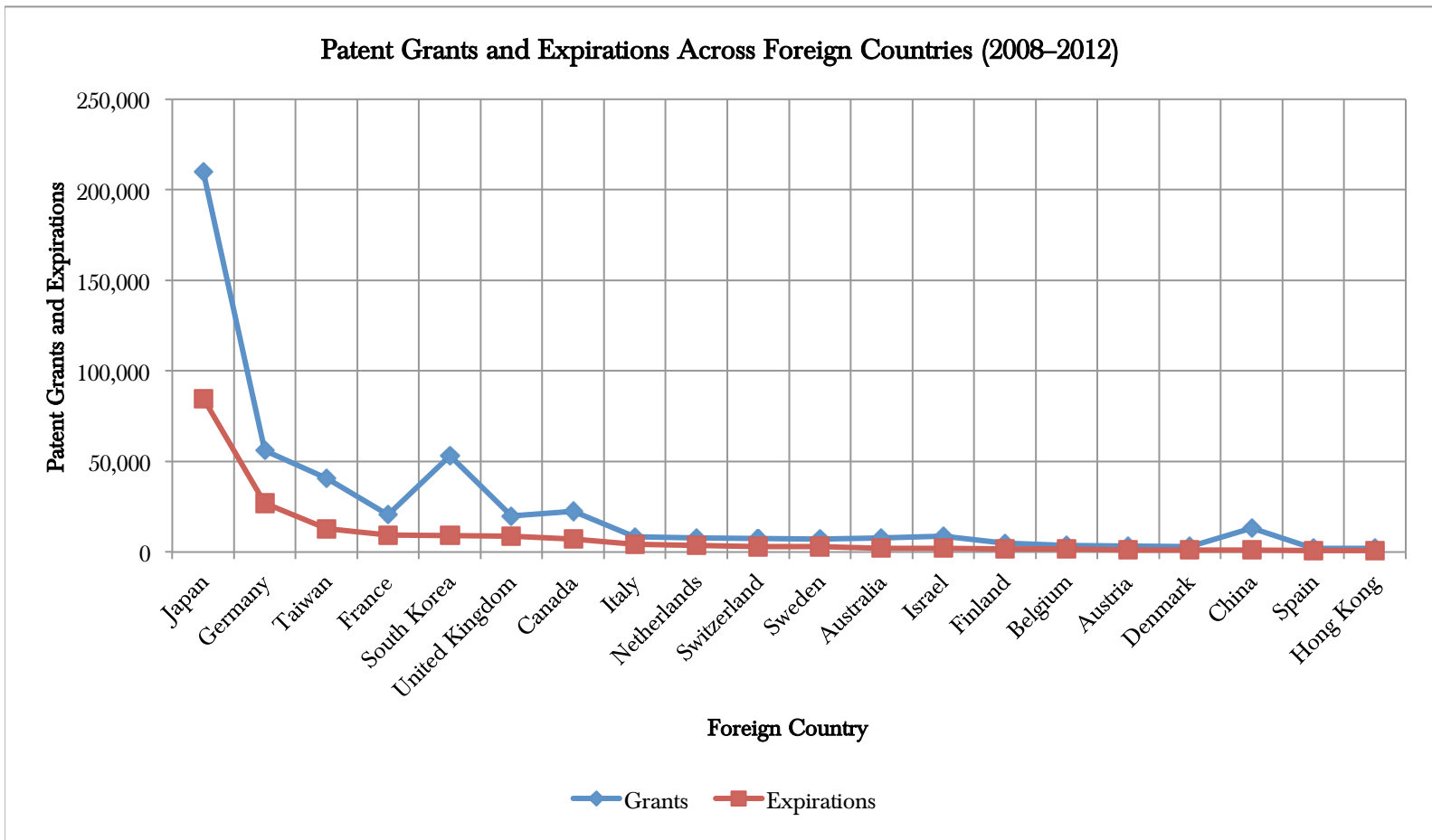


Figure 12. Patent Grants and Expirations Across Foreign Countries (2008–2012) (six-month moving average)

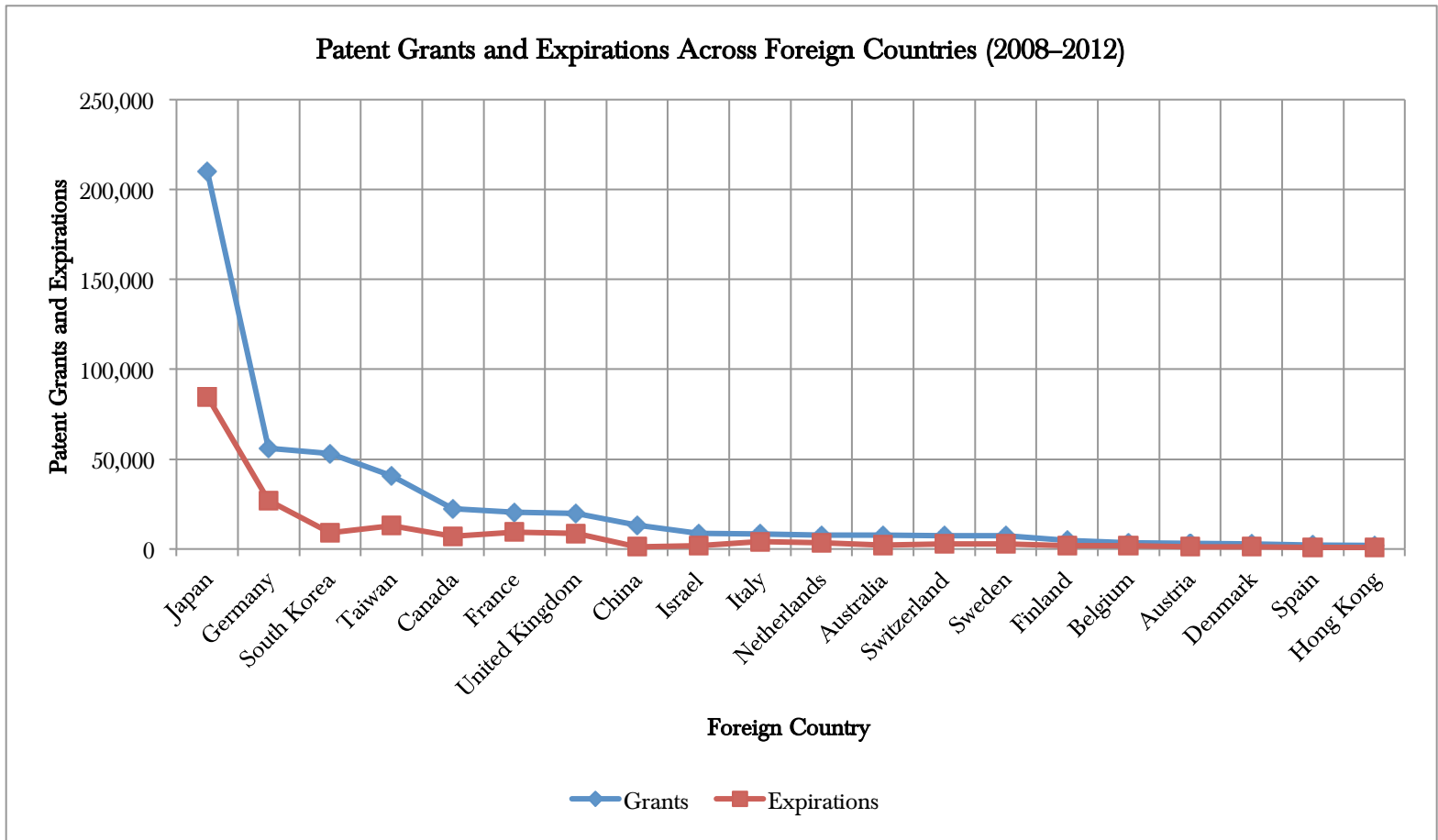


Figure 13. Patent Throughput of Expirations and Grants Across Foreign Countries (2008–2012) (log-log)

