

OBSERVING THE PATENT SYSTEM IN SOCIAL AND POLITICAL PERSPECTIVE: A CASE STUDY OF EUROPE

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Introduction

The major patent systems across the world seem substantially similar. They all reward inventors with intellectual property rights for a limited period of time, in exchange for disclosure about the methods of making the invention. They all bring scientific and legal knowledge to bear on the assessment of patent applications and the grant of patents. Although they may exhibit minor national or regional quirks, their governing laws and approach to patentability are also substantially the same. In fact, many of them work actively to ensure harmonization of their laws and practices. Finally, in most places, patent systems are thought to play a central role in encouraging innovation and therefore economic growth.

But this is not the full story. In this chapter, we argue that when patent systems are understood through a social and political lens, they exhibit many differences that are important for understanding both their role in contemporary societies and their possible futures. In order to make this argument, we use the European patent system as a case study. Although distinguished scholars have argued that it is largely similar to its counterpart in the United States,¹ we argue that the European patent system's distinct history, and social and political context, shape its policies and practices in important ways.

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1. PETER DRAHOS, *THE GLOBAL GOVERNANCE OF KNOWLEDGE: PATENT OFFICES AND THEIR CLIENTS* (2010).

In particular, we demonstrate that it has developed a distinctive response to the activist challenges that have plagued patent systems over the past three decades. We hope that our approach and findings will encourage social scientific analysis of legal institutions, and of patent systems in particular. Although some historians and anthropologists have examined aspects of intellectual property closely², this area of scholarship is still extremely limited.

We begin the chapter by exploring the political history of the European patent system. We demonstrate that it was developed as part of a *European innovation policy* apparatus in the wake of World War II. This scope and orientation shaped its practices and policies. We then briefly describe the rise of activist challenges to the system since the 1980s. European activists have rather similar concerns as those fighting other patent systems across the world: they demand that intellectual property regimes change to take into account the broad implications of their decisions, including the consequences of trade liberalization for the developing world, the rights of citizens across the world to affordable healthcare, the ethical boundaries of markets, and the appropriate limits of scientific inquiry. The European patent system's history and social and political position have made it particularly sympathetic, we argue, to these challengers and led it to shift its culture and practices. These shifts may lead to long-term changes in the system that would be difficult to predict if we focused solely on the law.

These conclusions are based on qualitative research conducted from 2007 to 2012. This included over one hundred interviews with US and European patent office and other government officials, advocacy groups, patent lawyers, inventors, and other stakeholders. We also analyzed a variety of documents including: patent office publications; individual patents (and associated documents, including challenges and oppositions); archival records on the development of the US and European patent offices (held, for example, at the archives for the European Commission, European Parliament, Council of Europe, European Free Trade Association, and the European Economic Community); transcripts of congressional, parliamentary, and patent office hearings (from the eighteenth century to the present); and US Supreme Court cases from the eighteenth century to the present. Finally, participant observations were conducted at multiple patent office hearings and meetings in both the United States and Europe.

2. See, e.g., B. ZORINA KHAN, *THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT: 1790–1920* (2009); CORI HAYDEN, *WHEN NATURE GOES PUBLIC* (2003); CHRISTOPHER MAY & SUSAN K. SELL, *INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY* (2006); INGRID SCHNEIDER, *DAS EUROPÄISCHE PATENTSYSTEM. WANDEL VON GOVERNANCE DURCH PARLAMENTE UND ZIVILGESELLSCHAFT* (2010); Daniel Kevles, *Diamond v. Chakrabarty and Beyond: The Political Economy of Patenting Life*, in *PRIVATE SCIENCE: BIOTECHNOLOGY AND THE RISE OF THE MOLECULAR SCIENCES* (Arnold Thackray ed., 1998).

I. The History of the European Patent System

Creators of the European patent system built it with explicit policy goals in mind. After decades of war on the continent, they hoped that it would stitch European countries together to create a common, democratic future of economic prosperity and peace. Building the system, however, was not easy. The process lasted almost thirty years, and required extensive negotiations. Through the construction of this system, negotiators not only took an important step toward the creation of European law and a European economy, they also took steps toward creating the ideas of the European public and public interest.

The first significant steps toward a European patent system occurred in 1947, when France and the “Benelux” countries (Belgium, the Netherlands, and Luxembourg) established the International Patent Institute (IPI) in The Hague (Netherlands) to coordinate their efforts to determine a patent application’s novelty.³ Although most European countries had patent systems by this time, they differed in many respects, including what each considered patentable subject matter, how applications were reviewed, who was eligible for a patent, and what the grant of a patent actually meant. The IPI was the first effort among European countries to establish a unified approach to the search process and the novelty determination.⁴ IPI personnel would investigate the prior art (relevant patents and scientific publications) and produce a “search report,” which was then used by the national patent offices. Soon afterwards in 1949, the new Council of Europe (CoE) took up the idea of a unified European patent system as one of its first tasks. A unified patent system, according to the CoE, would help it ensure its goal: “to achieve a greater unity between its members for...facilitating their economic and social progress.”⁵ The Council’s Committee on Legal and Administrative Questions described its interest by noting “that technical progress and development of inventions make increasingly imperative the pooling of the means and resources of each of the Member States of the Council for the protection of the inventor and of national industries which benefit from his activities.”⁶ At the time, Council membership comprised Belgium, Denmark, France, Ireland, Italy, Luxembourg, the Netherlands, Norway, Sweden, and the United Kingdom. From the outset, proponents saw the European patent

3. D. GUELLEC & B.V.P. DE LA POTTERIE, *THE ECONOMICS OF THE EUROPEAN PATENT SYSTEM: IP POLICY FOR INNOVATION AND COMPETITION* (2007).

4. Eda Kranakis, *Patents and Power: European Patent-System Integration in the Context of Globalization*, 48 *TECH. & CULT.* 689 (2007).

5. NEILL NUGENT, *THE GOVERNMENT AND POLITICS OF THE EUROPEAN UNION* (2010).

6. Committee on Legal and Administrative Questions, Council of Europe, Recommendation 23—European Patents Office (Doc 110) (1949), *available at* <http://assembly.coe.int/Main.asp?link=/Documents/AdoptedText/ta49/EREC23.htm>.

system as a policy instrument that, by providing industrial rights to the inventor, would provide public benefit through industrial, and therefore economic, growth.

The first proposal, offered by French senator Henri Longchambon, suggested a European “Patents Office” that would issue inventor’s certificates that would establish the novelty and patentability of an invention.⁷ In this scheme, national patent offices would still grant and administer the actual patents. The Council established a Committee of Experts on Patents, composed of each member country’s highest patent officials, to study Longchambon’s draft proposal. Members of this committee soon agreed that although the goals of the proposal were good, they were not yet “practicable,” and then began to work on initial steps toward the idea of a European patent system. Work toward the creation of a European patent system can be divided into two projects. First, negotiators needed to develop a unified approach to the processes of search and examination and to the definition of patentable subject matter. Second, they needed to consider how to create appropriate governance, including a unified European patent office. Most of the countries involved in the negotiations already had a patent office that employed technical personnel and that had established its own practices and policies. What would become of them? Would they become part of a European patent system? How? How would their responsibilities change, and how would they be able to handle these changes? How would the governance of a patent system work? How would it be organized?

A. A European Approach to Patent Law

The CoE’s Committee of Experts on Patents focused on the first challenge, composing a Preliminary Comparative Study on Novelty and Patentability, in April 1951.⁸ This report identified the similarities and differences between member countries on a variety of issues including how they treated prior use of an invention for purposes of determining novelty, and whether and how they defined exclusions from patentability. The Committee’s treatment of these exclusions demonstrates the centrality of public policy concerns in developing the European patent system.

Most contentious were discussions about a unified approach to the patentability of “chemical products,” “foodstuffs,” and “horticultural products.” Although few countries allowed patents on both pharmaceutical products and

7. Committee on Economic Questions, Consultative Assembly of the Council of Europe, Creation of a European Patents Office (Doc 75) (1949).

8. Committee of Experts on Patents, Council of Europe, Criteria of Novelty and Patentability (1951).

the processes of making them, most either prohibited “product” patents because they facilitated monopolies that would be detrimental to the public’s health, or allowed patents on pharmaceutical products but also allowed compulsory licensing under certain circumstances in order to deal with the potential problems that a monopoly could create. These approaches demonstrated that European countries saw some limits to patentability as necessary to achieve public interest goals. The Austrian delegation described its position in the negotiation: “For the Austrian economy, the protection of chemical substances is unacceptable. Furthermore, it seems entirely inadmissible that foodstuffs, stimulants, pharmaceuticals, and disinfectants necessary for the preservation of the life and health of the general public should be subject to exclusive rights for the benefit of individuals.”⁹ Rather than assuming that the economic benefits that accrued to the patent holder would automatically achieve social benefit, some countries argued that the patent system had to take an active role in *balancing* public and private interests to achieve the public good.

Negotiators also had to contend with the “*ordre public*” exclusion contained in many national patent laws. In general, this exclusion prevented patents on inventions deemed contrary to public policy or morality, but there was considerable diversity in how different countries articulated the concept. Italy, for example, used the exception to disallow patents “detrimental to health,” whereas Ireland disallowed “inventions liable to cause an increase in the price of commodities, a hindrance to the freedom of commerce or any other public inconvenience.”¹⁰ Nevertheless, all of the negotiating countries agreed quickly that the European system should include a clause that prevented patents on inventions that were contrary to public policy or morality. In fact, there was almost no discussion of the matter. This suggests that the relevance of the public policy and morality clause was uncontroversial and obvious. Patent law was relevant to public policy, and therefore required a clause in the pan-European treaty to address potential conflicts.

The idea that patents should not be allowed on inventions that are contrary to public policy or morality can be traced historically in three directions. The first comes directly from the history of patent law, as the seventeenth-century English Statute of Monopolies prevents the issuance of patents that are “contrary to law,” “mischievous to the state,” or “generally inconvenient.”¹¹ It was then incorporated into the 1883 Paris Convention, one of the first international treaties regarding

9. Committee of Experts on Patents, Appendix II: Declaration by the Austrian Delegation CM (63) 101 (Strasbourg, France, 1963), at 16.

10. Criteria of Novelty and Patentability, *supra* note 8, at 19.

11. Chris Dent, “*Generally Inconvenient*”: The 1624 Statute of Monopolies as Political Compromise, 33 MELBOURNE UNIV. L. REV. 16 (2009).

intellectual property. The Convention stated that signatories could not allow patents that “mislead the public.”¹² The United States, however, does not have such an exception in its governing statute. Although Supreme Court Justice Joseph Story did suggest the existence of a “moral utility” exception in the nineteenth century, it appears rarely in modern US patent jurisprudence.¹³

The second origin of the public policy exception developed in the wake of the French Revolution in the eighteenth century, in which newly written administrative laws of all kinds referred to the concept of *ordre public* to demonstrate explicit attention to the public good.¹⁴ The third can be traced through international treaties: starting in the nineteenth century, international treaties (particularly those in Europe) began to include an “*ordre public* exception” to demonstrate recognition of national sovereignty in particularly sensitive areas.¹⁵ The TRIPS Agreement, a significant international treaty on intellectual property, contains the clause.¹⁶ Given the clause’s historical origins and meaning, it is likely that negotiators of the European patent system saw it simply as a necessary part of patent law, especially one that involved international negotiation and consideration of national sovereignty. As we will demonstrate later in the chapter, it is only in the wake of activist challenges that it gained the association with the ethical dimensions of patent law that it has now.

As the CoE’s Committee of Experts on Patents tried to develop agreement on a variety of issues including definitions of “industrial character,” “novelty,” “technical progress and creative effort,” “influence of prior rights and applications,” and “scopes and roles of the description and the claims,”¹⁷ they sought advice from stakeholders at both national and international levels. Each national delegation consulted with inventor, patent law, patent agent, and industrial associations in their country, and the Committee as a whole heard comments

12. S. Thambisetty, *Understanding Morality as a Ground for Exclusion from Patentability under European Law*, 12 EUBIOS J. ASIAN & INT’L BIOETHICS 48 (2002).

13. Andrew R. Smith, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159 (2003); B.D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685 (2003).

14. M.J.B. Bernier, *Droit Public and Ordre Public*, 15 TRANS. GROTIUS SOC. 83 (1929).

15. M. Forde, *The “Ordre Public” Exception and Adjudicative Jurisdiction Conventions*, 29 INT’L & COMP. L.Q. 259 (1980); Gerhart Husserl, *Public Policy and Ordre Public*, 25 VA. L. REV. 37 (1938).

16. C.M. CORREA, *INTELLECTUAL PROPERTY RIGHTS, THE WTO, AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS* (2000).

17. Lodovico Benvenuti, Written Question No. 73 to the Committee of Ministers by Mr. Heckscher (CM/AS (60)Quest73FinalE) (1960).

from the International Association for the Protection of Intellectual Property, the International Federation of Patent Agents, the International Chamber of Commerce, and the European Industrial Research Management Association.

Eventually, these negotiations led to the 1963 Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, which was signed by all Council countries (which by this point included Belgium, France, Italy, Luxembourg, the Netherlands, Ireland, Denmark, Norway, Sweden, the United Kingdom, Greece, Turkey, Austria, Cyprus, and Switzerland).¹⁸ It disallowed patents on plant and animal varieties, and on “inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation.”¹⁹ Despite the earlier controversy, it allowed patents on food and pharmaceutical products, and agricultural and horticultural processes, but provided signatories with a ten-year grace period to bring their policies into agreement with the Convention.

The 1973 European Patent Convention, which established the European patent system, relied heavily on the Strasbourg Convention. It incorporated the Strasbourg Convention’s two categorical exclusions (on plant and animal varieties and on inventions that violated *ordre public* or morality) and added a third: “methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.”²⁰ In identifying these exceptions, the creators of the European patent system were clearly thinking about it in terms of public policy, and were concerned that an unfettered patent system may not always achieve social benefit. These exclusions also suggested a broad approach to what might be counted as relevant knowledge and expertise in the patent system. Traditionally, participants in the patent system focused on industrial and patent law, and to a lesser extent economic and scientific expertise. Consider, for example, the stakeholders who participated in the CoE discussion described above. However, excluding methods of treatment and diagnostic methods “in the interests of public health”²¹ raised the possibility that public health and medical experts might be able to claim relevance and legitimacy in patent-related discussions, and that these discussions would consider

18. C. Wadlow, *Strasbourg, the Forgotten Patent Convention, and the Origins of the European Patents Jurisdiction*, 41 INT’L REV. INTEL. PROP. & COMPET. L. 123 (2010).

19. Council of Europe, Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, opened for signature Nov. 11, 1963, C.E.T.S. No. 047 (1980).

20. Convention on the Grant of European Patents, opened for signature 5 October 1973, 13 I.L.M. 268 (entered into force Oct. 7, 1977).

21. European Patent Office, Revision of the European Patent Convention (EPC 2000), Synoptic presentation EPC 1973/2000—Part I: The Articles, at 50, 2007.

public policy and public interest broadly. In addition, the *ordre public* exclusion could create an opportunity for a wide variety of individuals and groups to claim knowledge and expertise relevant to the relationship between morality and patent law. These openings, however, were not intentional. Negotiators never mentioned the possibility that such figures might be relevant to patent law. Rather, this broader approach was connected to negotiators' vision of the European patent system as a policy instrument, and as we will see it became quite useful to public interest groups later on.

B. Organizing the European Patent System

As the Council negotiated the substantive patent issues, the new European Economic Community and European Free Trade Association (which were both eventually absorbed into the European Union) considered the potential governance structure of a European patent regime. The EEC, which was created in 1957 among Italy, Germany, France, and the Benelux countries to facilitate European economic integration, saw unification of the patent system as an early priority.²² In 1962, its Committee of Experts (which, similar to the one convened by the Council of Europe, was made up of the heads of patent offices from the member states) proposed a European Patent Law that would create a single European patent that would coexist with existing national patents. A central European Patent Office would perform examination and granting functions, and the European Court of Justice and an Administrative Council made up of representatives from the EEC member countries would oversee its activities. Non-EEC countries would be allowed to participate in the system if the Administrative Council approved them. The structure envisioned by this proposal echoed the American system, with a central bureaucratic apparatus and external legislative and judicial oversight. However, this system would create a new layer of pan-European decision-making authority and expertise, which would coexist with the expertise and authority of national systems. Thus, it would create new challenges. What would European expertise in patent searching and examination mean? Would it be the same as national expertise? Would non-EEC countries accept decisions by the Administrative Council when they were not represented in it? Would the European patent office operate in all of the languages of its member states?

22. D. Thompson, *The Draft Convention for a European Patent*, 22 INT'L & COMP. L.Q. 51 (1973); F. Froschmaier, *Some Aspects of the Draft Convention Relating to a European Patent Law*, 12 INT'L & COMP. L.Q. 886 (1963).

Because EEC negotiators could not agree on whether, and how, non-EEC countries could participate in the proposed system, their draft proposal did not make much progress. In the meantime, the heads of patent offices from the member countries of the EFTA, which was then made up of Austria, Denmark, Norway, Sweden, Switzerland, and the United Kingdom, made another proposal: a “two-part arrangement,” in which there would be a unified system up to and including the grant of the patent, but then policies regarding the effects and validity of the granted patent would be determined separately for EEC and non-EEC member countries. In this proposal, the European office had fewer responsibilities and therefore, more limited political exposure.

The EFTA Memorandum attracted a great deal of interest. The French government, primarily at the request of French industry, advocated this proposal inside the EEC and soon the Chairman of the EEC’s expert committee incorporated it into a draft Memorandum for review and discussion. The EEC then used the EFTA proposal as the basis for discussion when it convened an Inter-Governmental Conference made up of the directors of the patent offices of its own member countries. The Conference included observers from the Council of Europe, the International Patent Institute, the United International Bureaux for the Protection of Intellectual Property (the predecessor of the World Intellectual Property Organization), the EEC Commission, patent agents, lawyers, and industrialists. By late 1969, the Inter-Governmental Conference had published its first preliminary draft with the aim of bringing “interested circles,” defined as “the private persons concerned, the inventors, the companies that will exploit the patents and produce the products, the patent agents, and the patent lawyers,” more actively into the discussion.²³ Thus, the parties began to discuss a framework that would include EEC and non-EEC member states in a system existing outside of the EEC. Discussion continued over the next few years, and in 1973, sixteen countries met in Munich to sign what became known as the European Patent Convention.²⁴ This Convention guides the European patent system today, and its basic organization is quite similar to the EFTA proposal: a common system for the examination and grant of a patent, with policy on effects and validity determined independently by each member state.

23. Thompson, *supra* note 22.

24. Twenty countries participated in the discussions. By 1977, seven had become full-fledged members. Today, there are thirty-eight member countries. See European Patent Office, Member States of the European Patent Organisation, <http://www.epo.org/about-us/organisation/member-states.html> (last visited Sept. 5, 2013).

C. Governing the European Patent System

The EPC established a European Patent Organization, composed of a European Patent Office and an Administrative Council, to grant patents.²⁵ The European Patent Office performs both bureaucratic and judicial functions, including receiving patent applications, conducting searches of prior art and examination of the application, and resolving legal questions through boards of appeals. The Administrative Council, composed of representatives from the member countries, performs supervisory and legislative functions. It meets periodically to review the rules and regulations governing the Patent Office and its personnel, to appoint adjudicators to the appeals boards, and to elect the Organization's president. It also determines whether and when to review the European Patent Convention itself. In most cases, each member country can cast one vote, and most decisions are made through a simple majority. The European Patent Organization is located in Munich, with additional branches in The Hague²⁶, Berlin, and Vienna, and its official languages are English, French, and German.

Because the European Patent Organization predates the 1993 Treaty of Maastricht establishing the European Union and because it has always included non-EU countries, it is a pan-governmental organization that operates independently. As a result, it is disconnected from European Union institutions, including the Parliament and European Court of Justice. This has important implications for how the system has developed and maintained its legitimacy.²⁷ While the policies of the US Patent and Trademark Office (USPTO) are guided by the US Congress and the federal court system, for example, the EPO's policies are largely its own, with the Administrative Council—composed of representatives from member countries—playing an important formal and informal role. Even if they are not translated directly into policy, EPO employees quickly learn about the concerns of Administrative Council representatives and do their best to address them.²⁸ Thus, in contrast to the USPTO, the EPO has enormous power to shape patent policy. As a result, it also plays a significant role in shaping the definition of European public interest, and the meaning of Europe itself. However, the EPO

25. See European Patent Office (EPO), The Administrative Council of the European Patent Organisation, EPO, <http://www.epo.org/about-us/epo/administrative-council.html> (last visited Sept. 5, 2013).

26. Initially, The Hague office did all searches (because it was previously the home of the International Patents Institute) and the Munich office did most of the examination (some examiners were in Berlin). Today, however, all examiners perform both search and examination.

27. J. Karanović, *Contentious Europeanization: The Paradox of Becoming European Through Anti-Patent Activism*, 75 *ETHNOS* 252 (2010).

28. Interview with Employee A, EPO, in Munich, Ger. (June 25, 2008).

has chosen to comply voluntarily with EU law, particularly when dealing with controversial issues. This not only ensures smooth harmonization between EU member states and EPO practices, but it also provides external legitimacy for the institution.

Although there are many similarities between the patent application process in Europe and in other major patent systems, a few differences are worth mentioning. After the EPO Receiving Section classifies a patent application according to its subject matter, it is sent to an Examining Division made up of three examiners. By contrast, only a single examiner reviews patents at the USPTO. Although one examiner plays the primary role at the EPO, all three review and sign off on the interactions with the applicant and the final decision. This team approach encourages examiners to seek advice and learn from one another, and also to develop a more uniform approach to search and examination. European examiners have similar backgrounds to their counterparts in other systems. They must have scientific or engineering training and learn the relevant patent law through a dedicated patent academy and through an apprenticeship. However, they must also be competent in at least two (and preferably all) of the Organization's official languages. Examiners tend to make a career at the EPO, in large part because it offers excellent benefits (including a substantial pension). This means that the examining corps has not only formal training but also considerable experiential expertise. It also means that they identify themselves with the goals of the institution, and often refer to themselves as "civil servants"²⁹ even though they are not part of a national government or the European Union. This contrasts with the United States, where retention of examiners has been a serious problem for over a century.³⁰

Once a patent is granted by the EPO, it becomes a bundle of national patents each of which can be independently governed in each country (which countries are a part of the bundle depends on the applicant's choice and the fees paid). Within nine months of a patent's issue, it can be opposed at the EPO on the grounds that the invention did not meet the criteria for patentability or that it was not sufficiently described, or that the granted patent goes beyond the initial application. By contrast, until recently, the United States had a re-examination process that only allowed patent challenges on "prior art" grounds.³¹ Before the creation of the European patent system, patent offices across Europe had developed a pre-grant opposition procedure to

29. Interview with Employee B, EPO, in Munich, Ger. (June 25, 2008).

30. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-1102, USPTO: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG (2007).

31. Although the recently passed America Invents Act (2011) permits post-grant review of patents by the USPTO, it is as yet unclear how this will be interpreted in practice. Pub. L. No. 112-29 § 1, 125 Stat. 284 (2011).

correct mistakes in their search, examination, and granting processes quickly and cheaply rather than forcing inventors to deal with lengthy litigation. This approach could be the result of the difficulty of negotiating litigation across member countries, or it could be the result of Europe's relative comfort with bureaucratic power (the United States, by contrast, is characterized by trust in the fairness of its litigation processes to achieve a fair and just result). Because of the challenges of granting patents that would be valid across Europe, including the costs of translation, the EPC changed it into a post-grant process.³² If a third party opposes a patent, an Opposition Division consisting of three technical examiners—two of whom were not involved in the initial examination—review the case. Approximately one-third of oppositions result in a patent's revocation, while another one-third results in narrowing the claims.³³

Applicants and third parties can appeal the decisions of the Receiving Division, Examining Division, or Opposition Division to a Technical Board of Appeal (similar to the USPTO's Board of Patent Appeals and Interferences). Technical Boards of Appeal are made up of either legally qualified members, technically qualified members, or a mixture of both, depending on the type of appeal. The final level of judicial review is the Enlarged Board of Appeal, which analyzes broad legal questions that are either referred by a Technical Board or by the president of the European Patent Office. This is in contrast to the United States, where the federal court system performs this function. In Europe, members of the appeals boards are full-time employees of the Office for a five-year fixed term, but they work in a separate Directorate-General from the examining corps. Cases cannot be appealed to the European Court of Justice because the Organization is not part of the European Union.

II. Challenging the European Patent System

Like its counterparts across the world, the European patent system has experienced growing challenges to its decisions, policies, and practices. Over the last thirty years, a wide variety of groups, including environmentalists, animal rights activists, patient advocates, scientists, and development organizations, have argued that it needs to develop a broader understanding of its responsibility to the public interest that would include ethical, social, environmental, and health

32. R. Singer, *The European Patent Enters a New Phase*, STAFF UNION EUR. PATENT OFFICE (1970), available at www.suepo.org/public/background/singer.pdf.

33. Dietmar Harhoff & Markus Reitzig, *Determinants of Opposition Against EPO Patent Grants—The Case of Biotechnology and Pharmaceuticals*, 22 INT'L J. IND. ORG. 443 (2004).

considerations.³⁴ Some also argue explicitly that human rights need to be balanced against the rights of the patent holder.

In Europe, these challengers have used two strategies. First, they try to influence the European patent system through the European Parliament. In the late 1980s, for example, challengers developed a large, global network of opponents when Parliament considered a Directive that would harmonize patent law regarding biotechnology across member states.³⁵ The biotechnology industry had strongly advocated this legislation (known as the EU Biotech Patent Directive), arguing that it would facilitate innovation and economic growth. The EPO also agreed to follow whatever legislation the European Parliament ultimately passed, as acceptance would facilitate relationships with patent offices in EU countries (most of whom sat on the EPO's Administrative Council), and it would also provide some political legitimacy for its decision-making in an area that was becoming controversial.

The Biotech Patent Directive generated controversy soon after the European Commission introduced it into the European Parliament in 1998. While the Commission saw the Directive as merely a legal and economic initiative, most Parliamentarians disagreed and urged attention to the ethical, social, ecological, and economic implications of patents.³⁶ Buoyed by support from Greenpeace and other groups, they refused to pass the law without some consideration of these issues. Many argued that the European Patent Convention's *ordre public* clause disallowed many biotechnology patents, particularly those involving life forms. They demanded that the Directive articulate this and clarify the clause's relevance to the implications of patents. Despite its original meaning allowing for sensitivity to national differences, this language had now created an opportunity for a vigorous debate about the role of social, ethical, and ecological concerns in discussions about patent law. By 1995, critics had won some concessions, but they

34. S. Parthasarathy, *Breaking the Expertise Barrier: Understanding Activist Strategies in Science and Technology Policy Domains*, 37 SCI. & PUB. POL'Y 355 (2010), available at <http://www-personal.umich.edu/~shobita/files/breaking%20the%20expertise%20barrier.pdf>; S. Parthasarathy, *Whose Knowledge? What Values? The Comparative Politics of Patenting Life Forms in the United States and Europe*, 44 POL'Y SCIENCES 267 (2011), available at <http://www-personal.umich.edu/~shobita/files/Parthasarathy%20policy%20sciences%20preprint.pdf>.

35. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213), 13; Steve Emmott, *No Patents on Life: The Incredible Ten-Year Campaign Against the European Patent Directive*, in REDESIGNING LIFE? THE WORLDWIDE CHALLENGE TO GENETIC ENGINEERING (Brian Tokar ed., 2001).

36. Emmott, *supra* note 35.

rejected the Directive in order to force the Commission to revise the language in line with their concerns.³⁷

The European Commission introduced an amended version in December 1995, which again mobilized challengers both inside and outside of Parliament.³⁸ The European Parliament debated the legislation for another two years and passed a revised version in July 1998.³⁹ The final Directive included some attention to critics' concerns. It specified the EPC's *ordre public* clause and prohibited, among other things, inventions that involved "commercialization or exploitation" of the human embryo (e.g., stem cells and methods of isolating them, embryos and methods of creating them). It outlawed patents on plant and animal varieties. It also required examiners to perform a risk/benefit "balancing" test when considering patents on animals, to ensure that the benefits to humanity outweighed the risks to the animal involved.⁴⁰ It gave the *ordre public* clause bioethical meaning, and also made patent law an important political issue ripe for widespread public engagement. In fact, it was the first time that the European Parliament had deliberated for so long on an issue, and had such an impact on policy.

In the years since, challengers have continued to lobby the European Parliament to address their concerns regarding the patent system. In the early 2000s, they persuaded it to reject a directive designed to harmonize laws governing software patents. Various groups including the EuroLinux Alliance and the Foundation for a Free Information Infrastructure argued that such patents would stifle innovation.⁴¹ Challengers have also convinced the European Parliament to issue non-binding "resolutions" condemning decisions by the EPO to grant specific patents including those covering genes linked to breast and ovarian cancer

37. Interview with Rep., Women's Environmental Network, in London, UK (2007).

38. Global 2000 & Kein Patent auf Leben, Directive: Legal Protection of Biotechnological Inventions (Munich/Brussels, May 25, 1997); Church of Scotland Science, Religion, and Technology Project, Churches Challenge European Parliament on Patenting Life, *available at* <http://webzone1.co.uk/www/srtproject/meppat.htm> (1997); Dinham, B, Pesticides Trust, et al. to P Stevenson, Compassion in World Farming et al., Suggested Plans for Meeting with John Battle MP (July 24, 1997).

39. Directive 98/44/EC, *supra* note 35.

40. I. Schneider, *Can Patent Legislation Make a Difference? Bringing Parliaments and Civil Society into Patent Governance*, in *POLITICS OF INTELLECTUAL PROPERTY: CONTESTATION OVER THE OWNERSHIP, USE, AND CONTROL OF KNOWLEDGE AND INFORMATION* 129 (S. Haunss & Kenneth C. Shadlen eds., 2009); Peter Drahos, *Biotechnology Patents, Markets, and Morality*, 9 E.I.P.R. 441 (1999).

41. Karanović, *supra* note 27.

susceptibility (known as the BRCA genes), the cryopreservation of germ cells, and stem cells.⁴²

In addition to challenging patent policy at the European Parliament, many challengers have mobilized against specific patents issued by the EPO. If they deem a patent to be problematic, they both launch a public relations effort (including press conferences, press releases, and street protests) and use the EPO's official opposition process. As discussed above, the EPC designed the EPO's opposition process to reduce post-grant litigation and enhance patent quality. Challengers, however, have used it to force the EPO to consider the consequences of its actions, often by arguing that a problematic patent violates the *ordre public* clause. They have opposed dozens of patents this way, including those that cover life forms, traditional knowledge, and important drugs.

In one of the largest challenges that proved to be particularly important for the EPO, twenty-one groups (including Greenpeace; Belgian and Swiss chapters of No Patents on Life; and British, German, and Austrian animal rights organizations) opposed a patent on a mammal genetically engineered to contract cancer (known worldwide as the Harvard "Oncomouse" patent). The patent was controversial even before it was granted: multiple groups submitted third-party observations to the EPO, urging it not to issue the patent because it violated the *ordre public* clause. EPO granted the patent in 1992, arguing that it passed a "weighing up" test in which EPO compared the benefits to humankind with the animal's suffering. Challengers responded to the EPO by filing twenty-one oppositions, and engaged the bureaucracy in a debate over what constituted relevant knowledge for determining a violation of the *ordre public* clause.

Ultimately, the Opposition Division asked the inventors to rewrite the patent to cover only rodents. If we focus on the legal consequences of the Oncomouse decision, we may observe only the challengers' impact on the individual case. However, interviews with EPO officials suggest that it was a major turning point in the culture and orientation of the office. One high-level official recalled that period:

[W]hen the Oncomouse Harvard patent was granted in 1992, a big storm arose that nearly swept away the EPO, because people [here] were so strongly inward looking at this place that they didn't realize what was going on. That the work that they were doing was not just considered to

42. See, e.g., European Parliament, European Parliament Resolution on the Patenting of BRCA1 and BRCA2 ("Breast Cancer") Genes, (Oct. 3, 2001), available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+MOTION+P5-RC-2001-0633+0+DOC+XML+V0//EN>; European Parliament, Resolution on the Decision by the European Patent Office with Regard to Patent No. EP 695351 Granted on 8 December 1999, O.J. C378 (Dec. 29, 2000), at 96–97.

be of relevance to pharmaceutical companies and other innovators, but there was a strongly social component as well. And this is the bitter lesson they had to learn....⁴³

During and after the Oncomouse controversy, challengers involved in the case and other like-minded groups filed oppositions against dozens of other patents.⁴⁴ They challenged patents on genes, stem cells, genetically modified plants and animals, and methods of gene and embryo manipulation, among many other things. In each case, challengers used evidence and expertise and invoked civil rights that the EPO had not traditionally considered. As they had to contend with these issues, EPO officials began to believe that they had to find a way to incorporate such concerns into their decision-making. One noted:

In general, I think that it's important...for people dealing with patents to keep in mind where the system comes from. What its legitimacy and its social basis are. So to really keep in mind the social contract of private benefit and public benefit and incentive for innovation on the one hand but disclosure and promoting innovation for the public good on the other hand. I think that probably has been lost....⁴⁵

Both the debates at the European Parliament and the individual oppositions at the EPO attacked the practices, policies, and laws of the European Patent Office. Challengers argued that the EPO was not considering the public interest adequately, and they used a variety of tactics to demonstrate this. The EPO could have responded as the USPTO did, for example, by arguing that such concerns were irrelevant. But its personnel did not, in part because of the system's history and political context. It had always been part of the emerging policy apparatus of Europe, and its employees saw themselves as civil servants. Therefore, the EPO could not ignore the cries of challengers who claimed to represent the public interest. Furthermore, its structure and position as a pan-governmental organization outside the European Union connected it directly to the European citizenry. While the USPTO could look to the US Congress to deal with political concerns

43. Interview with Employee A, EPO, in Munich, Ger. (June 25, 2008).

44. See, e.g., Greenpeace, *Liste Der Einsprechenden Gegen Patent EP 695 351/ Sammeleinspruch Greenpeace Stand 17.4.00* (Apr. 18, 2000); *Kein Patent Auf Leben, Sehr Geehrter Herr Wolinski, Beilegend Möchte Ich Nochmal Acht Dokumente in Das Beschwerdeverfahren Einbringen* (Nov. 4, 2004); see also S. PARTHASARATHY, *BUILDING GENETIC MEDICINE: BREAST CANCER, TECHNOLOGY, AND THE COMPARATIVE POLITICS OF HEALTH CARE* (2007).

45. Interview with Employee B, EPO, in Munich, Ger. (June 25, 2008).

and represent the will of the public, the EPO stood alone and therefore had to think more strategically about maintaining its legitimacy.

III. Systemic Responses

High-level officials at the EPO tried to address these issues through changes to its organization and culture. One set of initiatives focuses on educating its employees, including examiners, about the concerns of activists, national governments, and the media. In the early 1990s, *The Gazette*, the EPO's internal newsletter that is distributed to all employees, began to publish original articles about ethics and biotechnology, reprint relevant EPO press releases announcing the activist oppositions, and display photographs of the protests occurring outside of its buildings.⁴⁶ Previously, it had published only internal announcements, including listings of job openings, promotions, and new employees; short articles about foreign visitors to the EPO; and announcements about and reviews of (mostly social) EPO events. In 1992, for example, the *Gazette* announced an essay competition on "Patents and Ethics in the Context of Modern Technology" among employees at the EPO. Two winners received 15000 and 10000 German marks (about \$10,000 and \$6,500, respectively) with the essays published not only in the *Gazette*, but also in major European newspapers (*Financial Times*, *Le Monde*, *Neue Züricher Zeitung*, and *Süddeutsche Zeitung*).⁴⁷ The EPO's decision to engage its employees in discussions about the social and ethical dimensions of patenting is quite interesting. Officials could have decided that coverage of these issues would be distracting or demoralizing, or perhaps worst of all, interrupt the objectivity of their employees' work. However, they decided the opposite. Thinking more about the issues of controversy, high-level officials seemed to believe, would make all employees do a better job.

Internal discussions about the social and ethical implications of patenting grew considerably in the 2000s, when Alain Pompidou, a trained biomedical scientist and doctor, became president of the EPO. Pompidou had long been involved in discussions about the appropriate development of biomedicine and biotechnology, and sought to encourage such discussions in the Office. For example, he asked the EPO's Learning and Development Directorate (which is in charge of all personnel training efforts) to organize a series of lectures entitled "Ethics and Science: Are They Connected?" The purpose of the nine lectures,

46. B. Karet, *Patents and Ethics in the Context of Modern Technology*, EPO GAZETTE (Newsletter) (Munich) 1992, at 13–17.

47. *Patente auf Lebewesen und Gene*, FRANKFURTER ALLGEMEINE ZEITUNG (July 14, 1993), at N1.

which were simulcast in the EPO's Munich and Hague offices and held over the course of a year and a half, was to "increase staff awareness of the ethical aspects of novel technologies."⁴⁸ Pompidou suggested the list of speakers for the series, most of whom were European professors of philosophy or bioethics. He sought to use the series to teach the EPO's personnel, and examiners in particular, "that patents were no longer limited to technical and legal subject matter. It should be looked at in broader context."⁴⁹

This training effort also emphasized the relevance of social and ethical expertise to better work output, although it was not explicitly connected to the patent decision-making process. Perhaps the grandest attempt to change the EPO's practices was the "Scenarios" project, a multi-year effort initiated in 2004 to encourage strategic thinking about the future direction of the Office and the role of the patent system in global society. These efforts began with interviews of over one hundred scholars and stakeholders from all over the world, who were asked to predict and discuss the different social, political, and economic pressures that the Office might face by the year 2025. A small group of personnel from the EPO—including people from all departments and levels—interviewed both traditional stakeholders and experts (e.g., from inventor organizations, patent law firms, high-technology companies) and new players in this arena (e.g., Greenpeace, philosophers, political scientists, international development organizations). The effort was meant to expose the EPO's personnel and the public to new sources of expertise about the role of the patent system in society, while also providing external players with an opportunity to shape the future of the organization.

The EPO's team then used this interview data to construct four possible future scenarios. Although all of them touched on the activist challenges in some way, the "Trees of Knowledge" scenario addressed social and ethical concerns directly. In this scenario, the EPO's personnel tried to predict the kinds of dilemmas that might arise if the grassroots movements continued to grow and public trust in government, industry, science, and technology continued to erode. In particular, authors of this scenario organized the discussion around three "key" questions: "How can public and private interest in IP [intellectual property] be reconciled for the benefit of society? How are the ethical and moral dilemmas raised by technology reflected by the patent system? Where should the limits of patentability be drawn? By whom?"⁵⁰ These were large and complicated questions, which required contemplation of issues that were quite new. Until

48. S. Bayrak, *Ethical Issues in Engineering and Science*, EPO GAZETTE (Newsletter) (Munich), July–Aug. 2007, at 15.

49. Interview with Employee D, EPO, in Munich, Ger. (Feb. 9, 2009).

50. EUR. PATENT OFFICE, SCENARIOS FOR THE FUTURE 83 (2007).

relatively recently, they might have seemed inappropriate for deliberation by a technical bureaucracy such as the EPO.

The final report of the Scenarios project was unveiled in April 2007 at a large event in the EPO's Munich Office.⁵¹ Major figures in European politics and policy—including German chancellor Angela Merkel—participated, and not surprisingly, the event was well-attended by the EPO's employees.⁵² All EPO employees received copies of both the final report and a book of the interview transcripts, to expose them to new ideas. Although most examiners have day-to-day contact with inventors and patent lawyers through the examination process, they rarely hear, for example, the arguments of the Church of Scotland regarding the patentability of living organisms.

Since the report's release, and as new presidents have taken over, the EPO has gotten involved in a variety of policy discussions. In 2009, it hosted a workshop designed to enhance its relationship with civil society groups, including the nongovernmental organizations that had attacked its work for decades. And in 2010, concerned about whether the monopolies created by patents were hurting climate change mitigation efforts by stifling access to innovation, the EPO (with the United Nations Environment Programme and the International Centre for Trade and Sustainable Development) issued: *Patents and Clean Energy: Bridging Evidence and Policy*.⁵³ It had clearly extended its responsibility to cover the implications of patents, and no longer focused simply on the “technical” job of issuing them. Furthermore, it seemed to acknowledge that simply granting intellectual property rights might not achieve the public good.

European Patent Office officials have also instituted changes to the patent examination process. The EPO has developed a Sensitive Cases, or SeCa, system, to identify and deal with applications it deems controversial. The SeCa system begins at the classification stage. The EPO's Receiving Section marks with a 3x5-inch sticker applications assigned to technical departments (known as “Clusters”) that the Communication department has identified as particularly controversial (e.g., biotechnology, nanotechnology). The sticker provides a series of prompts meant to guide examiners through an assessment of an application's sensitivity, and procedures for additional review. Two aspects of this system

51. Press Release, European Patent Forum (Apr. 18, 2007)

52. *Id.*

53. U.N. ENV'T PROGRAMME, EUR. PATENT OFFICE & INT'L CTR. FOR TRADE & SUSTAINABLE DEV., *PATENTS AND CLEAN ENERGY: BRIDGING EVIDENCE AND POLICY - FINAL REPORT* (2010), available at http://www.unep.ch/etb/events/UNEP%20EPO%20ICTSD%20Event%2030%20Sept%202010%20Brussels/Study%20Patents%20and%20clean%20energy_15.9.10.pdf (last visited Sept. 5, 2013).

deserve special note. First, it is formalized through preprinted stickers and a systematic change in the administrative routine of the classification department and specific Clusters. Second, it focuses on applications in technical fields that personnel in the Communication department recognize as publicly controversial. These two elements thus serve as a constant reminder to examiners of the consequences of their work and the gravity of their responsibility to the European public.

When an examiner receives an application with a SeCa sticker, she must conduct an additional determination of sensitivity in addition to her evaluation of scientific and legal patentability. This determination also involves an assessment of whether the application might be in violation of the *ordre public* clause of the EPC and its elaboration in the EU Biotech Patent Directive. Usually, the examiner judges the sensitivity of an application using a set of examples provided by supervisors and the examiner's own intuition.⁵⁴ The only exception is the "balancing" test that examiners must perform when considering the patentability of animals. Even in these cases, however, examiners receive no training to help them perform this systematic ethical analysis; they must rely on their own judgments. One examiner explained his approach,

It's a bit in the discretion of the examiner to decide what he thinks is [sensitive.]... But it's a balancing act between the patient and the suffering animal. And of course in some cases, for a cat if you have cosmetic purposes and if that causes suffering. But in other cases it might be more difficult for you to decide if it has a small medical benefit and you have a lot of suffering....⁵⁵

Although high-level officials at the EPO have sponsored many initiatives to emphasize the relevance and legitimacy of social and ethical knowledge, they have not trained examiners to deploy this knowledge in a systematic or rational way in patent decision-making. Even when they are required by law to engage in ethical reasoning, examiners have had to rely on their individual judgments. Upon request, they can also receive input from the EPO's patent law experts to facilitate their decision-making.

If the examiner ultimately makes a determination of sensitivity, the application must be reviewed and certified by Team and Directorate supervisors and the director of the Cluster. If they agree with the examiner's assessment, the application is registered in the SeCa database, which is available to all of the EPO's

54. Interview with Employee F, EPO, Munich, Ger. (2009).

55. Interview with Employee E, Munich, Ger. (Aug. 11, 2008).

employees. A specially designated SeCa Advisory Board, made up of examiners, patent lawyers, and public relations personnel inside the EPO periodically reviews the database so that they can be aware of the progress of these applications, and prepare if the examiner decides to issue a patent based on that application. Meanwhile, the examiner proceeds with the review process. If she made the sensitivity determination because she believes that the application is contrary to the *ordre public* clause, she will reject it and advise the inventor about the problem. The inventor may decide to revise the application to avoid the problem, or simply challenge the rejection. As with all other applications, this process continues until the patent is either issued or rejected. Overall, officials hope that the SeCa system will encourage examiners to scrutinize their work more carefully, and ask themselves: “What’s happening here? Do we have a quality problem? Are you granting patents you shouldn’t be granting?”⁵⁶

The SeCa system, however, is only part of a multi-pronged crisis management system. The EPO issues press releases and fact sheets when it grants a patent that is likely to become controversial, after controversies have erupted, and in response to general areas of controversy (e.g., patents on living organisms or software)—describing the issues of public concern and the reasons behind its decision-making.⁵⁷ These external relations efforts are overseen not only by the Communications department, but also by newly created Issue Management Groups (IMGs), composed of examiners, patent lawyers, and public relations specialists, all from inside the organization.⁵⁸ Each IMG specializes in one controversial technical area (e.g., computer-implemented inventions, biotechnology), and helps communications officials develop strategies to deal with patent applications that have been identified through the SeCa system while also helping them interact generally with stakeholders on issues that have become controversial. Issue Management Group members are often sent out as envoys to patent-related events throughout Europe, so that they can listen to the concerns of various groups and also explain the position of the Office. They also might review drafts of press releases, or speak to members of the EPO’s Administrative Council or the EU’s Parliament to alert them to the impending issuance of a controversial patent. The IMGs and increased contacts with the press were created to better communicate with the public and explain the EPO’s decisions, while also gathering information about issues of public concern for further discussion inside the EPO.

56. Interview with Employee A, EPO, Munich, Ger. (June 25, 2008).

57. See, e.g., Press Release, European Patent Office, Opposition Hearing on Genetic Stem-Cell Patent (2002); European Patent Office, Hintergrundinformationen zum “Öl-Mais”-Patent, Fact Sheet (2003).

58. Interview with Employee A, EPO, in Munich, Ger. (June 25, 2008).

Conclusion

This chapter has demonstrated major changes taking place in the European patent system, in response to the activist challenges that have emerged over the past three decades. If we had focused our analysis on the European patent system's response through case law, the picture would have looked quite different. First, we might have focused on the debate over the EPC's *ordre public* clause, rather than understanding this debate as part of a large, global challenge to the way that patent systems understand their responsibility to the public interest. Second, we would have probably observed the uneven and limited legal outcomes achieved by challengers and concluded that these activists are little more than a minor and temporary irritation to the European patent system.

When we explore these challenges and the responses by the European patent system in historical, social, and political context, not only do we see a much more comprehensive challenge, but also a more comprehensive response. The European patent system has responded to challengers legislatively, through non-binding resolutions and binding Directives. It has also responded organizationally and culturally. The European Patent Office has informed its employees about the nature of these challenges and changed its administrative routines through the SeCa system and the IMGs. It has also begun to take an active role in policy debates, issuing research reports focused on the implications of patents in controversial areas including climate change. These changes serve to teach EPO employees about the complex consequences of their work, and their responsibility to keep the public benefit at the forefront of their minds. These initiatives suggest that the EPO sees itself in a balancing role, rather than assuming that assigning rights to the patent holders will automatically benefit the public interest. Examiners learn, for example, to keep in mind the costs and benefits of patents and to understand that these costs and benefits extend beyond the economic realm. They are, however, provided with only limited guidance regarding how, exactly, to incorporate this understanding into the everyday practice of patent examination.

The European patent system's response seems less surprising when considered in historical context. Born out of the rubble of two world wars, it has always been more than a special legal domain. It was, and is, an important policy instrument designed to strengthen the idea of a unified Europe. Furthermore, even as its creators debated its structure and orientation, they considered its implications for public health, public policy, and even public morality. As a result, when challengers demanded that the system do a better job of considering the public interest, its insiders could not argue that such issues were irrelevant. Rather, they struggled to determine *how* to do a better job fulfilling the system's responsibilities.

But will these organizational and cultural changes have a long-term impact on decision-making by the European patent system? It is impossible to say. There are

signs that it has already had an impact, and that the system is only increasing its attention to the complex implications of patents. A representative of Greenpeace noted: “The Patent Office has completely changed its attitude. . . . I think there are more internal quality checks and internal meetings and people following these discussions. So it has changed definitely.”⁵⁹ But, there remains little guidance as to how, exactly, examiners should consider the broad implications of patents in their decision-making. Regardless, as we forecast the future path of the European patent system, we must consider its efforts in this area. As we have demonstrated, to focus solely on its legal decision-making would hamper our ability to understand what it is and how it might evolve.

Overall, we have demonstrated the importance of understanding legal institutions—and particularly patent systems—in their social and political context. This kind of analysis can be difficult and time-consuming, requiring data-gathering from personnel and records that do not seem directly connected to decision-making or legal precedent. However, this approach not only puts legal analysis in perspective, but it also demonstrates how factors outside of the law shape a legal domain’s past, present, and future.

59. E-mail from Greenpeace Rep. #1 to authors (Aug. 8, 2008) (on file with author).

