1-1-2011

Dynamic Patent Governance in Europe and the United States: The Myriad Example

Kali Murray
Marquette University Law School, kali.murray@marquette.edu

Esther van Zimmeren
University of Leuven, esther.vanzimmeren@law.kuleuven.be

Publication Information
Kali Murray & Esther van Zimmeren, Dynamic Patent Governance in Europe and the United States: The Myriad Example, 19 Cardozo J. Int'l & Comp. L. 287 (2011)

DYNAMIC PATENT GOVERNANCE IN EUROPE AND THE UNITED STATES: THE *MYRIAD* EXAMPLE

Kali Murray[*] *and Esther van Zimmeren*[**]

ABSTRACT

This Article examines the emerging elements of a new model for patent governance. It is divided into four parts. In Section One, we develop a model of dynamic patent governance. This model extends the theoretical framework of network governance, to explain the emergence of networks in the decision-making infrastructure for the public and private actors in the patent system. Dynamic patent governance widens this theoretical framework in two key ways. First, dynamic patent governance, within its formal dimensions, is based on the idea that heterogeneous administrative actors regulate the grant and enforcement of patents. This challenges a perspective that sees patent examination agencies as the sole actor of importance within the patent system. Second, dynamic patent governance, within its informal dimensions, highlights that the patent administrative regime is shaped by the fluid relationship of diverse actors to these heterogeneous administrative actors. Section Two explores the consequences of a more dynamic patent governance context. Section Three applies this model to explore the recent Myriad litigation in the United States and Europe. Section Four focuses on some particular challenges that dynamic patent governance poses to: (1) the impulse to centralize patent administration and litigation; and (2) the efficiency of the patent system.

TABLE OF CONTENTS

I. INTRODUCTION

It started out in a typical manner. On August 12, 1994, a patent application was filed in the United States Patent Office (USPTO) that claimed as its primary invention, a DNA[1] isolated sequence for what

* Kali Murray, Assistant Professor, Marquette University Law School. Equal contribution by each author. I would like to thank Ernest "Dutch" Igoni for his support this year. I would also like to thank my research assistant Andrew Spillane for his steadfast dedication to this complex project.

** Esther van Zimmeren, L.L.M, Research Fellow, The University of Leuven, Centre for Intellectual Property Rights. Equal contribution by each author.

[1] DNA is the term used for the chemical compound known as deoxyribonucleic acid, which serves as a basic source of genetic material. 2-D ATTORNEY'S DICTIONARY OF MEDICINE D-

has been identified as the BRCA1 gene, as well as a method for identifying that specified gene in a comparative sample.[2] One year later, on August 12, 1995, a similar patent application was filed at the European Patent Office (EPO).[3] Other patent applications swiftly followed, including a patent application filed in December 1995, for another key isolated DNA sequence, identified as the BRCA2 sequence, as well as a method for identifying that specified gene in a comparative sample.[4] Indeed, patent applications for the same inventions have been filed in jurisdictions other than the United States and Europe.[5]

The *Myriad* patents (called so because they are in large part owned by one corporation, Myriad Genetics, Inc., (Myriad) located in Salt Lake City, Utah), have prompted strong reactions in jurisdictions all over the world, including the United States, Europe, and Australia.

33566 (Matthew Bender & Co. 2009).

2 The patent application on the BRCA1 gene was initially filed on August 12, 1994. U.S. Patent No. 289,211 (filed Aug. 12, 1994) [hereinafter '289 application]. After a number of successively filed continuation-in-part applications, U.S. Patent Number 5,747,282 was issued on May 8, 1998. U.S. Patent No. 5,747,282 (filed June 8, 1995) (issued May 8, 1998); *see also* U.S. Patent No. 5,693,473 (filed June 7, 1995) (issued Dec. 7, 1997). A number of methods for the process of detecting specific mutations in the BRCA1 gene, as well as methods for comparing the individualized tumor and non-tumor BRCA1 gene sequence of a patient sample, originated from the now abandoned '289 patent application. *See* U.S. Patent No. 570,999 (filed June 7, 1995) (issued Jan. 20, 1998); U.S. Patent No. 5,710, 001 (filed June 7, 1995) (issued Jan. 20, 1998); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996) (issued May 19, 1998).

3 European Patent No. 705,902 (filed Aug. 12, 1995).

4 The patent application that identified the BRCA2 sequence was initially filed on December 18, 1995. U.S. Patent No. 573,779 (filed Dec. 18, 1995) [hereinafter '779 patent application]; U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (issued Nov. 17, 1998). A method for comparing the individualized tumor and non-tumor BRCA2 gene sequence of a patient sample also originated from the now abandoned '779 patent application. U.S. Patent No. 6,033,857 (filed Mar. 20, 1998) (issued Mar. 7, 2000).

5 Myriad filed for a patent under the Patent Cooperation Treaty for the BRCA1 gene sequence in February 1996. WO/1996/005307 (filed on Feb. 22, 1996). The patent application entered into a national sequence in Korea, Finland, Mexico, and New Zealand. *(WO/1996/005307) 17q-Linked Breast and Ovarian Cancer Susceptibility Gene*, WIPO, http://www.wipo.int/portal/index.html.en (search WIPO for "WO/1996/005307"; then follow "(WO/1996/05307) 17-q LINKED BREAST AND OVARIAN CANCER . . ." hyperlink; then click "National Phase" tab) (last visited Apr. 3, 2010). A patent was issued in New Zealand in 1998, but it was rejected in Korea in 2003. *Id.* Likewise, Myriad, along with listed co-inventors, including the Trustees of the University of Pennsylvania, HSC Research Development Limited Partnership, and Endo Recherle, Inc., filed for a patent under the Patent Cooperation Treaty, for the BRCA2 gene sequence in 1996. *See* WO/1997/022,689 (filed Dec. 17, 1996). The patent application entered into a national phase application in Canada, Mexico, Japan, and New Zealand. *(WO/1997/022689) Chromosome 13-Linked Breast Cancer Susceptibility Gene*, WIPO, http://www.wipo.int/portal/index.html.en (search WIPO for "WO/1997/022689"; then follow ("WO/1997/022689) CHROMOSOME 13-LINKED BREAST CANCER SUSCEPTIBILITY. . ." hyperlink; then click "National Phase" tab) (last visited Apr. 3, 2010). A patent was issued from New Zealand in 2000. *Id.*

These patents have prompted controversies because they seem so personal, in that these inventions cover such things as the breast and ovarian cancer genes, BRCA1 and BRCA2, and their mutations, as well as diagnostic and therapeutic applications based on the gene's sequence. One patient, Lisabeth Ceriani, explaining her opposition to gene patents, stated, "gene patents," are "turning our bodies into commerce."[6] Thus, the various *Myriad* debates have raised significant moral and practical conundrums for patent law.

Equally interesting (but less commented upon) is that in addition to all of its guises, *Myriad* provides a compelling example of a changed policy environment in patent law. The *Myriad* debates take place in a policy environment in which calls for patent reform are common. Congress once again squabbles over whether to create a new post-grant review proceeding while across the pond[7], the European Union has resumed the debate whether to create an EU-wide patent[8] along with a

6 Elizabeth Weise, *Is it Unfair to Patent Genes? Successful ACLU Lawsuit Against a Bio-Tech Company Has Some Celebrating, Others Alarmed*, USA TODAY, Apr. 10, 2010, at 10B.

7 *See* Patent Reform Act of 2011, S. 23, 112th Cong. (2011); Patent Reform Act of 2010, S. 515, 111th Cong. §§ 321-36 (2010); Patent Reform Act of 2009, H.R. 1260, 111th Cong. §§ 321-36 (2009). For further discussion of patent law, see Angela Payne James et al., *Recent Developments in Patent Law and the Potential Impact on Patent Litigation, in* PATENT LITIGATION 2009 249, 287 (PLI Patents, Copyrights, & Literary Property Course Handbook Series No. 982, 2009).

8 The Belgian Presidency made European Union patents a priority. *See* PROGRAMME OF THE BELGIAN PRESIDENCY OF THE EU COUNCIL (2010), http://www.eutrio.be/files/bveu/media/documents/Programme_EN.pdf. Similar major initiatives by former presidencies have failed due to stagnating negotiations. *See, e.g.*, Press Release, European Parliament, Swedish Ministers Outline Council Presidency Priorities (Sept. 4, 2009), *available at* http://www.europarl.europa.eu/news/expert/infopress_page/008-60075-244-09-36-901-20090901IPR60074-01-09-2009-2009false/default_en.htm (discussing legislative work on the community patent as a priority of the Swedish Presidency of the European Union); Press Release, Swedish Presidency of the European Union, Breakthrough for EU Patent During the Swedish Presidency, (Dec. 4, 2009), *available at* http://www.sweden.gov.se/sb/d/12407/a/136614 (discussing the EU Member States' agreement on a common European Union patent court that will try cases on both the European Union patent and existing European patents). Unfortunately, the Belgian Presidency also failed to advance a common patent agenda. As a result, a number of EU Member States decided to launch a procedure for so-called "enhanced cooperation" which permits a group of at least nine Member States to create new EU legislation without the cooperation of all the Member States. *See* Letter by 10 Member States to the European Commission to Commissioner Michel Barnier, (Dec. 7, 2010), *available at* http://www.fd.nl/csFdArtikelen/WEB-HFD/y2010/m12/d08/20892331. The European Commission then submitted a proposal for enhanced cooperation of a unitary EU patent. *Commission Proposal for a Council Decision Authorizing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection,* COM (2010) 0790 final (Dec. 14, 2010). "Enhanced cooperation" is also supported by the European Parliament and the Council of the European Union. Press Release, European Parliament gives go-ahead for enhanced cooperation, (Feb. 15, 2011), *available at* http://www.europarl.europa.eu/en/pressroom/content/20110215IPR13680/html/EU-patent-Parliament-gives-go-ahead-for-enhanced-cooperation; Press Release 7506/11, Council authorizes enhanced cooperation on creation of unitary patent protection,

centralized court to hear patent disputes. These debates, along with recurrent controversies, such as *Myriad*, while often viewed in isolation from each other and seemingly preoccupied by different concerns, actually reflect a shared experience in different jurisdictions—a reevaluation, if not an outright crisis—over how public authorities regulate the grant and subsequent enforcement of patents.

Why, at present, does the ability of administrators, to effectively regulate patents, seem to be compromised? The obvious answer, critics contend, is that patent administrators are failing in their most basic tasks. Specifically, critics claim that patent administrators are failing to examine patent applications quickly, and, if those patents are actually examined, issuing poor quality patents.[9] Moreover, patent administrators often cannot stop a patentee from engaging in behavior that may distort the functioning of a market, such as patent thickets,[10] restrictive licensing techniques, and the litigation claims of so-called patent trolls.[11]

The solutions are seemingly easy. Provide more funding and hire

(March 10, 2011), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=PRES/11/54&format=HTML&aged=0&language=EN&guiLanguage=en.

9 The deficient "quality" of patents has been cited as an ongoing problem in the current patent system. Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System,* 87 N.C. L. REV. 1341, 1343 (2009) (citing Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System: Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J 989, 996–97 (2004)). *See* Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System,* 17 BERKELEY TECH. L.J. 763, 765 (2002) (suggesting that critics of the Patent Office assert that the patents granted by the same are of poor quality and "facially" invalid or broader than the actual innovation disclosed in the patent application). Bruno van Pottelsberghe de la Potterie has sought to measure how patent quality can be determined. *See* Bruno van Pottelsberghe de la Potterie, *The Quality Factor in Patent Systems* 12 (ECARES, Working Paper No. 2010-027, 2010), https://dipot.ulb.ac.be:8443/dspace/bitstream/2013/59650/1/2010-027-VANPOTTESLBERGHE-qualityfactor.pdf ("Quality is defined as the extent to which patent systems comply with their own patentability conditions in a transparent way. It is therefore possible to gauge quality through a two-layer framework: the first layer would be composed of the legal standards that describe the patentability conditions of a national patent system. The second layer is characterized by the operation design put in place to meet those standards.").

10 A patent thicket can be defined as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 7 INNOVATION POLICY AND THE ECONOMY 119-50 (Adam Jaffe, et al., eds., 2001) (analyzing patent pools and cross-licenses as a solution for patent thickets, in particular in a standard setting context).

11 The term "patent troll" is a pejorative term used for an entity that enforces its patents against one or more alleged infringers in a manner generally considered rather aggressive or opportunistic and which often does not have an intention to manufacture or market the patented invention. Therefore, a less pejorative label for this type of entities is "non-practicing entity." *See* John R. Allison, Mark A. Lemley & Joshua Walker, *Extreme Value or Trolls on Top? The Characteristics of the Most Litigated Patents*, 158 U. PA. L. REV. 101 (2009).

more examiners to examine patents quickly.[12] Eliminate the ability of patent trolls to bring superfluous claims.[13] Impose mandatory licensing rules[14] or use new types of licensing models to provide relief from post-enforcement control by patentees.[15]

However, patent reform debates in Europe, the United States and elsewhere are not simply about improving the functioning of patent regulators. Indeed, various controversies, of which *Myriad* is one, indicate that a broader set of questions is at play. Whose interests does patent law serve? Patent-holders? Competitors? The public? Who is in the best position to address these respective interests? The legislature? The executive? The judiciary? Is there a role for the patent community in this respect? And if so, how could the patent community optimally exercise this role? These practical controversies have led to even broader philosophical inquiries. Is patent law still fulfilling the most basic functions of law? Has it reached its limits? Are other models more appropriate in an ever-changing technological environment?[16]

12 Kesan, *Carrots and Sticks to Create a Better Patent System, supra* note 9, at 765 (stating that "[s]everal commentators have noted that the Patent Office is being asked to perform miracles because it operates under significant budgetary constraints."). *See* Arti K. Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199, 218 (2000) (noting that one straightforward patent reform proposal involves increasing the number and quality of patent examiners).

13 Christopher A. Cotropia, *The Individual Inventor Motif in the Age of the Patent Troll*, 12 YALE J.L. & TECH. 52, 62 (2010) (discussing patent trolls and hold-up, a term referring to the excessive licensing amounts patent trolls charge for the use of their patents, as a focus in modern patent reform); Paul J. Heald, *Optimal Remedies for Patent Infringement: A Transactional Model*, 45 HOUS. L. REV. 1165, 1199 (2008) ("To conclude, one thrust of current patent reform efforts focuses on remedies, with the most frequent object of discussing being the 'patent troll,' the non-exploiting owner of a patent whose business model is based on extracting licensing fees from unintentional infringers.").

14 Joseph P. Bauer, *Refusals to Deal with Competitors by Owners of Patents and Copyrights: Reflections on the Image Technical and Xerox Decisions*, 55 DEPAUL L. REV. 1211, 1243–44 (2006) (analyzing how a patent owner may be able to unfairly extend its monopoly through contracts and licensing agreements, while discussing the mandatory sales and licensing remedy as problematic).

15 *See* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES AND LIABILITY REGIMES (Geertrui van Overwalle, ed., 2009) (analyzing different types of licensing models as a solution to patent thickets and patent hold-outs); Geertrui van Overwalle et al., *Models for facilitating access to patents on genetic inventions*, 7 NAT. REV. GENET., 143, 143-48 (2006) (reviewing different models, research exemption, licensing, collaborative licensing models, compulsory licensing to facilitate access to genetic inventions); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119-50 (Adam Jaffe, et al., eds., 2001) (analyzing patent pools and cross-licenses as a solution for patent thickets, in particular in a standard-setting context).

16 Geertrui Van Overwalle and Esther van Zimmeren, *Functions and Limits of Patent Law*, *in*

These questions are difficult ones. The variety of these questions exposes a key challenge to how patent law will be governed in a new era. The old model of patent regulation was, in a word, static. It relied on seeing the patent agency as a simple registrar of patents, with a limited ability to consider broader issues related to patent law and without further interference from other administrative actors or civil society. The deepening criticism suggests that this static model of governance is clearly deficient. What then should be the new model?

Hints of a new governance model have emerged. Academic and policy innovators have offered different "big picture" views of the newly emerging patent governance. For example, Dr. Francis Gurry, the Director General of the World Intellectual Property Organization (WIPO) has identified how patent policy-making has emerged from what he terms a "uni-modular system," where patent law's own policies drove the interests of regulators and stakeholders, to a multi-polar policy-making system, where the patent system considers and is impacted by other policy making areas, such as public health and antitrust.[17] Elsewhere, James Boyle has argued that *all* intellectual property law, including patent law, should embrace a greater concern for democratic decision-making by intellectual property regulators, as well as a greater institutional diversity in intellectual property decision-making (a process Boyle terms "cultural environmentalism").[18] While both Gurry and Boyle speculate about different aspects of a new governance model for the patent system, their work has not offered a coherent and detailed view on the new patent governance model.

This Article builds on insights expressed elsewhere in our individual scholarship on governance, as well as in the scholarship of others. We seek to define what patent governance looks like now and what we think it should look like in the future. We contend that patent

FACING THE LIMITS OF THE LAW 415, 424-30 (Erik Claes, et al., eds., 2009) (analyzing the failure of patent law to fulfill its regulatory function, its symbolic function and its "legal guarantees" function).

17 Francis Gurry, *The Evolution of Technology and Markets and the Management of Intellectual Property Rights*, 72 CHI. KENT L. REV. 369, 378 (1996) (discussing the increasing need for intellectual property law to address other areas of public policy and vice versa). *See* Peter K. Yu, *A Tale of Two Development Agendas*, 35 OHIO N.U. L. REV. 465, 527 (2009) (examining the impact of public health considerations on the treaty framework of TRIPS).

18 James Boyle, *Cultural Environmentalism and Beyond*, 70 LAW & CONTEMP. PROBS. 5, 6 (2007) (defining cultural environmentalism as "an idea, an intellectual and practical movement, that is supposed to be a solution to a set of political and theoretical problems . . . a set of mental models, economic nostrums, and property theories that each have a public domain shaped hole at the center"); JAMES BOYLE, THE PUBLIC DOMAIN: ENCLOSING THE COMMONS OF THE MIND 240-43 (2008) (proposing that the achievement of genuine democratic politics of intellectual property requires an institutionally diverse debate).

governance is gradually becoming—and should become—more dynamic. This means including more diverse administrative actors, from varied policy contexts, and enabling more interaction between these administrative actors, on the one hand, and an active public, on the other hand.

In Part Two, we will describe the contours of the emerging model of "dynamic" patent governance. In Part Three, we will analyze the potential consequences associated with the principles of dynamic governance. In Part Four, we will examine the lessons of the recent *Myriad* gene patent litigation in the United States and Europe in order to analyze how dynamic patent governance works in practice. Finally, utilizing lessons from the first four sections, in Section Five, we draw normative conclusions as to the impact of a model of dynamic patent governance on the particular challenges that currently confront the institutional design of the patent regime.

This Article proceeds from a particular perspective; we seek to integrate governance debates that occur and have occurred in both the United States and Europe. A common challenge has been that many academic and reform debates on patent law have carried on in isolation from each other. Perhaps, the best way to describe this situation is to resort to the old metaphor of the blind man and the elephant.[19] We all see the various administrative elements of the systems that we are familiar with, but in doing so, cannot perceive the larger picture: the changing nature of patent governance. Aware of this problem, this Article attempts to provide a more complete view of patent governance.

II. DYNAMIC PATENT GOVERNANCE: THE MODEL

A theory of dynamic patent governance seeks to address the impact of two key changes in patent law: (1) the emergence of a more diverse set of institutional actors; and (2) the emergence of a more diverse set of stakeholders in patent law. These two changes reflect the relevance of a concept that has been explored more thoroughly in other regulatory contexts, such as environmental[20] and international law—the development of the theoretical model of network governance.[21] Put

19 A famous western adaptation by John Godfrey Saxe, describes a tale of six blind men who traveled to see an elephant; each encountered a separate portion of the elephant along the way and vehemently disagreed as to the proper account of the elephant based on their isolated and varying experiences. JOHN G. SAXE, CLEVER STORIES OF MANY NATIONS 59-64 (1865).

20 Peter M. Haas, *Addressing the Global Governance Deficit*, 4 GLOBAL ENVTL. POL. 1, 13 (2004).

21 *Id.* at 13.

simply, the theoretical model of network governance is used to explain how a variety of autonomous actors operate in interdependent relationships—without necessarily being restricted to a hierarchical relationship—to govern the systems in which they participate.[22] The underlying idea of network governance is that the effective functioning and legitimacy of the system "as a whole" is more than the mere aggregation of individual public organizations' performances.[23] Thus, network governance differs significantly from classic theories of regulation, which tend to focus solely on the formal institutions of government and less on the interrelationships between formal institutions and informal actors outside of those institutions.[24]

We observe that the idea of network governance is emerging within the context of patent law, and extend this model in two additional ways. First, we claim that within its formal dimensions, the patent system should be analyzed as a whole, focusing on the roles played by various actors, rather than the individual institutional actors themselves. This focus on roles, rather than individual actors, also greatly facilitates comparison of governance systems between different jurisdictions.[25]

As we examine the roles of institutional actors, we contend that the formal dimensions of the patent system have been changed by the emergence of heterogeneous administrative and judicial actors. Heterogeneity of the patent system suggests that more than one administrative actor can and will seek to regulate the grant and

22 Orly Lobel, relying on a variety of recent scholarship, has identified a number of key characteristics of network governance, including: (1) participation by a variety of different actors at various stages of the legal process; (2) collaboration by these actors through the regulatory process; (3) institutional diversity that emphasizes a multitude of legal values in decision-making; (4) decentralization of power through state and regulatory actors; (5) the integration of different policy domains; (6) flexibility in regulatory solutions; (7) dynamism in policy outcomes that leads to more frequent revision of regulatory goals; and (8) a policy commitment to orchestrating the different actors within a networked system. *See generally* Orly Lobel, *The Renew Deal: The Fall of Regulation and The Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004-2005).

23 Susana Borrás, *The Governance of the European Patent System: Effective and Legitimate?*, 35 ECON. & SOC'Y 594, 598 (2006).

24 *See* Richard Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. REV. 437, 439-43 (2003) (analyzing major theoretical frameworks associated with the development of administrative law in the United States). *See generally* PAUL CRAIG, EU ADMINISTRATIVE LAW (2006) (analyzing the development of administrative law within the context of the European Union).

25 Our examination of this model in the following sections takes place primarily within the context of a comparative framework between the European Union and the United States, as is demonstrated by our primary reliance on these models throughout our text. We believe, however, that our model has relevance across diverse patent regimes, and so our examples in the footnote citations refer to a variety of different patent regimes.

enforcement of patents. Until recently, analyses of patent administrative law have exclusively focused on the role of the patent examiner in the issuance of a given patent. This approach ignores the impact that other regulators, like other agencies or subsequent judicial actors, may have on the ongoing evolution of patent law. Such an approach obscures a key insight, namely that, regulation of patent law is undertaken at multiple administrative sites during the life of an issued patent.[26]

Second, we believe that, consistent with the idea of network governance, the informal dimension of the patent regime has been impacted by a plurality of actors that actively influence legislation and policy-making, such as states, companies, national or regional agencies, international organizations, such as the WIPO and World Trade Organization (WTO), non-governmental organizations (NGOs), such as patient advocacy groups, human rights organizations, medical associations and scientific organizations. These actors are likely to have a number of instruments at their disposal, such as persuasion, economic pressure, norm creation and manipulation.[27] We deepen this theoretical insight, however, by examining the specific fissures between informal actors in the patent regime. In particular, we claim that the emergence of "new" actors on the patent scene, such as NGOs (whom we collectively term the "patent civil society"), brings them into conflict with the more settled stakeholders of the "epistemic" communities that have traditionally driven patent policy-decision-making.

Ultimately, we argue that the emergence of these trends—heterogeneous administrative actors and maturing patent communities—has led to a more dynamic administrative context for patent law. Therefore, it is vital to explore the patterns of formal and informal interactions among the wide variety of public and private actors that constitute the patent governance system, both at inter-organizational and inter-personal levels. We first explore the formal dimension in terms of the heterogeneous nature of the patent system. We next describe a maturing informal dimension in which different types of stakeholder communities seek to weigh in on the decision-

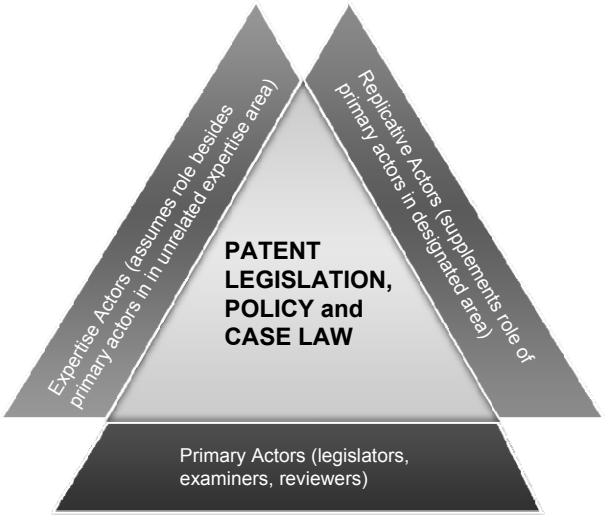
26 This heterogeneity framework has been previously introduced within the context of the United States. *See generally* Kali Murray, *The Cooperation of Many Minds: Domestic Patent Reform in a Heterogeneous Regime*, 48 IDEA: INTELL. PROP. L. REV. 289 (2008) (using doctrines of administrative framework, such as the *Chevron* deference framework, that are specific to the jurisprudential context of the United States, in discussing the heterogeneous framework). These doctrines are not discussed in this Article, as we are examining these issues within a comparative framework.

27 Scott Burris et al., *Nodal Governance*, 30 AUST. J. LEG. PHIL. 30, 31 (2005).

making by the formal actors.

A. Dynamic Patent Governance: The Formal Dimension and Heterogeneity

Susana Borrás defines the "formal" dimension of network governance as "the set of constitutive regulations that govern the interactions between the public [actors] that grant, control and rule about individual patents and their use, abuse and infringement in the market."[28] While patent literature has often focused on the role of the examining agency, the concept of heterogeneity examines a broader range of public actors. A heterogeneous perspective of institutional actors within the patent governance system starts with the assumption that the roles of institutional actors may be consistent across patent administrative systems. Two kinds of roles are possible. First, primary actors are tasked with regulating the resource on an ongoing basis. Second, secondary actors can be tasked to regulate a resource, by either replicating the role of the primary actor in a narrower content area, or by using their expertise derived from other content areas to impact patent law. Thus, actors within the context of patent law have to navigate an increasingly complex formal dimension. Diagram 1 provides a visual depiction of the primary actors (legislators, examiners, and reviewers), discussed in Part II.A.1, and their relationship to the secondary actors, discussed in Part II.A.2.



[28] Borrás, *supra* note 23, at 598.

1. The Formal Dimension: Primary Actors

We first examine the role of primary actors within a patent governance system. Primary actors (legislators, examiners, and reviewers) fulfill three key tasks in a patent administrative system. First, the legislative actor creates the regulatory framework for the other primary and secondary actors.[29] Second, the primary administrative actor determines whether the patent should be granted and whether an issued patent is valid or infringed. As such, patent reform efforts have typically focused on changing the behavior of the primary actors that fulfill the role of issuing a patent or determining that it infringes on a pre-existing one. Finally, the administrative and judicial review of a patent after its grant is the third major task of a patent system.

a. Primary Actors: The Legislator

The legislature plays an intermittent but important role within the context of patent policy-making. It sets the roles of the other actors through its grants of regulatory powers, which require considerable institutional, philosophical, economic, and policy choices.

Indeed, legislators are often responsible for the increased importance of the secondary actors. For instance, in the United States, congressional attempts to regulate patent law have led to the growing importance of a number of secondary actors. For example, Congress expanded the roles of the Food and Drug Administration (FDA) in the context of patent drug regulation in 1984;[30] the United States International Trade Commission (USITC) in 1988, in the context of import litigation;[31] the United States Trade Representative (USTR) in

29 As to the role of the legislative actors, this Article expands on the discussion contained in Kali Murray's article*, The Cooperation of Many Minds,* which emphasized the role of the legislative actor as an initiator of the institutional design of the heterogeneous regime. Murray, *supra* note 26, at 299. The role of the legislature, however, was seen as limited to the initial design. *Id.* at 299. Here, we emphasize that the legislative actor actually serves as a node within the patent governance system.

30 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 301 n.355, 360cc (2006); 28 U.S.C. § 2201 (2006); 35 U.S.C. §§ 156, 271, 282 (2006)). *See* Mary E. Wictorowicz, *Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France*, 28 J. HEALTH POL. POL'Y & L. 615, 631–36 (2003) (discussing FDA oversight); Devesh Srivastava, *The Food and Drug Administration and Patent Law at a Crossroad: The Listing of Polymorph Patents as a Barrier to Generic Drug Entry*, 59 FOOD & DRUG L.J. 339 (2004) (examining the role of the FDA in deciding the entry of generic drugs into the market is concerned with pharmaceutical and therapeutic considerations).

31 19 U.S.C. § 1337 (2006); Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529, 533 (2009) (asserting that the International Trade

1988, in the context of negotiating intellectual property agreements;[32] and the United States Department of Justice and the Federal Trade Commission (FTC) in the context of the review of patented pharmaceutical settlement systems.[33]

Legislatures, with their increased responsiveness to different stakeholders often play a crucial intervening role in the patent system. Legislative interference, however, bears significant risks. Legislative intervention is sporadic, in a temporal and ideological sense. In a temporal sense, different legislators may often add language to an enacting statute over time without consideration as to its textual consistency and clarity. A famous example of this in the United States is the Copyright Act of 1976, which has lost significant textual cohesion over time.[34] A European example is the EU Trademark Regulation, which was substantially amended over time and, as a result, had to be re-codified in the interest of "clarity and rationality."[35] Likewise, two ideological risks present themselves. First, legislators may undertake significant reform in response to the narrow concerns of epistemic elite without taking into account broader public concerns. Second, this risk can be compounded further if legislators are subject to industry pressure on a given issue. Each of these risks can undermine the credibility of a patent regime to the larger public.

b. Primary Actors: The Examining Administrator

The most basic task of any patent system is to provide inventors

Commission undertakes patent assessment under § 1337); Colleen Chien, *Patently Protectionist? An Empirical Analysis of Patent Cases at the International Trade Commission,* 50 WM. & MARY L. REV. 63, 110 (2008) (contending that the International Trade Commission may create patent policy inconsistent with precedents of the Supreme Court).

32 *See, e.g.*, Omnibus Trade Act of 1988, Pub. L. No. 100-418, § 1302, 102 Stat. 1107 (1988) (codified as amended at 19 U.S.C. § 2242 (2006)); Judith H. Bello & Alan F. Holmer, *"Special 301:" Its Requirements, Implementation, and Significance*, 13 FORDHAM INT'L L.J. 259 (1990) (describing the United States Trade Representative's authority to put countries it perceives to have inadequate intellectual property laws on watch lists under "Special 301" powers provided by the Omnibus Trade Act of 1988).

33 15 U.S.C. § 45 (2006); Lisa M. Ferri & Monique A. Morneault, *Reverse Payment Patent Settlements: The Interplay of Antitrust and Patent Policies,* 20 INTELL. PROP. & TECH. L.J. 14, 16-17 (2008) (discussing the FTC's power to review patent litigation settlements under the Medicare Prescription Drug, Improvement and Modernization Act); Murray, *supra* note 26, at 314, 327 (discussing the responsibility given to the FTC to analyze the antitrust and consumer consequences associated with the grant of a patent under section 5 of the Clayton Antitrust Act and the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)).

34 *See, e.g.*, David Nimmer, *Codifying Copyright Comprehensibly*, 51 U.C.L.A. L. REV. 1233 (2004) (examining the problematic revisions of the Copyright Act of 1976).

35 Council Regulation 207/2009, 2009 O.J. (L78) 1.

with a functional way to obtain a patent. Three models exist as to how to obtain a patent. The patentee can register a claim on an invention, rely on another examination conducted by another country or regional organization, or submit to a substantive examination. A patent registry is the simplest choice. A patent registry involves minimal effort on the part of the administrator since the potential patentee simply registers the patent without a substantive examination.

The direct contrast to the patent registry is an administrative system premised on substantive examination at the national level. Substantive examination, of course, is a complex undertaking. Such systems require significant investment in personnel and in articulating standardized examination and review procedures. The use of a patent registry, however, even if capable of resolving basic disputes,[36] such as how to resolve competing claims between inventors, may be untenable. Article 27 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement) requires signatory countries to carry out a substantive inquiry into novelty and inventive step.[37]

A number of systems have developed a median approach in which the administrator relies on another agency—a national agency and/or a regional organization—to conduct the relevant search and examination of the patent. The hybrid examination approach is possible given both the structure of the Patent Cooperation Treaty (PCT)[38] and regional treaties such as the Andean Pact.[39] These treaties allow a patentee to designate a state or regional entity responsible for the examination. The hybrid examination approach is particularly useful for developing countries as it allows them to comply with the TRIPS Agreement in the

36 Robert C. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights For Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 594-95 (1999) (noting that the patent registry system did not work, despite low entry barrier, because of high cost associated with determining disputes between potential patent litigants).

37 Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND VOL. 31 (1994), 33 I.L.M. 81, 1997 (1994) [hereinafter TRIPs].

38 PATENT COOPERATION TREATY, JUNE 19, 1970, 28. U.S.T. 7645, 1160 U.N.T.S. 231, *amended on* Sept. 28, 1979, *modified on* FEB. 3, 1984 AND OCT. 3, 2001, http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf (international patent treaty administered by WIPO covering one hundred and forty-two contracting states and providing a unified procedure for filing patent applications).

39 Andean Subregional Integration Agreement, May 26, 1969, 8 I.L.M. 910, *as amended by* Trujillo Protocol, Mar. 10, 1996. *See* Common Provisions on Industrial Property, Decision No. 486 of Sept. 14, 2002 of the Commission of the Andean Community, http://www.comunidadandina.org/ingles/normativa/D486e.htm) (discussing the bifurcated examination system of the Andean Pact).

face of considerable difficulties on the ground.

c. Primary Actors: The Reviewers

Two types of actors can review the consequences of a grant in an issued patent. Internal administrative actors can review the validity of an issued patent using designated administrative procedures. External judicial actors can undertake review of the validity and infringement of an issued patent. It is possible for the roles of these primary reviewers to overlap, but often these reviewers follow different procedures and have different responsibilities within the context of a given patent regime. Evidence exists that indicates that the availability of administrative and judicial review procedures in a patent system provides the maximum flexibility for parties seeking to challenge the issuance of a patent.[40]

Internal administrative review is quite varied. The two most common post-issuance procedures are re-examination and opposition. A re-examination typically involves a request to review the content of a patent in light of previously undisclosed information. The process of re-examination often has significant disadvantages including: (1) limits on what type of patent can be significantly re-examined;[41] (2) limits on the type of the appeal that can be undertaken in a dispute[42]; and (3) limits on the type of information that can be submitted.[43] By contrast, opposition proceedings generally offer the opportunity to challenge an issued patent on broader substantive and procedural grounds. For

40 Jay P. Kesan, *Office Oppositions and Patent Invalidation in Court: Complements or Substitutes?*, *in* PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 269 (Toshiko Takenada, ed., 2008) (examining the use of complementary initial trial and examination systems by Japan and concluding that institutional reasons exist for maintaining two systems). S*ee* Patentgesetz [Austrian Patent Act] Bundesgesetzblatt [BGBl] No. 259/1970, §§ 47 ¶ 1, 102 (Austria) (providing both re-examination and opposition as post-issuance procedures); *see also* Patentgesetz [Patent Act], Dec. 16, 1980, BUNDESGESETZBLATT, TEIL I [BGBl. I], §§ 81(4), 27(3) (F.R.G.) (as amended by Laws of July 16 and August 6, 1998).

41 *See, e.g.*, Patentgesetz [Patent Act] of 1970 § 91 ¶ 3 (Austria) (providing that re-examination allows the owner of the patent to make certain amendments to its original claim); Poland Industrial Property Law of 30 June 2000, art. 37(1), as amended, June 29, 2007, http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/poland_e/e_sangyou.pdf (providing that re-examination process allows a patentee to make restricted additions and corrections to its application).

42 *See, e.g.*, Patent Act of 1952, 35 U.S.C. § 306 (1952) (providing that only a patentee may appeal a disputed re-examination request).

43 Patents Act 1990 (Cth) s 101 (Austl.), http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/australia_e/e_tokkyo.pdf (providing that the Australian Patent Act allows a patentee and any other person to undertake a re-examination request on substantive patent grounds, but limits the right to appeal a re-examination request to the patentee).

instance, Article 100 of the European Patent Convention (EPC) allows opposition based, among other things, on allegations that the invention is not patent eligible, not new, does not involve an inventive step or is insusceptible of industrial application or that the invention has been insufficiently disclosed.[44] A broad number of parties can start opposition proceedings, and appeal in case of a disputed outcome.[45]

External judicial actors can undertake initial review of factual and legal issues that impact an issued patent, as well as appellate review of that initial review. The design of these basic roles, though, is subject to considerable variety. Such variety arises from two diverse sources. The first source of such jurisdictional variety is the difficulty of review associated with an issued patent. Reviewing an issued patent is not an easy judicial undertaking. The reviewer has to undertake several difficult legal inquiries associated with the validity and potential infringement of a patent. In addition, the technical nature of the underlying technology can complicate patent review.

Often, then, the question is whether patent law should be subject to a specialized external review that takes into consideration the difficulty of these inquiries. Patent systems have answered this question in different ways, including: (1) creating a specialized trial court to address patent-related questions;[46] (2) creating a specialized appellate court that reviews generalized initial review;[47] (3) allowing a full-fledged judicial proceeding within the administrative agency and then allowing for subsequent review by general appellate proceeding;[48] and (4) providing for a specialized trial and appellate review.[49] Thus, while the challenge

44 *See, e.g.*, Convention on the Grant of European Patents art. 100, Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter European Patent Convention], *available at* http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html (follow links to different Convention articles) (outlining grounds for an opposition proceeding).

45 *Id.* art. 99(1) (outlining the type of party that may bring an opposition proceeding under the EPC); *id.* art. 107 (outlining the broad right of appeal to the opposition proceeding).

46 *See, e.g.*, The Patents Act, 1977, c. 37, § 97(l) (Eng.), http://www.jpo.go.jp/shiryou_e/s_sonata_e/fps_e/pdf/england_e/e_tokkyo.pdf (providing that petitioners may directly appeal decisions of the Intellectual Property Office to the Patent Court, a specialized trial court, and subsequently appeal those decisions to the Court of Appeal and the House of Lords).

47 *See, e.g.*, Patentgesetz [Patent Act] of 1970 § 65(1)-(2) (Austria) (providing that an independent federal appellate court, the Federal Patent Court, be established for the purpose of hearing appeals from decisions of the examining sections or patent divisions of the patent offices).

48 *See, e.g.*, Patentgesetz [Patent Act] of 1970 §§ 57 ¶ 1, 70 ¶¶ 1-3 (Austria) (providing that final decisions of the technical and legal department may be appealed to the appellate division of the Patent Office and then to the Supreme Patent and Trademark Board, and that final decisions of the nullity department may be appealed to the Supreme Patent and Trademark Board as the highest level of authority).

49 For instance, in Japan, the Tokyo and Osaka District Courts enjoy jurisdictional authority

presented by specialization is common to all patent systems, significant experimentation exists over how to solve this challenge. For instance, the experience of the United States, which since 1982 has had centralized appellate review, has prompted significant debate over whether a specialized court creates the risk of excessive insularity and inadequately nuanced jurisprudence.[50] At the same time, Europe has for decades been contemplating the creation of a centralized litigation system.[51] A major impetus for imposing centralized litigation in Europe is the complexity of patent law in the post-grant phase, as well as the possibility that national courts may, for instance, issue different opinions regarding the validity of the same patent.[52]

External review of patents also can vary because of a second

over design and utility patent infringement. The Intellectual Property High Court enjoys exclusive appellate jurisdiction over patent infringement appeals. *See* David Hill & Shinichi Murada, *Patent Litigation in Japan,* 1 AKRON INTELL. PROP. J. 1, 151 (2007) (outlining the division of judicial authority over patent related materials).

50 *See* Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1646–49 (2007) (contending that the limited jurisprudence of the Federal Circuit arises because of its "institutional position, failure to adapt its common law to changing circumstances, reticence to consider empirical and economic literature and expansive judicial authority"); *compare* Rochelle Cooper Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE W. RES. L. REV. 769, 770 (2004) ("Practitioners appear to be in general agreement that centralizing patent appeals in a single court is a vast improvement over regional adjudication." (citing Carl Tobias, *The White Commission and the Federal Circuit*, 10 CORNELL J. L. & PUB. POL'Y 45, 58 (2000))).

51 *Draft Agreement on the European and Community Patents Court and Draft Statute*, (Working Document 7928/09 PI 23 COUR 29, 2009), http://register.consilium.europa.eu/pdf/en/09/st07/st07928.en09.pdf.

52 For example, the European Central Bank has challenged the Document Security System's [DSS] patent in numerous jurisdictions. To date, the validity of the DSS's patent has been upheld in the Netherlands and Spain. *See* Rb. Gravenhage 12 Maart 2008, 269923/HA ZA 06-2495 (De Europese Centrale Bank/Document Security Systems, Inc.) [European Central Bank v. Document Security Systems] (Neth.), *available at* http://www.boek9.nl/index.php?//The+European+Central+Bank+vs.+Document+Security+Systems%2C+Inc.////22333/; Mary Stone, *Court Rules Document Security Systems Patent Valid in Spain*, ROCHESTER BUS. J., Mar. 24, 2010, http://rbj.flex360hosting.com/article.asp?aID=183392. The patent has been invalidated in Germany, the United Kingdom, Austria, Belgium, and France. *See* Mary Stone, *Document Security Systems Loses in German Court*, ROCHESTER BUS. J., July 9, 2010, http://www.rbj.net/article.asp?aID=184435; Press Release, Document Security Systems Announces Ruling in Patent Validity Lawsuit in United Kingdom (Mar. 26, 2007), *available* at http://documentsecurity.com/press_releases.php?id=72; *Document Securities Systems, Inc. Announces Ruling in Patent Validity Hearing by Austrian Patent Office,* REUTERS, Nov. 20, 2009, http://www.reuters.com/finance/stocks/keyDevelopments?rpc=66&symbol=DMC&timestamp=20100804150600; *Document Security Systems Announces Ruling in Patent Validity Lawsuit in Belgium Court*, PR NEWSWIRE, Nov. 3, 2009, http://www.prnewswire.com/news-releases/document-security-systems-announces-ruling-in-patent-validity-lawsuit-by-belgiumcourt-68964912.html; Cour' d'appel [CA] [regional court of appeal] Paris, ch. 1, Mar. 17, 2010, No. 08/09140 (Fr.), http://www.eplawpatentblog.com/2010/March/SCN_20100317152247_001%5B1%5D.pdf.

source of institutional multiplicity—the relationship of the external judicial actor with the broader system of judicial authority. For instance, Australia and Canada allow both federal and state courts to undertake an initial review of patents. By contrast, the United States only allows federal courts to review patent cases.[53]

The European "constitutional"[54] system has proven to be a particularly resonant example of how the structure of the patent regime can impact policy-making. Specifically, the interplay between regional and national institutions results in a complex regulatory environment in which to review the consequences of a given patent. The EPO, which is an inter-governmental body independent of the institutional framework of the European Union, can review an issued patent through an opposition proceeding.[55] Within the European "constitutional" system, once the EPO has issued a patent**,** the European patent becomes a "bundle" of national patents, which are subject to judicial decisions on validity and infringement in all the different Member States.[56] The European Courts in Luxemburg do not have any powers regarding patents granted by the EPO.[57] As a result, no system currently exists for issuing a European Union wide determination on the validity and infringement of a given patent.

The difficulties of this structure are amplified by the basic differences in the legal culture between common-law and continental law systems at the national level. Judicial actors within a common law system may more readily accept their roles as active policymakers[58] in setting patent policies than judges in continental law systems. The Court of Justice of the European Union has repeatedly been criticized for its activist role in other matters beyond patent law.[59] Thus,

53 28 U.S.C. § 1338(a)(2006) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademark.").

54 The European Union nor the European Patent Office have an underlying "constitutional" structure as they cannot be regarded as states. We continue, however, to use the term, first, for reasons of comparison, and second, to stress that the historical, underlying institutional structures are the main cause for complexity at the European level.

55 European Patent Convention, *supra* note 44, art. 99.

56 *Id.* art. 64.

57 *See, e.g.*, G2/06 WARF/Stem Cells, [2009] E.P.O.R. 15 (EPO Enlarged Bd. App.)

58 Judicial reviewers (e.g. Court of Appeals for the Federal Circuit) in the United States are often reluctant to acknowledge their role as policymakers, insisting rather that they decide disputes between parties, despite the often-clear consequences of their decisions. *See* Colleen Chien, *Patent Amicus Briefs: What the Courts' Friends Can Teach Us About the Patent System*, 1 U.C. I. L. REV. (forthcoming Dec. 2010).

59 *See, e.g.*, PATRICK NEIL, THE EUROPEAN COURT OF JUSTICE. A CASE STUDY IN JUDICIAL ACTIVISM (1995); Trevor Hartley, *The European Court, Judicial Objectivity and the Constitution*

foundational conceptions of the appropriate exercise of judicial discretion may also play a key role in how external review of patent law takes place.

2. The Formal Dimension: Secondary Actors

Primary actors, obviously, have a strong role to play within patent law. Patent doctrine, though, has become more diverse over time. It has incorporated new subject matter, such as topics related to public health, antitrust, unfair competition and trade. These changes have had the consequence of strengthening the role of what we term secondary actors[60] within the domestic and regional patent systems. These secondary administrative actors may have significant authority to articulate policy over issued patents that are outside of the orbit of the primary actors. The roles of these actors can be placed into two categories, replicative and expertise actors.

Initially, a replicative actor serves to supplement the role of a primary internal or adjudicative actor. These actors may serve to replicate the policy determinations of the primary actors. These replicators may have a significant impact on the development of doctrinal development. For example, the Plant Variety Protection Office within the U.S. Department of Agriculture (USDA) reviews and grants Certificates of Plant Variety Protection (CPVP), extending breeders up to twenty-five years of exclusive control over new sexually reproduced or tuber plant varieties meeting certain criteria.[61] The CPVP function of the USDA mirrors and supplements the patent-granting powers of the USPTO, but these powers apply exclusively to asexually produced plants and provide mutually exclusive remedies.[62] Although CPVPs do not duplicate plant patents, jurisprudence produced by CPVP litigation inevitably adds to the body of plant patent doctrine, albeit indirectly, through policy determinations. Thus, any discussion of patent policy-making necessarily includes an understanding of these additional actors since they can have a significant effect on the doctrinal development of patent law.

A secondary actor can also assume authority over patent policy

of the European Union, 112 L. Q. REV. 95 (1996); Hans-Wolfgang Micklitz, *Judicial Activism of the European Court of Justice and the Development of the European Social Mode in Anti-Discrimination and Consumer Law* (EUI LAW, Working Paper No. 2009/19, 2009).

60 A typology of secondary actors (replicative and expertise actors) and several examples of secondary actors (e.g., U.S. Department of Agriculture and US Federal Trade Commission) is provided below. These actors are further defined in the Chart in Part II.A.

61 Plant Variety Protection Act, 7 U.S.C. §§ 2321-2582 (2006).

62 Plant Patent Act, 35 U.S.C. § 161 (2006).

because of a designated expertise in an unrelated subject matter. Two kinds of expertise actors are common within a patent regime. Competition regulators may examine the impact of the behavior of a patentee on competition law.[63] Drug administrators may review a previously patented drug.[64] While these types of expertise actors may supplement the policy determinations of the primary actor, these actors can become potential rivals to the policy actor in defining the limits of an issued patent or the behavior of the patentee. For example, if the competition authority would limit the ability of patent owners to restrictively license a patent, such a limitation could weaken the power of a patentee to decide on the exploitation of the patent.

3. The Heterogeneous Actors in Network Governance

The activity of heterogeneous institutional "actors" creates an increasingly decentralized regulatory environment in which to address issues associated with the grant of a patent. Despite the increasingly

63 John DeQ Briggs, *Intellectual Property and Antitrust: Two Scorpions in a Bottle*, 10 SEDONA CONF. J. 65, 66 (2009) (examining the role of the Federal Trade Commission and its suggestion that the U.S. Patent and Trademark Office consider the possible harm to competition before extending the scope of patentable subject matter); JONATHAN D.C. TURNER, INTELLECTUAL PROPERTY LAW AND EU COMPETITION LAW (2010) (examining the regulatory framework for the exploitation and licensing of intellectual property rights, including patents).

64 The role of the Food and Drug Administration is well understood within the context of the patent law of the United States**.** *See* Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J.L. & TECH. 321, 335 (2009) (quoting Professors Robert Merges, Peter Mennell and Mark Lemley, in regard to administrative review in the United States, "[a] patent does not automatically grant an affirmative right to do anything; patented pharmaceuticals, for instance, must still pass regulatory review at the Food and Drug Administration to be sold legally."). Drug regulators' roles in other countries are equally interesting. For example in Canada, while the provincial governments exercise the primary control over the license of patented pharmaceuticals, the federal government of Canada can supplement these policies by determining whether a drug can be sold or has been sold at an excessive price. *See* Melanie Bourassa Forcier & Jean-Frederic Morin, *Canadian Pharmaceutical Policy: International Constraints and Domestic Priorities*, *in* AN EMERGING INTELLECTUAL PROPERTY PARADIGM: PERSPECTIVE FROM CANADA 81, 87-89 (Ysolde Gondreau, ed., 2008). By contrast, in Europe, legislation does not allow "patent linkage," which operates by linking market approval for generic medicines, as well as their pricing and reimbursement status, to the patent status of the original reference product. *European Commission Final Report for the Pharmaceutical Sector Inquiry* at 130, (July 8, 2009) [hereinafter *Pharmaceutical Sector Inquiry*], http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (explaining that " . . . the authorisation to market a medicinal product is taken on the basis of scientific criteria concerning the quality, safety, and efficacy of the medicinal product concerned: these criteria are related to public health considerations, and no other criteria should be taken into account. All other issues relating to private law, such as for example, the patent status of the medicinal product, are to be dealt with on the basis of patent laws before the competent courts . . . ."). This has the consequence of disaggregating market approval of generics from broader patent issues.

decentralized nature of network governance, the role of formal institutional actors may actually be strengthened since they can serve as centralized points in this decentralized policy environment.

Scott Burris, Peter Drahos and Clifford Shearing have termed these centralized points as "nodes" within the networks.[65] These "nodes" are entities with a set of technologies, mentalities and resources that mobilize the knowledge and capacity of members to manage the course of events.[66] While nodes may take a wide variety of forms, from legislators and government agencies through NGOs to firms or even gangs, formal patent actors—whether primary or secondary—can serve as crucial nodes in network governance.[67] By serving as "nodes," formal patent actors can formalize the roles of different stakeholders within a given community by offering a forum and associated procedures where stakeholder concerns can be heard, such as re-examination and opposition procedures.

Moreover, formal patent actors can themselves collaborate on patent policy and procedure, thus intensifying their organizational power within the network. This way, they create "super-structural nodes."[68] Super-structural nodes are the sites that bring together different nodal organizations so as to concentrate resources and technologies of the individual nodes for a common purpose.[69] Super-structural nodes have emerged consistently within the patent regime, and can be either short-term or long-term in nature. For instance, the USPTO, the Japanese Patent Office (JPO), and the EPO have collaborated to create a "super-structural" node by way of "Trilateral Co-operation."[70] This trilateral co-operation has a number of objectives, such as improving the quality of examination processes, reducing the processing time of patent applications, improving the quality of incoming applications, developing common infrastructure for

65 *See generally* Burris et al., *Nodal Governance, supra* note 27; Peter Drahos, *Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach*, 77 TEMP. L. REV. 401, 401-24 (2004); Scott Burris, *Governance, Microgovernance and Health*, 77 TEMP. L. REV. 335, 335-58 (2004); Peter Drahos et al., Group Discussion at RegNet Conference: The Nodal and the Global (Dec. 10, 2003).

66 *See generally* Burris et al., *Nodal Governance*, *supra* note 27. For instance, a patent examining agency has specific procedures (examination and rulemakings) and tools (e.g., budget and/or databases) to carry out its specific tasks. Applicants and other stakeholders can use these procedures to influence the decision-making process. Thus, patent examining agencies can serve as a formalized "node" within the context of network governance.

67 Burris et al., *Nodal Governance, supra* note 27, at 38.

68 *Id.* at 31-38.

69 *Id.* at 31-38.

70 TRILATERAL, http://www.trilateral.net (last visited Sept. 3, 2010).

electronic systems and search tools, and solving common problems related to the protection of industrial property rights by harmonizing the practices of the three Offices.[71]

B. Dynamic Patent Governance: Its Informal Dimension

The informal dimension of dynamic patent governance is increasingly contributes to the dynamic nature of patent governance. Recent patent governance has seen the emergence of a wide continuum of stakeholders entering the patent system, whose aims and objectives are potentially in conflict with each other.

Modern patent law has typically relied on well-organized and well-informed epistemic communities, which have played an out-sized role in patent law decision-making. Epistemic communities, as identified by Susana Borrás, share a set of:

> [W]orldviews, common understandings, norms, routines and daily practices that define the interactions among public and private organizations and individual actors in the patent system. [Patent] Governance [then] takes place within networks of stakeholders, patent professionals and practitioners, who form powerful [epistemic] communities—sometimes competing against each other—and whose interactions decisively influences the shape of the patent system.[72]

These epistemic communities have formed increasingly powerful networks that work to influence patent policy-making across multiple institutional forums.

Recently, however, patent law has also been impacted by what we term a more loosely defined, "patent civil society." This civil society is often composed of constituted groups of consumers, patients, physicians, scientists, interested citizens, and other non-patent experts, that seek to participate in patent policy-making. This patent civil society has played a disruptive role, in recent patent policy-making, often criticizing the basic norms of the well-settled epistemic communities. This Part considers both the epistemic communities and patent civil society in turn.

1. The Informal Dimension: Epistemic Communities

Patent law is widely regarded as a very complex field of law because of its difficult legal framework, procedures and concepts, as

71 *Id*. *See infra* Part V.B.

72 Borrás, *supra* note 23, at 598.

well as the inherently technical nature of patents. The complex nature of patent law has led to decision-making by highly qualified technical and legal experts.[73] The dominant core of these epistemic communities consists of transnational firms with important patent portfolios, technically sophisticated lawyers, legal academics, and legally trained scientific experts and officials. Such actors have a strong impact on the patent system as well as patent policy on the national, regional and international levels. Over the past decades, patent governance has become the almost exclusive province of an epistemic community of patent experts.[74]

Epistemic communities continue to shape patent law reform, policies, and doctrine. First, epistemic communities have been closely involved in shaping the various proposals for patent *law* reform discussed on both sides of the Atlantic. Epistemic industrial and professional organizations[75] actively engage with legislators throughout the patent reform process since most politicians do not have any expertise with respect to patents.

Second, the inauguration of new *policies* concerning patent procedure and issuance is often preceded by internal and/or external consultations. Epistemic participants continue to shape policies which are favorable to them in these internal or external consultations. The types of consultations may vary due to various administrative cultures. Consultations can range from relatively informal discussion forums, where all interest groups have an opportunity to be represented, to more formalized procedures, in which *ad hoc* panels or institutionalized bodies consider policies with accompanying formalized procedures. An example of an informal consultation are the public hearings conducted in 2006 by the European Commission on "Future Patent Policy in Europe," whereas an example of a more formalized procedure is the notice and comment rule-making conducted by the USPTO under the

73 William Gormley has proposed a framework that seeks to explain levels of public interest in certain subjects. *See generally* William Gormley, *Regulatory Issue Networks in a Federal System*, 18 POLITY 595 (1986). He classifies patent law as an area characterized by high complexity (significant technical specialization) but low salience (relevance to the public). *Id.* at 598. The emergence of a broader patent civil society suggests that the salience of patent law has been improving in a significant sense.

74 PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? (2003).

75 Examples of such professional organizations are the International Association for the Protection of Intellectual Property (AIPPI), the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP), and the American Intellectual Property Association (AIPLA).

Administrative Procedure Act.[76] While in principle the latter process would seem likely to prompt significant epistemic participation, broader discussion forums offer a platform to both epistemic communities and civil society to provide their insights. Experience shows, however, that in practice these broader forums are often reduced to an active discussion between leaders from epistemic communities, with most civil society participants not having an opportunity to actively participate in the discussion.

Third, in many countries, expert judges play an important role in the development of patent case law. Review by primary judicial actors is often a specialized form of external review. This specialization can be realized in different ways. The views of expert judges with a specialization in patents are generally highly regarded—though not free from criticism by patent scholars and patent practitioners. In fact, they are often invited as key speakers at patent conferences and parliamentary hearings to explain recent caselaw, to comment on potential gaps in the patent governance system, and to discuss the need for patent reform. At these meetings they engage with members of the epistemic communities and exchange opinions and experiences. Such informal discussion platforms have not been accessible to the broader civil society.

The involvement of epistemic communities has proven to be a mixed blessing. On the one hand, such experts safeguard a level of expertise required by the complex nature of patent law, thus helping to guarantee high quality and efficient decision-making in the patent policy arena. On the other hand, fears of "insider governance" and "collective action" exist due to the continued involvement of a small group of experts and stakeholders.

2. The Informal Dimension: The Patent Civil Society

A loosely organized patent civil society stands in contrast to the more well-defined and powerful epistemic communities. This patent civil society consists of what John Clark has termed "policy-influencing civil society organizations," such as development and human rights NGOs, environmental and other pressure groups, trade unions, consumer organizations, faith-based and inter-faith groups, and certain professor organizations.[77] Examples of these organizations within the

[76] *Commission Public Hearing on a Future Patent Policy in Europe*, COM (2006) 170 (Jul. 12, 2006), http://ec.europa.eu/internal_market/indprop/docs/patent/hearing/report_en.pdf.

[77] JOHN CLARK, GLOBALIZING CIVIC ENGAGEMENT: CIVIL SOCIETY AND TRANSNATIONAL ACTION 1 (2003).

context of patent law include the Public Patent Foundation,[78] Greenpeace,[79] Doctors without Borders,[80] Amnesty International,[81] various farmer's associations,[82] medical associations,[83] patient groups,[84] and centers for genetic research and testing.[85]

The emergence of patent civil organizations has had significant consequences for patent law. These organizations typically adopt a critical stance towards the overall goals of a given patent regime. For instance, the mission statement of the Public Patent Foundation (PUBPAT) states:

> Specifically, PUBPAT works to strengthen the patent system by introducing a healthy amount of non-patentee input to help the system achieve high quality and balanced policies. At its core, our work is based on the fundamental concept of protecting freedom from illegitimate restraint. Since patents are, by nature, government-granted restraints on freedom, every Tuesday (the day of the week the Patent Office issues new patents) there are roughly 3,500 new things that no American is allowed to do, and there is no fair use defense to patent infringement like with copyright and trademark. Thus, although we do believe that a properly functioning patent system can help a vibrant innovative economy, great care must nonetheless be taken to avoid the negative effects that over-patenting, unmerited patenting and excessive patent rights can have on society.

---

78 PUB. PATENT FOUNDATION, http://www.pubpat.org (last visited Aug. 25, 2010).

79 *Patents on Life*, GREENPEACE INTERNATIONAL, http://www.greenpeace.org/international /en/campaigns/agriculture/problem/genetic-engineering/ge-agriculture-and-genetic-pol/patents-on-life/ (last visited Aug. 25, 2010).

80 Access to Medicines, DOCTORS WITHOUT BORDERS, http://www.doctorswithoutborders. org/news/allcontent.cfm?id=84 (last visited Aug. 25, 2010).

81 Amnesty International, Amnesty International urges WTO members to respect human rights obligations in trade negotiations in Hong Kong, AI Index: IOR 30/016/2005 (Dec. 9, 2005), *available at* http://www.amnestyusa.org/document.php?id=ENGIOR300162005& lang=e.

82 *Keep Out Patents on Conventional Seeds and Animals*, NO PATENTS ON SEEDS, http://www.no-patents-on-seeds.org/images/documents/the_global_appeal.pdf (listing the farmer's associations signing an open letter to the Enlarged Board of Appeal of the European Patent Office, Government Representatives, [and] the Executive Boards of Agrobusiness Companies).

83 Larry Storer, *World Medical Associations, AMA Oppose Medical Method Patents*, VEIN THERAPY NEWS, http://veintherapynews.com/index2.php?option=com_content&do_pdf=1&id= 109 (last visited February 7, 2011).

84 *Pathologists and Patient Groups Challenge BRCA1 & BRCA2 Gene Patents in Court*, DARK DAILY, (Feb. 12, 2010), http://www.darkdaily.com/pathologists-and-patient-groups-challe nge-brca1-brca2-gene-patents-in-court-212.

85 *About Patents, Other Intellectual Property & Human Biotechnology*, CENTER FOR GENETICS AND SOCIETY, http://www.geneticsandsociety.org/section.php?id=94 (last visited March 20, 2011).

> The best way to do that is to ensure that all of the interests affected by the patent system, including the public interest in freedom from unjustified restraints, are adequately represented.[86]

The Public Patent Foundation's mission statement is reflective of "patent civil society" norms in its insistence on: (1) the importance of a "public interest" that should explicitly limit the reach of patent law; (2) the failure of current patent norms to adequately address these issues related to the public interest, such as, for example, broadening access to pharmaceutical drugs; and (3) the necessity of organized actors that seek to advance norms which can adequately address existing problems. Notably, while the Public Patent Foundation and other NGOs view themselves as public interest advocates, they still use standard epistemic strategies such as *inter partes* examination at the USPTO and opposition procedures at the EPO.[87]

Despite the deployment of such epistemic strategies, we still claim, however, that the patent civil society differs from more established epistemic communities. First, while organizations, such as the Public Patent Foundation and Greenpeace, deploy common epistemic strategies, the emergence of novel participants that build on expertise outside of patent law has expanded the boundaries of patent discourse. For example, in 2009, Doctors Without Borders, whose work has largely been in the area of international medical assistance, initiated a campaign to pressure the nine major pharmaceutical companies to create patent pools for new treatments in HIV/AIDs.[88] Doctors Without Borders is representative of a "new" patent-policy participant, whose participation draws on "expert" knowledge that is not related to the traditional epistemic community. In doing so, Doctors Without Borders can be seen as playing a role similar to the "expertise" actors in the formal dimension. The "expert" role of Doctors Without Borders is complemented by its use of aggressive advocacy strategies not typically deployed by the traditional epistemic community. For instance, Doctors Without Borders combined its advocacy on behalf of "patent pooling" with an extensive letter-writing campaign to the nine major

---

86 *About PUBPAT*, PUB. PATENT FOUND, http://www.pubpat.org/About.htm (last visited Sept. 2, 2010).

87 *PUBPAT Activities*, PUB. PATENT FOUND, http://www.pubpat.org/activities.htm (last visited Sept. 2, 2010) ("PUBPAT's primary tool for protecting the public domain is filing requests for re-examination with the PTO.").

88 Press Release, Doctors Without Borders, Drug Companies Called on to Pool HIV Patents (September 30, 2009), *available at* http://www.doctorswithoutborders.org/press/release.cfm?id=3970&cat=press-release.

pharmaceutical companies.[89]

Second, the concerns of patent civil society groups are not always easily translated in "common patent vocabulary" that includes such statutory requirements as patent eligible subject matter, obviousness, and inventive step. Therefore, many of the existent formal procedures may prove resistant to incorporating those concerns. Mechanisms may exist, however, that advance participation in patent-decision-making. For example, in opposition proceedings to challenge the validity of a given patent, members of patent civil society frequently invoke Article 53(a) of the European Patent Convention, which states that no patents will be granted for inventions the commercial exploitation of which be contrary to the "ordre public or morality."[90] Article 53(a)'s explicit commitment to "public" values allows these members of the patent civil society to invoke inter-disciplinary public concerns in their advocacy.

Finally, addressing "public interest" concerns in patent law has been profoundly disruptive to the settled expectations of institutional actors and the epistemic community insofar as "public interest" concerns often question the underlying norms of the modern patent regime. These norms have tended to stress the importance of ownership rights as necessary to ensure the "public interest," in promotion of research and development, and innovation.

III. DYNAMIC PATENT GOVERNANCE: ITS CONSEQUENCES

What are the consequences of instituting a system that incorporates dynamic patent governance? We identify two major consequences. First, dynamic patent governance fosters a greater fluidity between the formal and informal dimensions of governance. Second, dynamic patent governance has prompted an ongoing reappraisal of broader public mechanisms within the legislative, executive and judicial nodes. We consider each in turn.

A. Consequence One: Fluidity Between The Formal and Informal Dimensions

A key consequence of dynamic patent governance is a more fluid interaction between the formal and informal dimensions of the patent

89 *Make it Happen Campaign Update*, DOCTORS WITHOUT BORDERS (Oct. 7, 2009), http://www.doctorswithoutborders.com/news/article.cfm?id=3993&cat=field-news.

90 *See, e.g.*, G2/06 WARF/Stem Cells, [2009] E.P.O.R. 15 (EPO Enlarged Bd. App.); T-0315/03 In re The President and Fellows of Harvard College/Method for Producing Transgenic Animals (6 Jul. 2004) (EPO Bd. App.).

governance system. We stress that dynamic patent governance differs from other theories in that it stresses that patent governance includes two trends—heterogeneity in the formal dimension, and a maturing patent public in the informal dimension. These two trends feed each other continually as various stakeholders compete at different sites within the network to achieve their policy outcomes. In particular, the existence of multiple primary and secondary actors can serve as a platform where different stakeholders can try to impact policy-making and reform.

This fluid policy environment has two noteworthy consequences. First, a more diverse regulatory environment can be more responsive in assessing newly identified problems within the patent context. For instance, the Department of Agriculture and the DOJ recently held their first workshop on competition policy in the agricultural sector. This workshop included an analysis of patent law in the seed patent context, [91] an issue provoked by a growing "food politics" around the origins of food production in a modern economy.[92] In the area of climate change, the United Nations Environmental Program (UNEP), the EPO and the International Centre for Trade and Sustainable Development (ICTSD) are jointly collaborating on the development of a study that aims to enhance understanding of the role of patents in generating access to environmentally sound technologies. [93] This study hopes to provide useful input into ongoing discussions on technology transfer in the context of the United Nations Framework Convention on Climate Change (UNFCCC).[94]

Second, a more fluid policy environment offers interested parties (whether in the epistemic or patent civil society) a wider range of diverse administrative levers. An important example of such an expansion of participation in the patent system is the use of citizen petitions under Section 505(Q) of the Federal Food, Drug and Cosmetic Act,[95] which in its implementing regulations[96] provides that any person

91 Press Release, Department of Justice, DOJ and USDA Hold First-Ever Workshop on Competition Issues in Agriculture (March 12, 2010), *available at* http://www.justice.gov/atr/public/press_releases/2010/256496.htm.

92 Michael Pollan, *The Food Movement, Rising*, N.Y. REV. BOOKS, (June 10, 2010) (book review), http://www.nybooks.com/articles/archives/2010/jun/10/food-movement-rising/?pagination=false.

93 Press Release, European Patent Office, EPO, UNEP and ICTSD to work on green patent study (Apr. 27, 2009), *available at* http://www.epo.org/news-issues/news/2009/20090427.html.

94 *Id.*

95 21 U.S.C. § 355(q) (2010) (allowing for the submission of citizen petitions within the context of the submission of generic pharmaceutical drugs).

96 21 C.F.R. § 10.30 (2011) (outlining guidelines for submission of citizen petitions within

can submit a good-faith petition[97] in response to the submission of a generic drug application. The ability to participate in agency decision-making at all stages is notably limited within the context of administrative patent decision-making, although recent experiments, such as the peer-to-patent system, and the ability for third parties to file observations or statements at the EPO,[98] may provide interesting avenues for public participation.

B. Consequence Two: Reappraising the Public's Role in Formal Dimensions

The second consequence of dynamic patent governance is a reappraisal of the public's role in decision-making. In particular, as primary and secondary actors serve as "nodes" at the different decision-making points, a key question at each node will be how to determine the best method for public participation. Thus, dynamic patent governance has begun to prompt a reappraisal of how the public can participate in patent decision-making at each respective node.

1. Consequences at the Legislative Node

As we discuss, *infra*, the legislative "node" has emerged as a key forum in the current patent regime. The legislative process in the patent context is subject to a number of key pressures (such as temporal and ideological uncertainty). But its greatest danger is that legislators may yield to intense interest group pressure, with variable outcomes that often do not take broader "public interest" values into consideration. For instance, Jay Kesan and Andreas Gallo claim that patent reform efforts in the United States have been dominated by a group of what they term "inventors' 'pressure groups'," [99] which include individual inventors, universities, big-sector-based corporations and small-sector-based corporations.[100] The dominance of the "inventive" community at the expense of other potential societal interests risks the use of the

the context of generic pharmaceutical drug provisions).

97 Gerald F. Masoudi, *Legal Developments in the Enforcement of Food and Drug Law*, 63 FOOD & DRUG L.J. 585, 588-89 (2008) (outlining the inclusion of citizen petition verification procedures under Section 505(q) of the Food and Drug Administration Amendments Act of 2007).

98 European Patent Convention, *supra* note 44, art. 115.

99 Jay Kesan & Andres Gallos, The *Political Economy of the Patent System*, 87 N.C. L. REV. 1341, 1352–54 (2009).

100 *Id.* at 1353. Kesan and Gallos divide the corporate inventor interest into four categories: (1) "Big IT;" (2) "Big Pharma and Biotech companies;" (3) "Small IT;" and (4) "Small Pharma and Biotech Companies." *Id*.

legislative process as a method to intensify certain inequities within the pre-existing patent regime. In particular, it may strengthen the tendency of politicians to over-rely on epistemic communities at the expense of other viable civil society stakeholders. Full reliance on a small group of patent law experts for patent policy-making and patent law harmonization has the potential to lead to serious democratic deficits in patent policymaking.

The revival of the legislative actor, in a crucial role, then, raises one key question: are there effective methods for including a wide range of actors who represent a broad set of inventive interest groups, or further the goals of the traditional epistemic community? Patent law reform in the United States has not offered any significant innovation in this respect. Patent law reform has followed the usual template for legislative decision-making in the United States, with limited opportunities for testimony before legislative sub-committees, as well as closed negotiations between key legislators, such as Senators Patrick Leahy and Orrin Hatch.[101]

Patent reform in Europe, however, has used a broader range of consultative processes to address a more varied set of public interests. Europe has used several methods to allow for the involvement of a critical layer of citizens. First, the European Parliament (EP) has employed the traditional method of having a comprehensive study from independent experts[102] preceded[103] and followed[104] by workshops in order to inform discussion in the EP. There are two issues that deserve some more attention. First, this study explicitly included a reconsideration of the governance of the European Patent System.[105]

101 William L. Warren, *Patent Law Reform in the Works Again: Third Time Could be the Charm for Legislative Efforts that Benefit Investors and Job Growth*, GENETIC ENGINEERING AND BIOTECHNOLOGY NEWS, May 1, 2010, http://www.genengnews.com/gen-articles/patent-law-reform-in-the-works-again/3271.

102 ROBIN COWAN ET AL., EUROPEAN PARLIAMENT, SCIENTIFIC TECHNOLOGY OPTIONS ASSESSMENT: POLICY OPTIONS FOR THE IMPROVEMENT OF THE EUROPEAN PATENT SYSTEM (Sept. 2007), http://www.europarl.europa.eu/stoa/publications/studies/stoa16_en.pdf.

103 Before the draft of the report, a workshop was organized on November 9, 2006, where several independent experts and stakeholders were invited to present policy options and debate them with members of the EP and the expert working group. *See STOA Workshop on Policy Options for the European Patent System*, THE DANISH BOARD OF TECHNOLOGY (Nov. 22, 2006), http://www.tekno.dk/subpage.php3?article=1345&language=uk&category=11&toppic=kategori11.'s

104 After the final draft of the report, a second workshop was organized on June 14, 2007 to discuss the findings of the expert working group, where the working group presented the report and discussed it with members of the EP and the audience. *See STOA Workshop: Policy Options for the Improvement of the European Patent System*, http://www.tekno.dk/pdf/projekter/patent-system STOA/p07_STOA_Patent_Workshop_Programme.pdf.

105 At the first workshop, two well-known patent governance scholars were invited: Peter

Though the recommendations of the working group on governance issues were limited and focused primarily on transparency and information exchange on patent policy, the initiative to put patent governance on the agenda is nevertheless welcome. Second, compared to the limited opportunities for testimony during hearings before the U.S. Congress—in theory—anyone interested in these workshops could have attended, and there were many opportunities for the general audience to be heard. Unfortunately, in practice, the number of participants from the patent civil society and the number of members of the EP attending the workshops was relatively limited. The second method employed by the European Union is that the European Commission, which has the ability to propose legislation in the form of directives or regulations, can initiate a consultation combined with a public hearing, where all interested civil society groups can be represented. In January 2006, the European Commission began this process and launched a consultation on the patent system in Europe.[106] It received over 2500[107] responses which were closely studied and summarized, and which were decisive during discussion of topics at the public hearing. At the hearing, about forty pre-selected stakeholders were invited to give their views, and the members of the audience could also comment.[108] Third, the EPO undertook a significant, strategic, forward thinking, planning process that consulted a wide range of academics and other patent administrators using different so-called "scenarios."[109] While the EPO does not pursue a legislative agenda, its

Drahos and Ingrid Schneider. Peter Drahos presented the theoretical model of network governance and its application in the patent system. Peter Drahos, Dir., Ctr. for Governance of Knowledge and Dev. Regulatory Inst's. Network, Austl. Nat'l Univ., Governance of the European Patent System: A Separation of Powers Approach (Nov. 9, 2006), http://www.tekno.dk/pdf/projekter/patent-system-STOA/Drahos.pdf. Though the working group did include a short analysis of network governance and the informal and informal dimension, in our opinion the recommendations drawn from the model were limited. *See* ROBIN COWAN, ET AL., *supra* note 102, at 34-36.

106 *European Commission Questionnaire On the Patent System in Europe* (Jan. 9, 2006), *available at* http://ec.europa.eu/internal_market/indprop/docs/patent/consult_en.pdf.

107 *Commission Public Hearing on a Future Patent Policy in Europe*, *supra* note 76.

108 *Id.*

109 EUROPEAN PATENT OFFICE, SCENARIOS FOR THE FUTURE (2007), http://documents.epo.org/projects/babylon/eponet.nsf/0/63A726D28B589B5BC12572DB00597683/$File/EPO_scenarios_bookmarked.pdf (June 2007). Scenario development is widely used in policy planning when organizations wish to test strategies against uncertain future developments to understand different ways that future events might unfold. *See generally* Paul Schoemaker, *Multiple Scenario Development: Its Conceptual and Behavioral Foundation*, 14 STRATEGIC MGMT J. 195-96 (1994). The scenarios were presented to constitute plausible, relevant and challenging stories about possible future developments with respect to the global patent system. EUROPEAN PATENT OFFICE, SCENARIOS FOR THE FUTURE, *supra* note 109, at 1. The issues examined by the

use of "scenarios" may also be an interesting approach for legislators that consider reforms.

Thus, the efforts in Europe offer interesting lessons on a broader set of methods that could be used to conduct patent reform within the legislative node.[110] First, the heterogeneity of the institutions involved in writing patent regulations and creating policy; such as the EPO, the European Commission, the EP, and the Council of the European Union, has valuably led to the development of a more experimental culture which is better suited to use public participation mechanisms in attempts to reform the patent system. Second, due to the broader range of public interests involved in the reform process in Europe, reform efforts in Europe can be seen as more "forward-looking" and less reactionary than similar attempts in the United States. Nevertheless, the legitimacy of the European initiatives is also open to criticism. In a narrow sense, some of the consultative projects, like the EPO's Scenarios Project, still primarily rely on the traditional epistemic community, and accordingly provide for weak interaction with a wider spectrum of stakeholders. In a broader sense, the European Union's legislative experimentation with the involvement of more stakeholders may create a significant risk that patent policymaking is subject to decision paralysis in light of greater democratic participation. The consultation procedure that delivered over 2500 responses illustrates this point. The only way to effectively overcome this is to engage sufficient manpower and manage the process with clear deadlines to deal efficiently with stakeholder feedback. Therefore, at the workshop that followed the consultation procedure a number of representative stakeholders were pre-selected and had to be extremely brief and concise in their comments.[111]

European Patent Office cover broad policy questions: "How might IP regimes evolve by 2025?" and "What global legitimacy might such regimes have?" *Id.* The European Patent Office's "Scenarios for the Future" report aimed at encouraging strategic conversation among a wide range of stakeholders. *Id.* The document was written in lay terms in order to reach a wide audience. Four scenarios are presented: *Market Rules* (business), *Whose Game?* (geopolitical), *Trees of Knowledge* (societal) and *Blue Skies* (technological). *Id.* They were developed by the European Patent Office scenario builders, but they reflect—as far as possible—different perspectives obtained through interviews. *Id.*

110 *See* Ingrid Schneider, *Can Patent Legislation Make A Difference? Bring Parliaments and Civil Society into Patent Governance?*, *in* POLITICS OF INTELLECTUAL PROPERTY: CONTESTATION OVER THE OWNERSHIP, USE AND CONTROL OF KNOWLEDGE 129-57 (Sebastian Haunss & Kenneth Shadlen eds., 2011) (examining the effect of the European governance process on the inclusion of a broader civil society).

111 Indeed, an examination of the agenda for the public hearing demonstrates a substantial number of scheduled speeches and presentations. *See Public Hearing: Speechs and PPT Presentations*, EUROPEAN COMMISSION (Sept. 1, 2008), *available at* http://ec.europa.eu/internal_

2. Consequences at the Administrative Node

Dynamic patent governance has had two key consequences within the context of the executive node. First, like their legislative counterparts, primary examining agencies have begun to engage in significant experimentation as to widening institutionalized access for third party participation in patent decision-making, in light of the increasing demand for greater decision-making accountability. Second, examining agencies have begun to compete with secondary actors in launching relevant policy initiatives within the patent regime.

Examining agencies have experimented with a variety of participatory mechanisms. At the most basic level, examining agencies have begun to strengthen their "transparency" mechanisms that provide access to information about the issuance of patents and their associated procedures. These transparency mechanisms have taken a variety of different forms. First, agencies have strengthened formal "publication" requirements as to the application and their relevant prosecutions. In particular, agencies have strengthened access to the files associated with the entire prosecution process, as well as the opinions issued by examiners and internal reviewers. This has prompted a significant empirical assessment of patent practice. Second, agencies have experimented with "informal" transparency mechanisms. For example, in 2010 the USPTO, under the leadership of the current commissioner David Kappos, started a blog by agency officials that aims to provide greater transparency to the regulated public.[112] This practice was "copied" by the EPO in 2011.[113] Moreover, the USPTO initiated another informal "transparency" mechanism, the Ombudsman Pilot Program, which is designed to enhance the application process for patentees by providing assistance for problems that may arise during prosecution.[114] This new tool could become even more relevant if the Ombudsman Program could not only assist applicants but also make itself available for feedback from the public on a broader range of issues.

Agencies have also tested strengthened "deliberative" mechanisms that include "open" third-party participation at the initial stage of review

market/indprop/patent/hearing_speeches_en.htm.

112 *Director's Forum: David Kappos' Public Blog*, U.S. PATENT & TRADEMARK OFFICE, http://www.uspto.gov/blog/ (last visited Feb. 26, 2011).

113 The President of the European Patent Office also launched a blog. *See, e.g.*, *President's Blog*, EUROPEAN PATENT OFFICE (Apr. 05, 2011), http://blog.epo.org/?banner=homepage.

114 *Ombudsman Pilot Program*, U.S. PATENT & TRADEMARK OFFICE, http://www.uspto.gov/patents/ombudsman.jsp (last visited Feb. 26, 2011).

of a patent. While many examining agencies permit third parties to participate in review of a patent, it is often in a somewhat "closed" manner that is limited to an observational role. For example, at the EPO, third parties may present observations concerning the patentability of a published European application.[115] Moreover, they can present written statements during the course of proceedings before the Board of Appeal.[116] However, no certainty exists that these statements will influence the outcome of the application, as the Board can address these statements as it thinks fit.[117] In practice, the Board generally takes such observations into consideration.

Recent innovations, however, have sought to create "open" participation by third parties in the examination of the patent itself. Stakeholder participation is at the core of the community patent review (CPR) pilot projects in Japan[118] and the "peer to patent" pilot at the USPTO.[119] These projects invite the scientific community to provide comments on patent applications (e.g., through patent Wikis), for the purpose of creating an open review process for patent prior art. Notably, while both sets of mechanisms are most likely to be used by the traditional epistemic communities, as a result of these changes they can now be used by any participant, and thus, are not predicated upon such epistemic participation.

The innovations adopted by the examining agencies may be a response to the second consequence of dynamic patent governance at the executive level: the competition of secondary actors to conduct relevant policy initiatives within the patent regime. The rise of secondary actors can be attributed to the failure or lack of power of examining agencies to respond to the arguments of various patent activist networks.

Secondary agencies can be more responsive in two significant

115 European Patent Convention, *supra* note 44, art. 115(1).

116 Decision of the Administrative Council of 7 December 2006 Approving Amendments to the Rules of Procedure of the Enlarged Board of Appeal of the European Patent Office, art. 11b(1), 2007 O.J. EPO 303, 308, http://archive.epo.org/epo/pubs/oj007/05_07/05_3037.pdf.

117 *Id*.

118 TOKKYOCHŌ [JAPAN PATENT OFFICE (JPO)], KOMYUNITEI PATENTO REBYU NI KANSU RU CHOUSAKENKYUU [RESEARCH ON COMMUNITY PATENT REVIEW] (2010), http://www.jpo.go.jp/shiryou/toushin/chousa/zaisanken.htm#2001. The latest developments associated with this project are referred to as "peer to patent Japan." *Peer to Patent Japan (P2PJ)*, INST. OF INTELL. PROP (2009), http://www.iip.or.jp/e/e_p2pj/.

119 For more information on the USPTO's pilot project, see Peer to Patent: Community Patent Review, PEER TO PATENT, http://www.peertopatent.org (last visited Aug. 10, 2010). *See also* Beth S. Noveck, *"Peer to Patent:" Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123 (2006).

ways. First, secondary actors can be more responsive in their ideological functions. For example, acting in their expertise capacity, authorities in charge of monitoring competition in the market have viewed settlement agreements between pharmaceutical and generic competitors and patent clusters quite skeptically.[120] Second, secondary actors can offer additional amenable avenues for public participation, in order to respond to pressure from the patent community.

IV. DYNAMIC PATENT GOVERNANCE: THE *MYRIAD* EXAMPLE

We have proposed a complex model for new patent governance, but its real measure as an effective model is based on its usefulness as a way to explain the complex reality underlying the current patent regime. We believe that—although this case is already widely discussed as to its merits—the *Myriad* debates in the United States and Europe are particularly useful in demonstrating the emerging contours of patent governance in two key respects. Initially, the *Myriad* debates in both jurisdictions offer sharp contrasts in how to successfully incorporate the maturing patent civil society into patent governance. Furthermore, the *Myriad* debates offer an example of how to manage ongoing heterogeneity within the institutional design of the formal dimension of patent law.

A. The Myriad Example, Lesson One: A Maturing Patent Civil Society Needs "Doors" to Knock On

The *Myriad* debates will be remembered as instrumental in the assessment of how a maturing patent civil society can participate in patent decision-making in a dynamic civil society, (in both the United States and Europe). Indeed, a comparative assessment reveals that interest groups in Europe effectively participated in challenging the *Myriad* patents far earlier than in the United States. In the United States the available formal methods for third-party participation are more limited than in Europe. Therefore, ongoing participation in patent decision-making is far less certain. In both jurisdictions, an interesting tension has emerged between the availability of third-party review at the internal administrative review stage and a subsequent invalidity review at the external review stage.

In Europe, the controversy regarding Myriad's patents started early. In 2002, three patents based on the genes BRCA1 and BRCA2[121]

120 *See e.g.*, *Pharmaceutical Sector Inquiry*, *supra* note 64.

121 European Patent No. 0705902 (BRCA1) (filed Aug. 11, 1995); European Patent No.

and a fourth patent,[122] relating to a method for diagnosing breast and ovarian cancer were granted to Myriad Genetics. In response, a wide variety of stakeholders[123] launched an opposition proceeding under Article 99 of the EPC, and an appeal under Article 106 of the EPC. As a result of these proceedings, the scope of all patents has been significantly reduced. For instance, European Patent No. 0699754, on a method for diagnosing a predisposition for breast and ovarian cancer, which covered a broad variety of methods and mutations, now only covers a diagnostic method for a specific type of mutation, namely "frameshift mutations."[124]

The outcome of the *Myriad* debates in Europe offers some crucial lessons as to why the role of the civil society (as opposed to a more

0705903 (BRCA1) (filed Aug. 11, 1995); European Patent No. 0785216 (BRCA2) (filed Dec. 17, 1996). *See generally Bibliographic Data: EP 0785216 (A1),* EUROPEAN PATENT OFFICE, http://worldwide.espacenet.com/publicationDetails/biblio?DB=EPODOC&adjacent=true&locale=en_T1&FT=D&date=19970723&CC=EP&NR=0785216A1&KC=A1 (last updated Apr. 04, 2011). European Patent No. 0705902 related to "Nucleic acid probes comprising a fragment of the 17q-linked breast and ovarian cancer susceptibility gene" and was granted on 11/28/2001; opposition was filed in August 2002; appeal against the decision in opposition was filed on 11/15/2005 (T1213/05) but was rejected on 09/27/2007. The patent is maintained as amended in opposition. *Id.* European Patent No. 0705903 related to "Mutations in the 17q-linked breast and ovarian cancer susceptibility gene" and was granted on 05/23/2001; opposition was filed in February 2002; an appeal was lodged on 08/01/2005 (T0666/05) and led to a considerable limitation of the scope of the patent (11/14/2008). *Id.* European Patent No. 0785216 related to "Chromosome 13-linked breast cancer susceptibility gene BRCA2" and was granted on 01/08/2003; opposition was filed on 10/08/2003 and led to the decision that the patent will be maintained in amended form (B2 New Specification of the European patent on 06/07/2006). *Id.* For more information also see *SmartSearch,* EUROPEAN PATENT OFFICE, https://register.epoline.org/ (last visited Apr. 10, 2011) (providing a search tool to find information about patents registered with the European Patent Office).

122 European Patent No. 0699754 (BRCA1). European Patent No. 0699754 related to a "Method for diagnosing a predisposition for breast and ovarian cancer" and was granted on 10/01/2001; opposition was filed in October 2001; appeal against the decision in opposition was filed on 01/14/2005 (T0080/05). *See EP 0699754 – Method for Diagnosing a Predisposition for Breast and Ovarian Cancer*, EUROPEAN PATENT OFFICE, https://register.epo.org/espacenet/application?number=EP95305602&tab=main (last visited Apr. 10, 2011). In opposition the patent was revoked, but in the appeal initiated by the applicant, the European Patent Office allowed the applicant to reformulate the invention resulting in an amendment of the original patent, which now only covers a diagnostic method for a specific type of mutation, namely frameshift mutations. *Id.*

123 Some important stakeholders who participated in the initial Myriad disputes were e.g. the State of The Netherlands (in particular, its Department of Health, Welfare and Sports), Institut Curie, Assistance Publique-Hopitaux de Paris, Institut Gustave Roussy-IGR, Associazione Angelaserra per la Ricerca sul Cancro, the Sozialdemokratische Partei der Schweiz (SP Schweiz), Greenpeace, a number of individuals (die Erben von Herrn Dr. Wilhelms, Rolf E.), the Belgian Society of Human Genetics, and the "Vereniging van Stichtingen Klinische Genetica. *See supra* note 121; *see also supra* note 122.

124 European Patent No. 0699754 (filed Oct. 2001).

narrowly focused epistemic community) has emerged in Europe. The internal opposition and appeal procedures of the EPC are structured so that "any" person may challenge the validity of a patent on broad terms.[125] Thus, the internal administrative review of the EPC provides European "patent civil society" with the opportunity to participate in patent policy-making. Additionally, at this internal administrative review stage, the *Myriad* experience demonstrated that patent civil society is increasingly comfortable with the use of epistemic tactics. These relevant groups focused on the general patentability requirements (novelty and inventive step) in their challenge to the patents issued by the EPO, thus demonstrating that within Europe, these civil society advocacy groups are not limited by the complexity and technicality of patent law and use the available "epistemic" tools to fight controversial patents.

Achieving goals through external review of patents, though, has not been as simple in Europe. After the patent grant or the maintenance of the patent—potentially in amended form—the opportunity to challenge the patents in invalidity procedures before national courts remains open. However, the only opportunity to challenge a patent is to undertake external review of a patent in each individual member state of the European Patent Organization where the patent has been validated. This prompts a risk that different national courts will come to different conclusions as to the validity of each given patent. A number of groups, active in the EPO opposition proceedings, have suggested initiating invalidity proceedings on the national level in order to address the uncertain state of validity of the *Myriad* patents.[126] Apart from this uncertainty at the national level due to the institutional framework of the European Patent Organization, at least two national courts have referred preliminary questions[127] to the European Union Court of Justice in two cases relating to the EU Biotechnology Directive. This directive harmonizes the grant of patents in the biotech sector and has been

125 *Id.* art. 107 ("Any party to proceedings adversely affected by the decision may appeal."); European Patent Convention, *supra* note 44, art. 99 ("Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations.").

126 Correspondence between the authors and G. Matthijs, Professor of the Faculty of Medicine and Head of the Laboratory for Molecular Diagnosis, Department of Human Genetics, The University of Leuven (Jan. 2010) (on file with authors). G. Matthijs has been heavily involved in the European opposition proceedings on behalf of the Belgian Society of Human Genetics.

127 Case C-34/10, Brüstle v. Greenpeace (pending); Case C-428/08, Monsanto Tech. LLC v. Cefetra BV et al., 2011 F.S.R. 6.

incorporated into the EPC implementing rules.[128] Even though these preliminary questions do not directly relate to human gene patents, the preliminary rulings may create momentum to re-open the debate on the desirability of gene patents in general.

By contrast, when compared to Europe, the experience of patent civil society in the United States still remains underdeveloped. It was not until May 2009 that any significant challenge to the *Myriad* patents emerged. Members of the patent civil society were unable to utilize internal administrative avenues such as the current Patent Act to challenge the *Myriad* patents, because third parties are unable to oppose the grant of a patent under U.S. law (as was the case in Europe).[129]

The *Myriad* debate commenced as an invalidity challenge brought by the American Civil Liberties Union and the Public Patent Foundation at the Benjamin N. Cardozo School of Law, along with a number of other plaintiffs (individual patients, patient groups, physicians, academic researchers and medical societies).[130] These plaintiffs filed a complaint, claiming in part that isolated nucleic acids are not patentable subject matter, as they are products of nature and thus contrary to 35 U.S.C. § 101, which specifies what constitutes eligible subject matter under the Patent Act of 1952.[131] On March 29, 2010 (with an amended opinion issued on April 5, 2010), the United States District Court for the Southern District of New York held that the composition and method claims directed to DNA molecules possessing nucleotide sequences that translate BRCA1 and BRCA2 proteins are "products of nature"[132] or "abstract ideas" under Section 101 of the Patent Act. [133]

While the substantive holding of *Ass'n for Molecular Pathology v. USPT* has been widely reported,[134] an earlier denial of a motion to dismiss, which granted standing to the "public interest" plaintiffs, is of equal importance. In its decision to deny the motion to dismiss,[135] the

128 Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnical Inventions, arts. 1, 5, 1998 O.J. (L 213) 13 (EU).

129 U.S. patent law does not encompass an opposition procedure. The closest equivalent to the European opposition procedure, is the *inter partes* reexamination procedure in U.S. patent law. However, the grounds for reexamination are more limited than those in European opposition proceedings.

130 Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *as amended* (Apr 05, 2010).

131 *Id.*; 35 U.S.C. § 101 (2006).

132 Ass'n for Molecular Pathology, 702 F. Supp. 2d at 237-38.

133 *Id.*

134 *See, e.g.*, Danny Thompson, *Myriad Genetics Can't Patent a Human Gene*, SLATE (Apr. 7, 2010, 11:34 AM), http:///www.slate.com/id/2250082/.

135 Ass'n for Molecular Pathology v. USPTO, 669 F.Supp.2d 365 (S.D.N.Y. 2009).

district court held that the plaintiffs had standing because: (1) the statutory scheme of the Patent Act did not divest the plaintiffs of standing to pursue their constitutional claims;[136] (2) the plaintiffs suffered a fairly traceable injury because Myriad had refused to license its patents;[137] and (3) the plaintiffs' injury could be redressed because the policies of the USPTO led to the unwarranted issuance of the patents at issue.[138] This is a significant shift from previous precedent that suggested that the statutory scheme of the Patent Act precluded any judicial relief associated with the USPTO's issuance of a patent.[139] The outcome of the *Myriad* case, in *Ass'n for Molecular Pathology v. USPT,* indicates the success of a maturing U.S. patent civil society, and the potential to expand access to judicial review by building a creditable case for standing.The intense interest in *Myriad* demonstrates a desire to create a patent law amenable to the claims of interests beyond those of the patentee and its direct competitors. The ongoing interest in *Myriad* is also evinced by the unlikely set of parties that submitted *amicus curiae* briefs in the *Myriad* appeal currently before the Federal Circuit. The unlikely allies that submitted supportive briefs included the Cancer Council of Australia,[140] the American Medical Association,[141] Universities Allied for Essential Medicines,[142] Friends of the Earth,[143]

136 *Id*. at 385. The plaintiffs were also able to survive a challenge to the district court's exercise of subject-matter jurisdiction because the court determined that their claim was valid because federal district courts exercise subject-matter jurisdiction in "all civil actions arising under the Constitution." *Id*. at 382. Such a claim was possible because the Patent Act contained no remedy for the violation of constitutional rights that had accompanied the issuance of the disputed patents. *Id*. at 383. This holding was significant in light of precedent that emphasized that the statutory scheme of the Patent Act precluded the exercise of subject-matter jurisdiction. *Id*. It should be noted that the court did not address *how* an issuance of a patent can lead to an unconstitutional result. *See id.*

137 *Id*. at 385.

138 *Id*.

139 *See, e.g.*, Syntex (U.S.A.) Inc. v. USPTO*,* 882 F.2d 1570, 1572-74 (Fed. Cir. 1989) (statutory scheme of the Patent Act precluded a private judicial remedy for statutory violations by the USPTO).

140 Brief for Cancer Council Australia and Luigi Palombi as Amici Curiae Supporting Affirmance, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010), 2010 WL 5306807.

141 Brief for American Medical Association et al. as Amici Curiae in Support of Plaintiffs - Appellees and Arguing for Affirmance, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Dec. 6, 2010), 2010 WL 5306806

142 Brief for Universities Allied for Essential Medicines as Amicus Curiae in Support of Plaintiffs-Appellees, Supporting Affirmance, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Jan. 20, 2011), 2011 WL 585708.

143 Brief for the International Center of Technology Assessment et al. as Amicus Curiae in

the March of Dimes Foundation,[144] the American Association of Retired Persons,[145] the Southern Baptist Convention,[146] and the National Women Health Network.[147] The number and broad range of parties that submitted briefs in support of the decision of the district court not only evinces the important legal and factual questions *Myriad* presents *as* to the scope of Section 101, but also its status as a case that demonstrates the increasingly diverse participation of patent civil society.

Nevertheless, the ongoing appeal of this decision (on all grounds), creates uncertainty as to the ultimate impact of *Ass'n for Molecular Pathology v. USPT*, and indicates the limits of creditable patent civil society opposition in the United States. This is especially true in light of the uphill battle that patent civil society still faces in establishing standing before the Federal Circuit.[148] This contrasts sharply with recent developments in Europe, where the ability of third parties to broadly challenge patents has proven to be a useful tool in administrative level opposition and appellate proceedings.

B. The Myriad Example, Lesson Two: Managing the Heterogeneity "Thicket"

The *Myriad* example also highlights how the increasing heterogeneity of the formal dimension in patent law has transformed the policymaking landscape. Notably, the questions at stake in cases such as *Myriad*—the patenting of gene patents and their associated testing regimes—raise significant ethical and public health concerns. These concerns have prompted secondary agencies, with expertise in these

Support of Plaintiff-Appellees, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Jan. 20, 2011), 2011 WL 585709.

144 Brief for Amici Curiae Canavan Foundation et al. in Support of Plaintiffs for Affirmance, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Jan. 20, 2011), 2011 WL 585710.

145 Brief for AARP as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Jan. 20, 2011), 2011 WL 585711.

146 Brief for the Southern Baptist Convention as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Jan. 20, 2011), 2011 WL 585712.

147 Brief of Amici Curiae [of] the National Women's Health Network et al. in Support of Plaintiffs-Appellees, Ass'n for Molecular Pathology v. USPTO, 702 F.Supp.2d 181 (S.D.N.Y 2010), *appeal docketed*, No. 2010-1406 (Fed. Cir. Jan. 20, 2011), 2011 WL 598420.

148 Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 925-932 (1991)(limiting standing to for a variety of interest groups that sought to challenge an administrative determination of the USPTO under the Patent Act and the Administrative Procedure Act).

areas, to assert their competence. For instance, in 2002 the United States Secretary of Health and Human Services established the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) to examine "current patent policy and licensing practices for their impact on access to genetic technologies."[149] The membership of the Committee has to include at least two members who "shall be specifically selected for their knowledge of consumer issues and concerns and the view and perspectives of the general public."[150] In April 2010, the Committee composed of fourteen members, published its final report on patent licensing and genetic testing, which included recommendations that would: (1) support the creation of exemptions for infringement in the case of diagnostic testing; (2) promote the adherence to norms of access in genetic testing; (3) suggest more transparency in genetic testing licensing; (4) establish an advisory body on the health impacts of genetic patents and provide expertise to the USPTO on genetic testing issues; and (5) ensure equitable patient access to clinically useful genetic tests.[151] In response, Kathleen Sebelius, the Secretary of Health and Human Services, issued a restrained statement on July 2, 2010, which emphasized the commitment of the United States in maintaining "a competitive position in life science research and development."[152] In a curious move, Secretary Sebelius then dismantled the Committee in October 2010.[153]

The Committee's designated responsibilities and its ultimate report indicates how heterogeneous forums for patent policymaking can be useful in questioning general assumptions underlying patent law and the impact of patent law in particular fields. Such forums have a designated objective that is intersectional in nature. This intersectional focus can shift the ideological conception of patent law into new directions by incorporating diverse policy rationales. In its report, SACGHS

149 Establishment of the Secretary's Advisory Committee on Genetics, Health and Society, 67 Fed. Reg. 65, 126 (October 23, 2002).

150 67 Fed. Reg. at 127.

151 SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH AND POL'Y, U.S. DEP'T OF HEALTH AND HUMAN SERV'S., LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 4-6 (2010), http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf (including at least one dissent and abstention).

152 Letter from Kathleen Sebelius, Sec'y of Health and Human Servs., to Steven Teutsch, Chairman of the Sec'y's Advisory Comm. on Genetics, Health and Pol'y (July 2, 2010), http://oba.od.nih.gov/oba/sacghs/reports/Secretarys%20letter%20to%20%20SACGHS%20on%0Patents%20Report.pdf.

153 E-Mail from SACGHS [Sec'y's Advisory Comm. on Genetics, Health and Pol'y] (NIH/OD/OSP), to Daniel Vorhaus, (Sept. 27, 2010, 3:08 PM EST), http://www.genomicslawreport.com/wp-content/uploads/2010/09/SACHGS-Email.pdf.

emphasized the importance of ongoing research, ethical and public health rationales, which offered a distinctly critical viewpoint of traditional patent norms.[154] Therefore, we believe the potential utilization of actors such as SACGHS to advise the USPTO demonstrates a commitment to changing the debate over gene patents by broadening the institutional competence of other agencies to address the issues associated with gene patents. An organization such as SACGHS can hence function as an *alternative* super-structural node within the dynamic patent governance context. The question of institutional competence to address issues related to the public interest may continue to foster a heterogeneous and dynamic interrelated landscape in the patent governance system. The emergence of heterogeneous administrative forums in the United States appears in many respects to be a positive development for patent governance, as diverse ideological and institutional conceptions of the public interest are likely to be generated.

By contrast, the policy tension over the relevant ideological issues at stake in *Myriad* demonstrates the ways in which the heterogeneity of the administrative landscape is much more complicated for patent governance in Europe. Within the European context, the heterogeneity of institutions with conflicting policy goals may lead to difficulties in ascertaining who has the institutional competence to address the policy issues at stake in *Myriad*. The patent system of the European Union differs from the United States patent governance system, among other things, in that the European patent system consists of two *independent* institutional pillars: the European Patent Organization (including the EPO and the Administrative Council), on the one hand, and the European Union, on the other hand. The EPO retains its own ability to make significant policy choices during the grant and issuance of a given patent, along with the broader power of its Administrative Council to issue and amend regulations that implement the basic treaty provisions.[155] Policy governance is further complicated by the fact that the European Union (through the legislative procedures set for the European Commission, Council of the European Union and the European Parliament), also has power, to a certain extent, to issue regulations and directives that reflect its priorities. For instance, European Commission has been working towards the regulation of a

154 SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH AND POL'Y, U.S. DEP'T OF HEALTH AND HUMAN SERV'S., *supra* 151, at 72-85 (discussing multiple legal frameworks for the assessment of genetic testing).

155 European Patent Convention, *supra* note 44, art. 33.

unitary EU patent for a long.[156]

An additional consideration for the European Union is the proper functioning of its internal market in order to prevent trade barriers that may arise as a result of legal action taken in various Member States. Indeed, in 1998 the European Union issued its Biotechnology Directive, which sought to harmonize how each of its Member States protected biotechnological inventions. The European Union directed its Member States to protect biotechnological inventions, including isolated gene sequences.[157] It is notable, that—although the EPO is not formally bound by EU legislation—the Directive has explicitly been incorporated into the EPC[158] and now provides the EPO with more detailed guidelines with regard to the patenting of biotechnological inventions.[159] Finally, the Court of Justice of the European Union has begun to assert its own role in shaping the policy landscape of the European Union through its review of the parameters of the EU Biotechnology Directive in *Monsanto*.[160]

Thus, in many respects, the example of *Myriad*, and the related debates over the scope of gene patenting in the European Union, reveal the potential for a "heterogeneity thicket:" the existence of so many administrative actors that stakeholders may not be able to ascertain how to approach the various policies instituted by these actors.[161] Indeed, the European Society of Human Genetics (ESHG), one of the primary critics of the approval of the *Myriad* patents in Europe, has stressed that the "heterogeneity thicket" remains an important public policy concern in the European Union, noting that:

> In many countries, patent issues are dealt by the Ministry of Justice, even though the consequences affect the Ministry of Health. This dilemma represents the origin of some of the identified problems in this report. Discussion between these ministries is necessary.

156 *European Commission*, *Proposal for a Council Decision Authorizing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection*, COM (2010) 0790 final (Dec. 14, 2010).

157 Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnical Inventions, *supra* note 128, art. 5.

158 Implementing Regulations to the Convention on the Grant of European Patents, Dec. 13, 2006, pt. II, ch. V, r. 26(1) ("Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.").

159 T-272/95 In re Howard Florey Inst. of Experimental Physiology and Med. (23 Oct. 2002) (EPO Bd. App.), http://legal.european-patent-office.org/dg3/pdf/t950272eu2.pdf.

160 *See supra* note 127.

161 *See* S. Aymé, G. Matthijs, & S. Soini, *Patenting and Licensing*, *in Genetic Testing: Recommendations of the European Soc'y of Human Genetics*, 16 EUR. J. HUM. GENETICS S3 (2008).

> A better separation between the courts (such as the proposed European Patent Court) and the EPO is desirable, notably considering that EPO is at present not formally accountable to any other body in the EU.[162]

The ESHG's recommendation illuminates the dilemma of European patent heterogeneity, insofar as its structure has yet to find an optimal balance between centralization and diversity. Indeed, this is unlikely to change anytime soon as the latest proposals for a centralized European and EU Patent Court have been stalled, (temporarily), by the EU Court of Justice[163] because of their incompatibility with the EU Treaty and the Treaty on the Functioning of the European Union (TFEU).

V. THE CHALLENGES OF DYNAMIC PATENT GOVERNANCE

We have outlined the contours of dynamic network governance in patent law, and considered its real-world implications in the *Myriad* debates. In many ways, however, dynamic governance remains a maturing concept in patent law. Indeed, implementing the concept of dynamic patent governance will raise significant challenges in the system governing patent law. First, dynamic patent governance challenges the impulse to centralize patent administration and litigation so as to create largely uniform systems of law. Second, a dynamic patent governance environment may risk exacerbating administrative inefficiencies within the patent system.

A. Dynamic Patent Governance and the Question of Centralization and Diversity in Patent Law

The emergence of dynamic patent governance as a model seems to complicate a key concern of institutional design in administrative patent law: whether to centralize the judicial and administrative functions of the patent system. The United States' successful concentration of centralized appellate review in the Federal Circuit has prompted consideration, in the European Union, of specialized community-wide

---

162 *Id.* at S9.

163 On July 2, 2010, Advocate General Juliane Kokott provided an opinion advising the Court of Justice to find that, in its current draft, the proposed agreement is incompatible with EU treaty obligations. C-01/09 [Op. of Advocate Gen.], Avis au titre de l'art. 300, CE – Relations Exterieures at para. 6 (July 2, 2010). On March 8, 2011, the Court of Justice issued an opinion that largely agreed with the Advocate General's position. *Opinion 01/09 of the Court*, EUR. CT. OF JUSTICE. (Mar. 8, 2011), *available at* http://curia.europa.eu/jcms/jcms/j_6/ (type "08/03/2011" in the "from" bar; then click on "Avis 1/09" hyperlink).

trial and appellate level patent review.[164] Likewise, as heterogeneity has blossomed within the context of the administrative function of the patent system, centralization has also developed as an alternative to the potential problem of a "heterogeneity thicket." In both cases, proponents of centralization claim it brings a perceived uniformity in application of patentability standards, and therefore more clearly defined intellectual property rights.

How then does the proposed model respond to the current impulse for centralized governance within patent law? We make two claims. First, we think that fluidity between the informal and formal dimensions of patent law may have the unintended consequence of generating alternative forums for review of issued patents and related policy questions. Second, a model based on dynamic patent governance suggests that, in the institutional design of the patent system, it might be helpful to perceive centralization and diversity as a continuum of design choices, rather than an either/or dichotomy.

1. The Challenge of Centralization and "Unintended" Alternative Forums

Recently, the usefulness of centralized patent appellate review in the United States, (which has served as a model for the proposed centralization of external review within Europe and other patent systems), has been criticized. John Duffy and Craig Nard[165] advocate for a "polycentric" decision-making model, with the Court of Appeals for the Federal Circuit joined by a second appellate circuit. Such polycentric decision-making would be beneficial, according to Duffy and Nard, because it would create doctrinal competition in articulating jurisprudential standards and encourage more innovative jurisprudence to resolve difficult doctrinal issues of claim construction.[166] This has prompted written responses from scholars such as Judge Lee Plager and Lynne Pettigrew,[167] Rochelle Cooper Dreyfuss[168] and Lee

164 *Progress Report Enhancing the Patent System in Europe*, Doc. No. 14970/08 (2008), http://register.consilium.europa.eu/pdf/en/08/st15/st15674.en08.pdf.

165 Duffy & Nard, *supra* note 50, at 1623.

166 *Id.* at 1626-27.

167 Plager and Pettigrew contend that Duffy and Nard's polycentric decision-making incorrectly predicts that more polycentric decision-making will produce "better" decisions and moreover, disagree with Duffy and Nard's overall contention that judicial decisions, are a vehicle for policy directives. S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law's Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735, 1739 (2007).

168 Rochelle C. Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 823 (2008) (suggesting that incremental changes, rather than

Petherbridge,[169] offering defenses of centralization within patent governance.

The debate over uniformity within appellate policy determinations often depends on an either/or dichotomy. Either a singular appellate court exists that makes determinations related to patent law, or a dual appellate court (in the Duffy/Nard formulation) is an ideal position to undertake such decision-making. In a dynamic environment, however, it is possible to see already existent alternative appellate avenues in which different perspectives on patent law can be addressed.

A current example is the ability of pre-existing alternative appellate review within those cases that fall at the intersection of patent and antitrust pleadings. For example, the Court of Appeals for the Second Circuit, in *In re DDAVP Direct Purchaser Antitrust Litigation* (*In re DDAVP*), recently addressed the "novel question of standing that lies at the junction of antitrust and patent law."[170] *In re DDAVP* involved the efforts of a class of direct purchasers of the anti-diuretic DDAVP who argued that the defendants violated Section Two of the Sherman Antitrust Act. Specifically, the direct purchasers alleged that the defendants engaged in an exclusionary scheme under Section Two: (1) to procure the DDAVP patent by engaging in inequitable conduct; (2) to improperly list the fraudulently obtained patent in the FDA's Orange Book, thereby enabling patent infringement claims against potential infringement by competitors; (3) to prosecute sham infringement litigation against generic competitors; and (4) to file a sham citizen petition to further delay the FDA's Approval of Barr's Abbreviated New Drug Application (ANDA).[171]

The Second Circuit held that it had jurisdiction over the appeals. While three of the allegations did involve substantial questions of patentability, the fourth, which focused on the filing of a potential sham citizen petition at the FDA, supported a patent-independent theory of liability.[172] The Court addressed whether the plaintiffs, as direct purchasers, rather than direct competitors, had standing to raise a *Walker Process* claim.[173] The defendants contended that *Walker*

disruptive ones such as those suggested by Duffy and Nard, are needed to resolve the issues raised by a "maturing" centralized court).

169 Lee Petherbridge, *Patent Law Uniformity?*, 22 HARV. J.L. & TECH. 421 (2009) (contending that an empirical analysis demonstrates significant doctrinal diversity in appellate decision-making within the Federal Circuit).

170 In re DDAVP Direct Purchaser Antitrust Litigation, 585 F.3d 677, 682 (2d Cir. 2009).

171 *Id.* at 683.

172 *Id.* at 686-87.

173 *Id.* at 688. In *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), the Supreme Court held that a plaintiff could base a claim of antitrust injury on the

Process standing existed only if the party also had standing to challenge the patent's validity.[174] The defendants position would have limited standing based on direct purchases within this context because patent law generally reserves standing to those parties that are direct competitors.[175] The Second Circuit, reluctant to determine whether, as a *per se* matter, direct purchasers had a right to raise a *Walker Process* claim in every case, determined that it was appropriate in this case for plaintiffs to have standing in order to challenge an already "tarnished patent."[176] The Second Circuit ultimately held that plaintiffs had adequately stated an antitrust claim on which relief could be granted.[177]

While the standing and jurisdictional issues central to the Second Circuit's opinion in *In re DDAVP* are likely to the be unique to the administrative law jurisprudence of the United States, the Second Circuit's decision has resulted in the emergence of an alternative "node" within the patent governance network for review of patent-related competition issues. Such an alternative avenue of competition is also available in the European Union, as demonstrated by the General Court's recent opinion in *AstraZeneca v. European Commission* (*AstraZeneca*).[178] *AstraZeneca*, like *In re DDAVP*, is a case that is to a certain extent out of place in that, since no centralized EU patent exists, the courts of the European Union, sitting in Luxembourg, do not normally address patent-related issues. Nonetheless, once patents and/or supplementary protection certificates[179] are granted, the courts of the European Union can invoke competition law to define the boundaries of the patent owner's rights.

In *AstraZeneca,* the General Court upheld the decision of the European Commission, which had imposed a fine of € 60 million on AstraZeneca for abusing its dominant position by using the patent system and associated procedures to market pharmaceutical products

patentee's fraudulent behavior within the context of the acquisition of a patent.

174 In re DDAVP Direct Purchaser Antitrust Litigation, 585 F.3d at 684.

175 Kali N. Murray, *Rules for Radicals: A Politics of Patent Law*, 14 J. INTELL. PROP. L. 63, 77-80 (analyzing standing of direct competitors in the post-issuance context).

176 *In re DDAVP*, 587 F.3d at 691.

177 Murray, *supra* note 175, at 77-80.

178 Case T-321/05, AstraZeneca v. Euro. Comm'n, unreported July 1, 2010, *available at* http://curia.europa.eu (to search for this case, follow the "en" hyperlink; then type "T-321/05" in the "Case No" field and click "Search"; then follow "T-321/05" hyperlink where the date "2010-07-01" is listed).

179 In the EU, supplementary protection certificates operate as a *sui generis* extension of a patent that is available for medicinal products and plant protection products. They were introduced to compensate for the long time required to obtain authorization to put these products on the market. *See* Council Regulation 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products, 1992 O.J. (L 182) 1.

with the sole purpose of preventing or delaying the market entry of competitors to Losec (their anti-ulcer product), while also preventing parallel imports of Losec.[180] According to the Commission, AstraZeneca had made deliberately misleading representations to the patent offices of Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom so as to obtain supplementary protection certificates for Losec that conferred extended patent protection.[181] Moreover, the Commission sanctioned AstraZeneca for having de-registered the Losec capsule marketing authorizations in Denmark, Norway and Sweden so as to (1) delay and make more difficult the marketing of generic medicinal products and (2) prevent parallel imports of Losec.[182] This was contrary to the then existing law that required that the marketing authorization of the original product to be in force in the Member State concerned in order to qualify for a simplified procedure.[183] According to the Commission, AstraZeneca's deregistration of the Losec capsule's marketing authorizations had the effect of preventing the use of the simplified procedure. This in turn made getting marketing authorizations for generic medicinal products more time-consuming and difficult, thereby delaying the entry of generic competitors.[184] The General Court rejected most of AstraZeneca's arguments for annulment of the Commission's decision and held that the company had abused its dominant position, even though the Commission failed to prove part of its second contention.[185]

Unlike the Second Circuit's holding in *In re DDAVP*, under EU law the General Court did not have constrained jurisdictional authority since the Commission had imposed a fine on AstraZeneca as an exercise of its powers under Article 102 of the TFEU. This was a sufficient ground for the Court to claim jurisdiction under Article 263 of the TFEU. In this respect, *AstraZeneca* is not an exact parallel to *In re DDAVP*. Nonetheless, the General Court's holding in *AstraZeneca* illustrates that even in an utterly complex heterogeneity thicket, such as the European patent governance system, unintended formal actors are increasingly more willing to engage in review of patent-related issues. Technically, the courts of the European Union cannot exercise jurisdiction over claims involving patents granted by the EPO or

180 *AstraZeneca*, *supra* note 178 ¶¶ 612–13, 864.

181 *Id*. ¶ 305.

182 *Id*. ¶ 871

183 *Id*. ¶¶ 806, 808.

184 Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, 2006 O.J. (L 332) 24.

185 *Id*.

national patent offices. However, in *AstraZeneca,* the General Court exercised its ability to review acts of the European Commission intended to produce legal effects *vis-à-vis* third parties, such as competition decisions (acting as an expertise actor within the competition law context), and placed significant limits on the behavior of patent owners.

The Second Circuit's holding in *In re DDAVP* and the General Court's decision in *Astra-Zeneca* reflect what role centralization and diversity will likely play in judicial decision-making within a dynamic patent governance environment. First, both cases demonstrate that diversity of judicial decision-making and restraints on patent holder's behavior can occur at different nodes within the governance system without formal, statutory changes in the law. Second, *In re DDAVP,* in particular, demonstrates that the existence of heterogeneous administrative agencies may prompt new types of challenges within the context of patent law. The Second Circuit's reliance on a potentially sham citizen petition as a basis for an antitrust claim demonstrates the increasing importance of the FDA as a site for conflict within patent enforcement. The FDA, because of its review of pharmaceutical products, has re-shaped the patent landscape by providing pharmaceutical actors with a stronger incentive to engage in sophisticated strategies within the administrative context (such as the choice of whether to list a patent on the FDA's Orange Book); and the litigation context (such as increasingly offering incentives to primary pharmaceutical companies to enter into settlements with generic companies).[186] Finally, the role of direct purchasers in *In re DDAVP* exemplifies the involvement of a more diverse public in patent law; a patent "civil society" that may come to patent law from other fields (such as antitrust), or that may have goals that differ from direct competitors in asserting patent law claims. *In re DDAVP*'s expansion of standing to bring certain claims signals the part that broader patent civil society can play within patent law.

2. The Challenge of Centralization and the "Intended" Continuum of Institutional Design in Patent Law

The either/or dichotomy of centralization versus decentralization ignores the present reality of a partially de-centralized specialized appellate review. In addition, it affects reconsideration of the

186 *See generally*, Ron A. Bouchard et al., *The Pas De Deux of Pharmaceutical Regulation*, 24 BERK. L. & TECH. J. 1464, 1494 (2009).

institutional design of existing primary and secondary actors, as well as proposals for new patent related actors. Recent patent scholarship has begun to grapple with, (but not describe), what we identified in Part B as the heterogeneity thicket; the problem of too many individual actors seeking to regulate and enforce patents.

The solution to problems within patent governance has often been to suggest more "centralized" institutional design. For instance, Stuart Benjamin and Arti Rai[187] recently proposed an Office of Innovation Policy (OIP) that would review all regulations that impact "innovation" in the United States.[188] Pursuant to this proposal, any regulations related to patents, would have to be submitted to the OIP for review. Such centralized administrative review would be optimal, Benjamin and Rai contend, because decentralized policy review creates "disinformity, lack of focus on the regulatory objective, potentially significant transaction costs for regulated entities subject to a welter of different regimes, and significant government costs arising from so many regulators covering significant ground."[189] The proposed OIP would serve to centralize decision-making related to innovative policy in two key respects.[190] First, the OIP would be able to issue *ex ante* policy guidelines to agencies that would be used by agencies to identify the impact of their decision-making on innovation.[191] The agency would be required to include such an *ex ante* OIP policy determination in its administrative record. Any subsequent judicial review would then be required to undertake searching "hard-look" review to determine whether or not the agency effectively considered the "innovative" impact of its decision-making.[192] Second, consideration of OIP evaluation could be included in the *ex post* analysis undertaken by the Office of Information and Regulatory Affairs (OIRA) in its centralized review of the budgetary impact of a proposed agency regulation.[193]

Rai and Benjamin suggest that a future OIP could be instrumental in helping the executive branch create and integrate a uniform innovation policy among the various agencies, as well as harmonize the role of the legislative, executive, and judicial branches in implementing

187 Stuart M. Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 58–59 (2008).

188 *Id*. at 58.

189 *Id*.

190 *Id.* at 58-64 (dicussing the functions of the OIP).

191 *Id*. at 64.

192 *Id*. at 65.

193 *Id*. at 64.

that policy.[194] Rai and Benjamin acknowledge, however, one problematic aspect of their proposed OIP, namely, its likely insulation from public participation and accountability structures under the Administrative Procedure Act (APA).[195] Having concluded an empirical assessment of the public participation processes at the Federal Communication Commission (FCC), Benjamin and Rai contend that these procedures have limited value in improving innovation regulation. In particular, Benjamin and Rai note that comments were submitted "disproportionately" by well-organized groups and were often duplicative during informal rulemaking.[196] Thus, Benjamin and Rai contend that participation processes within the context of FCC informal rulemaking are "not essential, or even particularly helpful for the purposes of improving innovation regulation," and therefore would not be necessary for an OIP assessment.[197]

While there is much to admire about Benjamin and Rai's proposal, and its attempts to address an identified problem in our own model ("the heterogeneity thicket"), we struggle with the major flaw on which OIP is premised: the apparent lack of public participation that is contemplated as part of its design structure.

In particular, we struggle with what centralized review without public participation would mean in the context of patent law. Benjamin and Rai offer their critique of basic participation structures based on an analysis of such processes at the FCC.[198] Such a reference to the FCC's policy environment ignores the statutory constraints placed on public participation within the patent context. The Federal Circuit's recent decision in *Tafas v. Doll*[199] signals that at least some among its bench would seek to place significant constraints on the ability of the USPTO to undertake substantive policy review (under Section 553 of the APA). These constraints on the USPTO's ability to conduct substantive notice and comment rulemaking under Section 2 of the Patent Act limit the ability of the public to participate in the USPTO's interpretative determinations of its statutory responsibilities.[200] Substantive policy

194 *Id*. at 56.

195 An OIP *ex ante* or *ex post* review would not likely be considered "notice and comment" rule-making under Section 553 of the Administrative Procedure Act. *See id.* at 75; *see also* Administrative Procedure Act, 5 U.S.C. § 553(c) (2006) (outlining requirement for "notice and comment" rulemaking procedures).

196 Benjamin & Rai, *supra* note 187, at 73.

197 *Id.* at 75.

198 *Id.* at 59-60.

199 559 F.3d 1345 (Fed. Cir. 2009), *vacated*, 328 Fed. App'x. 658 (Fed. Cir. 2009), *appeal dismissed* 586 F.3d 1369 (Fed. Cir. 2009).

200 Kali Murray, *First Things, First: A Principled Approach to Patent Administrative Law*, 42

review is further constrained by limits on the ability of third parties, beyond a potentially infringing competitor, to raise pre-issuance or post-issuance challenges to administrative decisions undertaken by the USPTO during the re-examination procedure.[201] Moreover, new experimental tools created by the USPTO, such as the Peer to Patent Project, the Ombudsman Project, and the Director's Blog, will not compensate for these shortcomings. Strategic re-evaluation mechanisms such as the EPO's Scenario's project and large-scale consultations like those of the European Commission and the European Parliament on the future of patent policy also seem absent.

The existence of a "public interest" community that can organize around the accountability structures at the USPTO or actively challenge the issuance of administrative rules is, therefore, very limited. Efforts to further de-legitimize public participation in the patent governance system by proposing actors that would lack considerable opportunities for participation may have a deeper and lasting consequence in a constrained regulatory environment. A lean, centralized, super-structural node, such as the OIP proposed by Benjamin and Rai, can only serve as an acceptable model if public participation is appropriately guaranteed at the epistemic community and the civil society levels.

Rather than emphasizing decentralization or centralization as the principal solution, we suggest that a model of dynamic patent governance offers a compromise. A model of dynamic patent governance recognizes the needs for patent governance to acknowledge that decentralization and centralization are part of a broader continuum of design choices within the context of institutional design. So, we see a need for a transparent network consisting of (1) decentralized formal actors with appropriate procedures for public participation; and (2) centralized review at super-structural nodes. In this way, incoherence and duplication would be prevented by the centralized review mechanism, while at the same time access to expert advice from epistemic communities and from the patent civil society would be guaranteed at the decentralized level. A centralized, super-structural node, such as Benjamin and Rai's OIP—with *ex ante* and *ex post* powers to review policies related to innovation, including patent policy—would fit comfortably within a concept of dynamic patent governance that includes a variety of heterogeneous actors collaborating within a dynamic patent governance network. Such an integrated

J. MARSHALL L. REV. 29, 61-62 (2008).

201 Murray, *supra* note 175, at 77-85.

approach would not only be useful for the United States, but also for Europe, which is currently contemplating its first comprehensive Innovation Strategy.[202]

B. Dynamic Patent Governance and the Challenge of Efficiency

The other primary criticism of our model is that its obvious complexity would prompt even more administrative inefficiencies in patent governance. We argue, however, that dynamic patent governance may offer *more,* rather than *less,* administrative efficiency in patent offices.

The Trilateral Cooperation framework[203] between the USPTO, the EPO and the JPO offers an example of how to increase efficiency by exploiting the strengths of a governance network in a number of ways. First, the USPTO, the EPO and the JPO extended the existing sets of bilateral Patent Prosecution Highway (PPH) work-sharing agreements to a "fast-track" patent examination procedure for PCT applications under the pilot PCT-Patent Prosecution Highway (PCT-PPH) Program. PCT applications that receive a positive written opinion from either the International Searching Authority or the International Preliminary Examining Authority, or an international preliminary examination report from EPO, JPO or USPTO are subject to an expedited examination.[204] Second, these patent offices have engaged in the Tri-way Pilot Program, which expedites a search in each office, if the patent applicant has filed with either the EPO, JPO or USPTO as its office of first filing under the Paris Convention.[205] The Trilateral Cooperation framework provides a successful example of three patent offices coming together to expedite examination of the respective applications. This practical solution to expediting applications may also herald an increased consistency in the legal standards of each regime. This increased consistency is also reflected in the third major collaborative

---

202 *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Europe 2020 Flagship Initiative, Innovation Union*, COM (2010) 546 final (Oct. 6, 2010), http://ec.europa.eu/commission_2010-2014/geoghegan-quinn/headlines/documents/com-2010-546-final_en.pdf.

203 *See generally History*, THE TRILATERAL CO-OPERATION, *available at* http://www.trilateral.net/index.html;jsessionid=j5wskyqrynla (last visited Apr. 10, 2011).

204 *Pilot of Patent Prosecution Highway Program to use PCT Work Products*, PCT NEWSLETTER, No. 12/2009, at 1; *The Trilateral Offices commence PCT-Patent Prosecution Highway Pilot*, PCT NEWSLETTER, No. 02/2010, at 2.

205 Tri-Way Pilot Program Among The United States Patent and Trademark Office, the European Patent Office, and the Japan Patent Office, U.S. PATENT AND TRADEMARK OFFICE (Jul. 28, 2008), http://www.uspto.gov/web/patents/triwaypilot.html.

initiative between the three offices: the establishment of the Trilateral Biotechnology Working Group—whose mission is to faciliate similar practices in evolving areas of technology and patent law, with the ultimate goal of harmonization of practice among the Trilateral partners.[206]

Super-structural nodes, such as national patent offices collaborating within the Trilateral Cooperation framework, may also raise some concerns despite the opportunities they present. Preliminarily, the patent offices, while collaborating within a superstructural node, must still ensure that they are operating pursuant to domestic administrative authority. For instance, while the USPTO has entered into expedited search agreements based on its authority to govern the proceedings of its office under 35 U.S.C. § 2(b)(2),[207] its authority to join international treaties under the same section remains advisory.[208] Furthermore, these practices may insulate administrators from democratic accountability procedures, such as notice and comment rulemaking, or intensive consultation procedures that are open to a wider range of public interest groups.

The aforementioned concerns are not so dominant when it comes to establishing practical procedures aimed at expediting patent grants and limiting backlogs. However, for substantive policymaking projects these concerns appear more urgent. Therefore, it is vital to emphasize that despite collaboration at the level of an international super-structural node, the three patent offices/nodes that are part of the Trilateral Cooperation framework remain individually responsible for providing appropriate mechanisms for accountability within their own legal systems. Dynamic patent governance thus serves efficiency aims by facilitating and enabling collaboration by building super-structural nodes that fulfill new functions, while maintaining stable accountability mechanisms for legitimate policy-making within each individual node.

VI. CONCLUSION

Our proposed model seeks to refine early attempts by experts such as Francis Gurry and James Boyle to suggest a patent governance model with global significance. However, our proposed model still remains provisional, tentative, even. For, as the *Myriad* debates demonstrate, "events on the ground" are driving whether our proposed model will

206 *See Biotechnology*, THE TRILATERAL CO-OPERATION, *available at* http://www.trilateral.net/projects/biotechnology.html (last visited Apr. 2011).

207 35 U.S.C. § 2(b)(2) (2010).

208 *Id.* § 2(b)(8).

become a fully developed one.

Our model requires further development of its potential consequences and challenges. The impact of a more dynamic system of patent governance—in particular on doctrinal development—still remains uncertain. Subjects so long at the core of patent law—such as the nature of invention and what are the best legal devices to protect any given invention—may shift in response to interdisciplinary concerns in other fields. Concerns in other fields can range from public health concerns over access to drugs and genetic testing; to the relationships of patents to food, health and safety; to the role of patent law within the context of competition policy. At this stage in the development of our model, more questions than answers exist.

Yet, we think that articulating our model, even at this stage, has some useful outcomes. First, patent reform efforts at the legislative and administrative nodes may valuably benefit from conscious application of this model in a number of respects. Policy-making instruments used on opposite sides of the Atlantic may inspire reform at the legislative and administrative nodes. For instance, the USPTO could usefully adopt the "scenarios model" undertaken by the EPO as a way to foster a long-term vision for its changing role. Congress could consider some more informal consultation procedures—beyond carefully staged testimony—where a broader spectrum of stakeholders is represented. The EPO could become more transparent by having an equivalent to peer to patent review and the Ombudsman Pilot Program.

Second, we think that our model suggests that the institutional design of patent law needs to be effectively mediated between centralization and decentralization in the examiner and review nodes. In particular, institutional design needs to reflect the demands for increased participation of patent stakeholders (the epistemic community and the patent civil society alike) while safeguarding the need for efficient administrative governance.

Finally, our model implies that the role of the informal dimension is *a central* element in patent governance. The *Myriad* patent debates suggest that a wider audience is paying attention to patent governance, and patent administrators, by utilizing our model, can respond to the "voices" knocking at the door.

So, this is not so much a conclusion, but an invitation to reflect further on an evolving patent landscape.