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**This is the Accepted Version of the Following Article: The EPO as Patent Law-Maker  
in Europe**

## **The EPO as Patent Law-Maker in Europe**

### **ABSTRACT**

This article examines the role of European Patent Organization (EPO) in the European patent system. It shows how the delineation of European patent law has been handed over by governments to an autonomous, quasi-judicial technocracy at the EPO and reveals how the process of hollowing out economic and political factors in the grant of patents is assisted by the deference of national courts to the EPO and the creation of the Unified Patent Court. It suggests that these developments pose a threat to democratic governance of the patent system in Europe because the delineation of intellectual property rights has inherent economic and political dimensions which are not reducible to technical legal issues of interpretation or technocratic expertise.

### **INTRODUCTION**

In the last decade a rich body of scholarship has emerged on global constitutionalism and the role of courts in multi-level judicial review in democracies.<sup>1</sup> In Europe, two interdisciplinary centres have been created in Oslo and Copenhagen respectively to engage in long-term research projects on the origins, function and legitimacy of courts and the growing international judicialisation of global governance. At the iCON 2017 international conference on ‘Courts, Public Power and Public Law’, hundreds of presentations were devoted to the ascendancy of constitutional and international courts, commercial tribunals and the WTO whilst just one panel addressed the topic of intellectual property and specialist patent courts.<sup>2</sup> Yet, the growth of specialist patent courts poses unique and critical challenges for democratic governance because of the powerful monopolies created by intellectual property rights. This suggests that there is a gap in the burgeoning research on judicial governance in liberal democracies and the scholarship on global governance of intellectual property rights.<sup>3</sup> In Europe, the creation of the Unified Patent Court (UPC) has given rise to polarized views on the UPC’s relationship with the Court of Justice of the European Union

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<sup>1</sup> Notably R. Hirschl, *Towards juristocracy: the origins and consequences of the new constitutionalism* (Harvard University Press, 2009), S. Gill & A. Cutler. (Eds.), *New constitutionalism and world order* (Cambridge University Press, 2014)

<sup>2</sup> iCON-S 2017 Conference on “Courts, Powers, Public Law”, Copenhagen, July 5-7, 2017

<sup>3</sup> A rare exception is K. J. Alter & L. R. Helfer, *The Law and Politics of the Andean Tribunal of Justice*. (Oxford University Press, 2017). On the creation of specialist patent courts in the US, see Dreyfus, R. C. (2009). What the Federal Circuit Can Learn from the Supreme Court-and Vice Versa. *Am. UL Rev.*, 59, 787.

(Court of Justice). Much of this scholarship explores the constitutional avenues for closer integration of the UPC with the Court of Justice whilst implicitly assuming that more judicial involvement at a higher level will mean more checks and controls over commercial interests and ultimately more democracy in the grant and enforcement of patents in Europe.<sup>4</sup> Calls for greater involvement of the Court of Justice also tend to assume that democratization of the European patent system will be achieved with the aid of the Charter of Fundamental Rights as a legal brake on the rights of exclusivity and monopolies created by patents.<sup>5</sup> None of this scholarship engages with the theoretical and comparative empirical studies that question the wisdom that more courts and more human rights means more democracy. This paper is intended to begin the process of bridging the gap between the critical scholarship on judicial governance in liberal democracies and the IP scholarship on governance of intellectual property rights in Europe. The first part sets out the social and economic significance of patents and the threats to democratic governance posed by the rise of juristocracies. The second part examines the role and structure of the European Patent Organization (EPO). It argues that whilst the EPO is presented as a functionalist, a-political organization, in reality, the EPO is the main determinant of patent policy and patent law in Europe. The analysis further reveals that whilst the EPO is not an agency of the European Union, it exercises similar functions to European Union agencies but is fully insulated from control by national legislatures and the European Union. The last part examines the normative path dependencies resulting from the EPO's role in the grant of European patents and its privileged position as first interpreter of the European Patent Convention (EPC). It illustrates the deference shown to the EPO by generalist national courts through the case study of the UK Supreme Court's approach and it argues that this deference is indicative of the hegemony of the EPO whose role remains unaltered by the UPC.

## 1 The Origins of Patent Monopolies

Patents are economic rights which confer on patent holders the right to exclude others from using the patented invention for a minimum period of twenty years.<sup>6</sup> As such, patents enable patent holders to control markets and exercise a powerful monopoly since they prevent competition from others in the use and exploitation of the invention. This may seem paradoxical since patent advocates are also typically proponents of neo-liberal market freedoms but the tension between patent monopolies and free trade was well understood by economists in the nineteenth century who vigorously questioned the wisdom that patent monopolies would promote economic progress.<sup>7</sup> All the same, patent protectionism ultimately prevailed and paved the way for global harmonization of IP rights, originally through the adoption of the Paris Convention for the Protection of Industrial Property adopted in 1883 and the Berne Convention for the Protection of Literary and Artistic Works adopted

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<sup>4</sup> See for instance T. Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit', (2017) 48(3) *IIC-International Review of Intellectual Property and Competition Law* 254-285. T. Mylly, 'Hovering between intergovernmentalism and unionization: the shape of unitary patents', 54.5 (2017) *Common Market Law Review* 1381-1425

<sup>5</sup> C.S. Petersen, C. S. & J. Schovsbo, 'Decision-Making in the Unified Patent Court: Ensuring a Balanced Approach' in C. Geiger, C. Nard and X. Seuba (eds), *Intellectual Property and the Judiciary* (Edward Elgar, 2018) 231-254

<sup>6</sup> Article 33, Trade Related Agreement on Intellectual Property Rights (TRIPS)

<sup>7</sup> F. Machlup and E. Penrose, 'The patent controversy in the nineteenth century', (1950) 10(1) *The Journal of Economic History* 1-29

in 1886. Both treaties were later incorporated and IP protection expanded in the Trade Related Agreement on Intellectual Property Rights (TRIPS, 1994) adopted in the Uruguay round of the GATT negotiations which led to the creation of the World Trade Organization (WTO). TRIPS has been described as the most important international law treaty of the twentieth century because it imposes an obligation on all Members of the WTO to adopt minimum standards of intellectual property protection under the jurisdiction of the WTO dispute settlement system.<sup>8</sup>

In modern liberal economies, patents are justified as incentives on the grounds that they promote innovation and economic growth.<sup>9</sup> The utilitarian rationale is that rights of exclusivity act as incentive for investors who may recoup their costs during the life of the patent whilst others are stopped from imitating the invention. The ‘social-bargain’ theory of patents also posits that society benefits from disclosure of the technical details of the invention in the patent application as these details would otherwise typically be protected by commercial secrecy. Empirical evidence backing-up the theory is difficult to summon due to the complex causal network of economic factors contributing to the value of intangible property.<sup>10</sup> But the adverse impact of patents in different sectors of the economy and on countries at different stages of industrial development has been extensively documented in numerous studies.<sup>11</sup> In the IT sector in the US, industry leaders and economists have warned Congress that patents are stifling innovation instead of promoting it.<sup>12</sup> In the health sector, the main beneficiaries of patents have been transnational pharmaceutical corporations in economically advanced Western countries.<sup>13</sup> At the height of the AID crisis in Africa, when eight million lives were at stake, thirty nine pharmaceutical corporations invoked the obligations imposed by TRIPS on WTO Members to file a suit against the Mandela government to prevent import of generic, essential, life-saving medicines.<sup>14</sup> Two decades later, a UN High Level panel has reported that patent monopolies are continuing to prevent access to essential medicines in developing countries.<sup>15</sup> Meanwhile, the European Union’s IP policy in its Free Trade Agreements (FTA) with developing countries mirrors the US policy

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<sup>8</sup> The tension between IP protectionism and free market competition is discussed by J. Reichman ‘From free riders to fair followers: global competition under the TRIPS agreement’, (1996) 29 *NYUJ int’l L. & pol.* 11. Reichman argues that IP protectionism stands against the public interest in free competition and enjoins developing countries to counteract the adverse social and economic impact of TRIPS through the adoption of pro-competitive policies.

<sup>9</sup> See for instance D. Guellec and B.V.P de La Potterie, *The economics of the European patent system: IP policy for innovation and competition* (Oxford University Press, 2007) and T. Daiko, H. Dernis, M. Dosso, P. Gkotsis, M. Squicciarini, A. Vezzani, *World Corporate Top R&D Investors: Industrial Property Strategies in the Digital Economy*, A JRC and OECD common report (Publications Office of the European Union, 2017) using patent data as proxy for innovation.

<sup>10</sup> See S. Scotchmer, (1991) 5.1 ‘Standing on the shoulders of giants: cumulative research and the patent law’ *Journal of economic perspectives* 29-41 and World Intellectual Property Report, *Intangible Capital in Global Value Chains* (WIPO, 2017)

<sup>11</sup> J.E. Stiglitz, *Intellectual property rights, the pool of knowledge, and innovation* (National Bureau of Economic Research, 2014) and K.E. Maskus, *Intellectual property rights in the global economy* (Peterson Institute, 2000)

<sup>12</sup> J. Bessen and M.J. Meurer, *Patent failure: How judges, bureaucrats, and lawyers put innovators at risk*. (Princeton University Press, 2008)

<sup>13</sup> United Nations Secretary-General’s High Level Panel on Access to Medicines Report (2016)

<sup>14</sup> Medecins Sans Frontieres, 39 Drug Companies vs South Africa: People die for lack of affordable drugs as inhumane industry ignores reality, Press Release, 5<sup>th</sup> March 2001

<sup>15</sup> Op. cit. 14

in bi-lateral and multi-lateral FTAs, used as a vehicle to impose higher standards of intellectual property protection than those required by TRIPS (known as TRIPS-plus) to the benefit of private corporations and detriment of vulnerable populations.<sup>16</sup> In what critics have described as a form of neo-colonialism, the EU has been using its economically dominant position in FTAs to require Colombia and other developing countries to offer TRIPS-plus protection in the form of eight additional years of IP protection to drug manufacturers and an obligation to prevent access to clinical trial data for five years after the patent term has expired, thus delaying the entry of generics and increasing their cost.<sup>17</sup> Internally, the European Union's harmonization of intellectual property rights has also exceeded the minimum international standards of IP protection. For instance the European Union, in line the US, opted to increase the term of protection for copyright and related rights from 50 years after the life of the author to 70 years (Article 1(1) of Directive 93/98). Similarly, the controversial Directive on the legal protection of biotechnological inventions (Directive 98/44) extended patent protection to isolated genes and cells in line with the policy of the US patent office at the time. It bears noting that the policy of the US patent office was invalidated by the US Supreme Court thirty years later in a landmark case on the patenting of breast cancer genes.<sup>18</sup> Outside pharmaceuticals, the main concern has been the extension of patent protection in Article 27 TRIPS to "all fields of technology", thus including software, digital information and communication technologies.<sup>19</sup> In the European Union, intellectual property rights were extended to upstream data in the EU Directive on Legal Protection of Databases (96/9). Together with the practice of leading patent offices in industrialised countries around the world to lower the bar for the grant of patents, global harmonisation of intellectual property rights in the last three decades is rapidly leading to the appropriation of all fields of knowledge by IP holders. As noted by Heller, Boyle, Drahos, Correa, Reichmann, Mascus, Stiglitz, Plomer and others, the extension of intellectual property rights to the knowledge economy has erected barriers to the diffusion of knowledge, resulted in a closure of the scientific commons and created obstacles to the realization of fundamental human rights.<sup>20</sup> For this reason, patents in fundamental fields of science and technology have been conceptualized as a tax on knowledge as a public good and a power grab on the global governance of knowledge. The balance between the interests of investors and innovators,

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<sup>16</sup> H. Ullrich, R.M. Hilty, M. Lamping and J. Drexler, (Eds.), *TRIPS Plus 20: From Trade Rules to Market Principles* (Springer, 2016). X. Seuba, (2013) 16(5-6) 'Intellectual Property in Preferential Trade Agreements: What Treaties, What Content?' *The Journal of World Intellectual Property* 240-261. B.A.M. Araujo *The EU Deep Trade Agenda* (Oxford University Press, 2016)

<sup>17</sup> D. Acquah, 'Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU—Is There a Need to Rebalance?' (2014) 43(3) *IIC-International Review of Intellectual Property and Competition Law* 256-286

<sup>18</sup> *AMP v Myriad Genetics Association for Molecular Pathology v. Myriad Genetics*, No. 12-398 (569 U.S. 576 (2013))

<sup>19</sup> For an analysis of the impact see J. H. Reichman 'Reframing Intellectual Property Rights with Fewer Distortions of the Trade Paradigm' in R. Dreyfuss, *Framing Intellectual Property Law in the 21<sup>st</sup> Century* (CUP, 2018) 66-88

<sup>20</sup> J. Boyle, *The public domain: Enclosing the commons of the mind* (Yale University Press, 2008), P. Drahos, *The global governance of knowledge: patent offices and their clients* (Cambridge University Press, 2010), M.A. Heller, 'The tragedy of the anticommons: property in the transition from Marx to markets' (1998) *Harvard law review* 621-688. K.E. Maskus and J. H. Reichman, 'The globalization of private knowledge goods and the privatization of global public goods'(2004) 7(2) *Journal of International Economic Law* 279-320. J.E. Stiglitz, 'Knowledge as a global public good' in I. Kaul, I. Grunberg and M. Stern (eds) *Global Public Goods: International Cooperation in the 21<sup>st</sup> Century* (Oxford University Press, 1999) 308-326. A. Plomer, *Patents, human rights and access to science* (Edward Elgar Publishing, 2015).

between IP holders and IP users, between private corporate interests and the public is thus critical to the design of a fair and just patent system. As patent laws are still predominantly territorial, this balance is effected mainly through the national laws of WTO members implementing TRIPS, the national patent offices granting the patents and national courts where the patents are enforced. In Europe, the territorial patent model is complicated by the addition of the European Patent Organization (EPO) and the Unified Patent Court (UPC).

### **1.1 The complex web of European Patent Law**

In Europe, in addition to filing patent applications in national patent offices, applicants may file an application for a European Patent at the European Patent Office (EPO). The EPO was established under the European Patent Convention (EPC) in 1973 as the institution charged with the responsibility to administer the grant of European patents which, by contrast to national patents, may potentially be enforced in the territories of all the countries which are Contracting Members of the EPC.<sup>21</sup> Article 1 of the EPC states that the Treaty creates “A system of law, common to the Contracting States, for the grant of patents for invention” (Article 1). European patents are to be granted “... in all fields of technology for inventions provided that they are new, involve an inventive step and are susceptible of industrial application” (Article 52(1)). Once granted, a European patent has the same legal effect and is subject to the same conditions as if it had been granted by a Member State (Article 2, EPC). European patents granted by the EPO thus stand to be ultimately enforced in national courts and potentially invalidated in accordance with national laws. For this reason, the European patent is referred to as “a bundle of patents”. Typically, upon grant, applicants designate four or five countries where they choose to enforce the patent and thus potentially stand to face infringement or invalidity proceedings in four or five national courts in Europe in accordance with each of these countries national laws. However, the EPC also includes a mechanism to challenge the validity of a patent at the EPO. The EPO is composed of several divisions and contains an internal appeal procedure to challenge the validity of patents granted by the examining division.<sup>22</sup> A patent granted by the EPO’s examining division may be declared invalid for lack of novelty, inventive step or industrial application on appeal to the opposition division, Technical Board of Appeal or Enlarged Board of Appeal.<sup>23</sup> Crucially, the EPO Technical Boards of Appeal have developed an extensive body of decisions on the interpretation of these three criteria, described in the EPO’s website as “case law”.

The national courts of EPO member States are not legally bound by the “case law” of the EPO boards on the interpretation and application of the three patentability criteria in Article 52.<sup>24</sup> Nevertheless, as will be seen in part III, since members of the EPO have agreed to the EPC “common” system of law, national courts are heavily guided by the EPO’s interpretation of these requirements and are wary of invalidating a patent granted by the EPO because of the risks of unsettling commercial expectations. Thus, the role of the EPO in the grant of patents has turned out to be of paramount importance in giving substantive legal content to the three general, abstract requirements of patentability which may be subsequently revisited by national courts in invalidity or infringement proceedings. It is true that national courts formally retain authority and discretion to interpret the EPC requirements for an invention

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<sup>21</sup> Article 4 EPC

<sup>22</sup> Chapter III, EPC

<sup>23</sup> The Opposition procedure is set out in Part V EPC

<sup>24</sup> As noted in the EPO’s website.

post-grant. There is therefore a degree of variability in the outcome of validity and infringement proceedings in national courts relating to the same patent granted by the EPO.<sup>25</sup> Indeed, fragmentation of patent litigation post-grant and the associated legal uncertainty and costs to patent holders have been the main reasons for the European Union's ambition to create a single, central court for the enforcement of patents post-grant in the form of the UPC (and its unsuccessful predecessors).<sup>26</sup>

However, as will be seen below, the criteria of 'novelty, inventive step and industrial application' in Article 52 EPC are a hybrid mix of technical and legal components encompassing economic and social considerations. Consequently, the standards applied in the examination of patent claims by the EPO and other patent offices have important social and economic consequences. Low standards produce poor 'quality' patents which are costly to challenge and distort markets. Patents on trivial inventions and the artificial extension of patent terms by pharmaceutical corporations, known as "ever-greening" have detrimental consequences on public access to medicines. Some countries have sought to limit the discretion of patent offices and courts through legislative provisions. For instance, section 3(d) of India's Patent Act, requires follow-on patent applications to show therapeutic efficacy. The EPC contains no such qualification, so the interpretation of the three requirements in Article 52 is left to the EPO in the first instance and to national courts in the event of invalidity or infringement proceedings being launched at national level. In this way, the structure and governance of the European patent system hedges towards empowerment of the EPO, an autonomous international organization with administrative and financial autonomy (Article 4, EPC) formally discharging an administrative function but in reality assuming a quasi-judicial function outwith the legal controls applicable to other administrative, technically oriented bodies with similar functions in the national and European Union legal systems.

## 1.2 The Emergence of a European Patent Juristocracy

The hegemony of the EPO in developing the legal contours of economic patent policy in Europe under an administrative, technocratic mantle is facilitated by its legal insularity as an international organization and the deference of national courts to the decisions of the EPO boards. For this reason, it is arguable that the European patent system is evolving towards a patent juristocracy. As Hirschl notes, juristocracies are problematic because the transfer of power to autonomous, professional policy making bodies is typically effected insulate policy preferences from democratic control.<sup>27</sup> Whilst the rise of judicial power in liberal democracies is extensively discussed there is no comparative research interrogating the emergence of a patent juristocracy in Europe. Why might this be?

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<sup>25</sup> Graham, Stuart JH, and Nicolas Van Zeebroeck. 'Comparing patent litigation across Europe: a first look' (2014) 17 STAN. TECH. L. REV. 655 and Cremers, Katrin, et al. 'Patent litigation in Europe' (2017) 44.1 *European journal of law and economics* 1-44

<sup>26</sup> See H. Ullrich, Hanns, 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' (2002) 4 *European Law Journal* 433-491. On the history of the creation of the EPO and the EU's ambition to create a single patent court in the EU, see A. Plomer 'A unitary patent for a (Dis) United Europe: the long shadow of history' (2015) 46.5 *IIC-International Review of Intellectual Property and Competition Law* 508-533.

<sup>27</sup> Op. cit 1 at 16

One possible explanation is that the literature on global constitutionalism and juristocracies is not directly relevant to the governance of IP rights because its focus is on the transfer of political questions to the (constitutional) judicial arena, primarily through the entrenchment of fundamental rights in national constitutions (or supranational Treaties to which national countries accede). Fundamental rights are typically general and abstract in orientation leaving considerable discretion to courts to interpret the substantive content of the rights in more or less socially progressive ways. By contrast, it may be argued, the rights conferred by patents rest on three legal criteria whose interpretation is dependent on the determination of complex technical issues of fact leaving little room for judicial discretion.<sup>28</sup> Patent examiners and patent law judges typically evaluate complex scientific data as “patent law cases can turn almost entirely upon an understanding of the underlying technical or scientific subject matter”.<sup>29</sup> However, as will be argued below, the interpretation of these criteria still leaves discretion to patent offices and courts to determine the appropriate legal threshold for the grant of a patent. The exercise of this discretion inevitably entails policy choices based on political and economic assumptions and preferences which are obscured by the technical orientation of patentability criteria. Furthermore, it is also at least arguable that the grant of intellectual property rights by patent offices and courts advances the interests of economic and industrial actors much in the same way that judicialisation of constitutional rights advances the interests of political elites in democracies. The key difference, as will be seen, is that the judicialization of patents in Europe is facilitated by empowerment of a quasi-judicial, technocratic body of European patent officials (at the EPO). These officials apply a ‘common’ body of law (novelty, inventive step, industrial application) parading as technical rules emptied of policy content with the complicit assistance of national courts deferring to the EPO boards, as illustrated by the approach of the UK Supreme Court discussed in part III. The creation of a Unified Patent Court, arguably, represents an intensification of the rise of a patent juristocracy in Europe driven by a quasi-judicial bureaucracy at the EPO primarily for the benefit of private commercial interests and industry.

Thus, an important theme linking the scholarship on juristocracies and global constitutionalism with the study of patent governance, is the role of patent offices and courts in supporting the interests of private actors in neo-liberal market economies. As noted by Max Weber “the fundamental building block of every successful capitalist market is a secure ‘predictability interest’”.<sup>30</sup> A key aim of political elites in neo-liberal democracies is to promote economic growth and encourage investment through the adoption of “predictable laws governing the marketplace and a legal regime that protects capital formation and ensures property rights.”<sup>31</sup> These aims have been at the heart of the European project to harmonize the grant and enforcement of patents in Europe. They were the prompt for substantive harmonization of European Patent laws in the Strasbourg Convention of 1962 and the creation of the centralized, autonomous organization for the grant of European patents a

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<sup>28</sup> de Werra, Jacques. "Specialised Intellectual Property Courts-Issues and Challenges." (2016)., Seuba, Xavier, Christophe Geiger, and Linhua Lu. "The Evaluation and Modernisation of the Legal Framework for the Enforcement of Intellectual Property Rights." (2016).

<sup>29</sup> S. Breyer, “The interdependence of science and law”, *Judicature*, July-August 1998, vol. 82, n° 1, p. 25. Seuba, Xavier. "Scientific Complexity and Patent Adjudication. The Technical Judges of the Unified Patent Court." (2017).

<sup>30</sup> Quoted by Hirschl, *op. cit* 1 at 37

<sup>31</sup> *ibid*



decade later in 1973.<sup>32</sup> Legal security and commercial certainty was also central to the latest attempt by the European Commission to revive the longstanding project of unification of the European patent system, this time in the form of the Unified Patent Court whose existence is parasitic on the EPO.<sup>33</sup>

## 2 The EPO as patent law-maker

### 2.1 The EPO's functions: administrative or judicial?

The European Patent Office (EPO) is one of the three leading patent offices in the world in terms of the number of applications received (34,302), after Japan (43,285) and the US (57,881).<sup>34</sup> It is followed closely by China (31,031). In 2016, the number of patents granted by the EPO increased by 40%, a record high in the EPO's history.<sup>35</sup> The leading countries of origin for applications to the EPO in 2016 were the US, Germany, Japan, France and Germany.<sup>36</sup> The majority of patents were granted to applicants outside Europe. Since patents confer significant economic rights and competitive advantages on patentees and the EPO is the only institution in Europe with the power to grant European patents the EPO, *de facto* and *de jure*, exercises a dominant economic function in developing patent policy and patent law in Europe. Yet, structurally, the EPO's decision making powers on the grant of patents are insulated from oversight by national legislatures and judicial review by national courts and the Court of Justice. The EPO defies established legal categories in national legal systems and boundaries in international law.

At first sight, the EPO shares with other inter-governmental international organizations supposedly a-political and functionalist dimensions.<sup>37</sup> According to classical functionalist theories, international organizations are created by Member States to act as their agent in the pursuit of a common good and for this purpose are endowed with certain powers, privileges and immunities. Although functionalist theories differ in their analysis of the function of international organizations, as Klabbers notes:

Regardless of which narrative is adhered to, functionalism plays the same role in all of them as a seemingly neutral, seemingly a-political and purely technical device on how to organize international organizations ...<sup>38</sup>

Indeed, the 'genius' of functionalism lies precisely in presenting international organizations as a-political and serving the interests of all. The EPO's legal structure, powers and

<sup>32</sup> A. Plomer, 'A unitary patent for a (Dis) United Europe: the long shadow of history' (2015) 46.5 *IIC-International Review of Intellectual Property and Competition Law* 508-533.

<sup>33</sup> T. Jaeger 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48.3 *IIC-International Review of Intellectual Property and Competition Law* 254-285. D. Harhoff, *Economic Cost-Benefit Analysis of a Unified and Integrated European Patent Litigation System*, Final Report to the European Commission." (2009).

<sup>34</sup> WIPO, World Intellectual Property Indicators (WIPO, 2016 – Figures relate to 2015).

<sup>35</sup> <https://www.epo.org/news-issues/press/releases/archive/2017/20170307.html>

<sup>36</sup> EPO Annual Report (2016) <https://www.epo.org/about-us/annual-reports-statistics/annual-report/2016.html>

<sup>37</sup> J. Klabbers, 'The EJIL Foreword: The Transformation of International Organizations Law' (2015) 26.1 *European Journal of International Law* 9-82. See also and J. Klabbers, 'On Functions and Finance: Sovereign Debt Workouts and Equality in International Organizations Law' in J. P. Bohoslavsky & al. (eds) (2016) *Yale Journal of International Law-Special Online Edition on Sovereign Debt* 240-260

<sup>38</sup> J. Klabbers, op. cit. 45 (2015)

immunities epitomise these supposedly a-political functionalist dimensions. Functional cooperation is typically represented as “merely doing things states could be doing themselves, but doing them better – that is, more efficiently or cheaper.”<sup>39</sup> Likewise, the EPO was created to “strengthen co-operation between the States of Europe in respect of the protection of inventions”<sup>40</sup> and in order to provide a more efficient and cheaper system for the examination and grant of patents in Europe. To this end, the EPO was created by means of an international treaty instead of a European Union instrument because of the political fragmentation of the European Union (EEC) States at the time.<sup>41</sup> As reflected in Article 4 EPC, the EPO was originally conceived as an office discharging an administrative function, temporarily outside the legal order of the EEC for historical reasons but to be fully integrated in due course. In reality, the EU’s integration ideal has become ever more distant with the spectacular growth of the EPO.

The original vision of the EPO’s administrative function is reflected in the technical orientation of the EPO’s field of operation (patents) and the composition and legal structure of the EPO boards<sup>42</sup>. The boards are hierarchically ordered. The first layer comprises the examining division (ED), made up entirely of technically qualified officials (e.g. engineers, chemists, etc.).<sup>43</sup> From the ED, appeals may be made to the Opposition Division (OD), also composed of three technically qualified officials with an option to co-opt a legally qualified member.<sup>44</sup> The Technical Board of Appeal (TBA) is also composed of two technically qualified members and includes one legally qualified official.<sup>45</sup> Thus, as noted by Philip Leith, the EPC “imposes a technical majority upon all Boards of Appeal” except the Enlarged Board of Appeal (EBA) which has a majority of legally qualified members, but the EBA very rarely hears appeals on points of law.<sup>46</sup> Despite the overwhelming technical background of the EPO’s board members, as Jacob J. in *Lenzig* famously said the members of the EPO boards “are judges in all but name ...”.<sup>47</sup> Whether “it is rather a pity that they were not so-called by the Convention” is far from clear. An empirical study carried out by Leith at the turn of the millennium confirms that the boards’ functions straddle the administrative/judicial divide.<sup>48</sup> Leith’s interview of EPO officials reveals that whilst nominally referred to as ‘judges’, the culture of the Boards of Appeal has historically been “administrative and examination-led.” Nor was it clear these officials have “... the requisite judicial capacity to properly act in that role”.<sup>49</sup>

In particular, Leith shows how the methodology used by the Appeal Boards is basically documentation-driven and the decisions made by officials with a background in (patent)

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<sup>39</sup> Ibid.

<sup>40</sup> Preamble, EPC

<sup>41</sup> The UK was one of the leading countries for patent applications and grants but the UK was not a member of the EEC at the time. See A. Plomer (2015) op. cit. 30

<sup>42</sup> Articles 18 to 22, EPC

<sup>43</sup> Article 18, EPC

<sup>44</sup> Article 19, EPC

<sup>45</sup> Article 21, EPC

<sup>46</sup> P. Leith, ‘Judicial or administrative roles: the patent appellate system in the European context’ (2001) 1 *Intellectual Property Quarterly* 50-99.

<sup>47</sup> <http://www.lexology.com/library/detail.aspx?g=e2eb2e33-48b6-4386-b956-a8e6d00275e4> –

<sup>48</sup> *Lenzig* 1997 R.P.C. 245

<sup>49</sup> P. Leith, op. cit 56

<sup>49</sup> Ibid at 51

examination and technical skills rather than judicial skills in the administration of justice. Nonetheless, Leith notes that

“ whilst the culture of the EPO is largely a technical one this is not to say that the Boards of Appeal have not applied and interpreted the EPC in a manner which common law systems would describe as “judge-made law”.<sup>50</sup>

He cites as a striking example the EPO boards jurisprudence allowing software patents contrary to a literal reading of the EPC.<sup>51</sup> Leith notes that judicial law-making at the EPO may jar with the Enlarged Board of Appeals assertion in G1/97 that the EBA is not a legislative body. Whilst conceding that this may be true of the EBA, Leith points out that:

“we can see that, in effect, there has been legislating within the (Technical) Boards themselves...”<sup>52</sup>

Thus the formally technical and administrative orientation of the EPO in reality belies a quasi-judicial, law-making function. It goes hand in hand with the considerable degree of autonomy enjoyed by the organization in line with the basic idea of functionalism that the organization is acting as an agent with delegated powers to act on behalf of the contracting states. The decisions of the Boards of Appeal are strictly based on the EPC. Applicants whose applications are rejected cannot appeal to other tribunals or courts outside the EPO. A decision based on a procedural mistake by the EPO Boards can only be corrected by the Boards themselves.<sup>53</sup> As noted by the Enlarged Board of Appeal of the EPO in the WARF case<sup>54</sup> and argued by Spain at the Court of Justice of the European Union in Case 146/13, there is no mechanism within the EPC to require the organization and its boards to take into account, respect or apply any rules outside those contained in the EPC. The EPC’s role in the grant of European patents is thus structurally insulated from the national legal systems of the contracting members and the regional legal systems of the European Union and the Council of Europe. Much like other international organizations, the EPO boards’ decisions are therefore largely immune from interference by other organizations or courts<sup>55</sup> outside the formal mechanisms within the EPC through which contracting states may exercise control over the organization in the council, subject to majority voting and only as regards alterations of the EPO rules as distinct from review of specific cases heard by the Boards.

## 2.2 EPO v. national patent offices

When compared to national patent offices, the EPO’s core functions are largely indistinguishable yet, unlike national patent offices, the EPO’s decisions are not subject to external judicial review. Much like national patent offices, technically qualified officers at the EPO conduct the examination of patent applications and decide whether to grant a patent or

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<sup>50</sup> Ibid at 71

<sup>51</sup> See also P. van den Berg, ‘Patentability of Computer-Software-Related Inventions’ in the *Law and Practice of the EBA of the EPO during the First Ten Years*, Varl Heymanns Verlag, Munich, 1996 commenting on decision T-208/84 VICOM. O.J.E.P.O. 1987, 1 Varl Heymanns Verlag, Munich, 1996 commenting on T-208/84 VICOM. O.J.E.P.O. 1987, 14. See also T-1173/97 – Computer program product/IBM. O.J.E.P.O. 1999, 609

<sup>52</sup> Op. cit 56 at 89

<sup>53</sup> *Virgin Atlantic Airways Ltd v. Zodiac Seats UK Ltd and Delta Air Lines, Inc; The Comptroller General of Patents and the Secretary for State for Business, Innovation and Skills (intervening)* [2013] EWCA Civ 1713

<sup>54</sup> G 0002/06 (Use of embryos/WARF) of 25.11.2008

<sup>55</sup> A. Reinisch, *International organizations before national courts*. (Cambridge University Press, 2000)

not. They evaluate the factual, scientific and technical, evidence to determine whether the invention is novel or whether it has been previously published. They determine whether the invention discloses the requisite level of technical advancement or ‘inventive step’ to justify the grant of a patent and they also decide whether the claims fulfil the ‘industrial application’ requirement. Yet, the ‘inventive step’ and ‘industrial application’ requirements set out in Article 52 EPC are not purely technical requirements but hybrid criteria which require an evaluation of the technical aspects of the claims AND the application of a *legal* threshold which must be met for the patent to be granted. In national legal systems, the counterpart Article 52 EPC threefold requirements of novelty, inventive step and industrial application are typically embedded in legislation, e.g. in section 1(1) of the UK Patents Act. In the case of national applications filed with national patent offices, the requirements are interpreted and applied by patent offices in the first instance and subsequently subject to judicial review in the courts which may decide that the patent office has erred in its application or interpretation of the legal requirements and revoke or affirm a patent. The relative functions of national patent offices and their relationship to courts are thus typically respectively distinguished as administrative and judicial.<sup>56</sup> In common law systems, according to the classical administrative agency model, patent offices are administrative agencies with delegated powers under a statute to make determinations of fact, typically in a specialist field. On the other hand, the jurisdiction of courts, including specialist courts, is directed at questions of law and may extend to *de novo* review of mixed questions of fact and law. By contrast, the EPO boards are neither integrated in the national legal systems of European countries nor the European Union and therefore the standards which they apply are not subject to external legislative or judicial controls.

## 2.2 EPO v. EU Intellectual Property Agencies

In the European Union, the EPO boards arguably fulfil a similar function to the Boards of Appeal of the European Union Intellectual Property Office, a European Union agency responsible for the grant of the European Union Trademark.<sup>57</sup> Yet unlike the EUIPO, the EPO Boards decisions are not subject to review by the Court of Justice because the EPO is not an agency of the European Union, but an autonomous intergovernmental organization.<sup>58</sup> The question of whether the EUIPO boards, formerly known as OHIM, were agencies or courts arose in a 1999 case heard by the General Court of the European Union. The court acknowledged that OHIM Boards of Appeal enjoy a degree of functional independence in

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<sup>56</sup> In the US, see for instance E.F. Albertsworth, ‘Judicial Review of Administrative Action by the Federal Supreme Court’ (1921) 35.2 *Harvard Law Review* 127-153 and Shapiro, Martin M. *The Supreme Court and administrative agencies*. Vol. 2. Free Press, 1968. Benjamin, Stuart Minor, and Arti K. Rai. "Who's Afraid of the APA-What the Patent System Can Learn from Administrative Law." *Geo. LJ* 95 (2006): 269. B. Little, Brown, A. Rai, A. K. (2009) 157(6) *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control. University of Pennsylvania Law Review* 2051-2081.

<sup>57</sup> Details of the EUIPO’s origins, functions and governance may be found on the EUIPO website which explains that “[the regulation establishing the Office](#) was adopted by the Council of the European Union in December 1993 and revised on two occasions, in 2009 and in 2015. It created the European Union trade mark (formerly known as the Community trade mark) as a legal instrument in European Union law and established the EUIPO (formerly known as OHIM) as an EU agency with legal, administrative and financial autonomy. [Council Regulation \(EC\) No 6/2002](#) of 12 December 2001 created the registered Community design. On 23 March 2016, the Office changed its name to the European Union Intellectual Property Office upon the entry into force of Regulation 2015/2424.”

<sup>58</sup> See discussion of EU agencies in M. Navin-Jones, ‘A Legal Review of EU Boards of Appeal in Particular the European Chemicals Agency Board of Appeal’ (2015) 21(1) *European Public Law* 143-168

that their Members are not legally bound by instructions from the agency.<sup>59</sup> Notwithstanding, the court held that OHIM Boards were not judicial tribunals.<sup>60</sup> According to the Court of Justice, the Boards remain administrative bodies and not judicial bodies because: “A procedure is, initially, a matter for OHIM, its Opposition Divisions first of all and, then, on appeal, its Boards of Appeal which, in spite of the independence enjoyed by those departments and their members, remain nonetheless departments of the OHIM”.<sup>61</sup>

The legality of the decisions of the EU Trademark Boards is thus ultimately reviewable by the Court of Justice.. Admittedly, the distinction between the functions of agencies boards of appeal and courts is not entirely clear. Some scholars have argued that the Appeal Boards of EU agencies have extensive powers of review – including full de-novo review – a power not generally available to the Court of Justice. For this reason, it has been suggested, these Boards in reality function in a manner akin to a judicial or quasi-judicial body which in turn points to the need for deeper analysis of the constitutional status of agencies. Indeed, the conversion of Agency Boards into specialist courts has been underway in the EU since the entry into force of the Nice Treaty whose preamble alluded to the possibility of EU trademark panels becoming judicial bodies.<sup>62</sup> Needless to say, review of the EPO boards does not form part of the discussion since the EPO is not an agency of the EU. Compared to the Boards of Appeal of the EUIPO and national patent offices, the EPO is an outlier in Europe. It fulfils similar functions to other EU intellectual property agencies but the legality of its decisions is not subject to judicial control by the Court of Justice. Critically, the hegemony and insularity of the EPO will not be in any way diminished by the creation of the Unified Patent Court (UPC). On the contrary, the design of the UPC arguably intensifies the ascendancy of a patent juristocracy in the governance of the European patent system through the addition of a centralized specialist patent court to which member states have ceded exclusive jurisdiction and which stands at arms’ length from the Court of Justice.

### 3 Path Dependencies: EPO, EU and National Courts

For the last fifty years, the European Union’s ambition to create a single, central court for the enforcement of European patents has been frustrated by the EPO’s existence as an autonomous, international organization outside the European Union. After numerous

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<sup>59</sup> The legislative basis guaranteeing the independence of the Board Members is in [ex-] Art. 131(2)-(5) of Regulation 40/94. Case T-107/02 *GE Betz v. OHIM – Atofina Chemicals (BIOMATE)* [2004] ECR II-1845, paras 33. Also see Case T-171/06 *Laytoncrest Ltd v. OHIM* [2009] para. 27 – For a detailed discussion see Narvin Jones op. cit. 58.

<sup>60</sup> Case T-163/98 *Proctor & Gamble (Baby Dry)*, EU:T:1999:145, para.38

<sup>61</sup> Case C-29/05 *P OHIM v. Kaul* [2007] ECR I-2213 para. 51. On the limits of the CJEU’s review of other IP agencies see H. Ullrich, ‘Le contrôle juridictionnel limité de l’obtention et de la validité de la protection des variétés végétales par la Cour de justice de l’Union européenne ou les limites d’une autolimitation juridictionnelle en matière de propriété industrielle communautaire’ in *Le droit économique entre intérêts privés et intérêt général - Hommage à Laurence Boy*, Presses Universitaires d’Aix-Marseille, Aix-en-Provence 2016, 179 - 202

<sup>62</sup> J. Alberti, ‘New developments in the EU system of judicial protection: the creation of the Unified Patent Court and its future relations with the CJEU’ (2017) 24(1) *Maastricht Journal of European and Comparative Law* 6, 23

unsuccessful attempts dating back to the early 1960s to create an integrated court to provide a complete system of judicial protection on patents in the European Union, the latest initiative is the European Union's 'patent package'.<sup>63</sup> The 'patent package' consists of a European Union Patent with Unitary effect (EUPUE), created by two EU regulations<sup>64</sup> enforced by a central court, the Unified Patent Court (the UPC). The UPC is an international court created by an international Treaty. Notwithstanding, the UPC will have exclusive jurisdiction over the EU unitary patent in the first instance and after a transitional period, the UPC will also exercise exclusive jurisdiction over the classical, EPC European patent, currently prosecuted in national courts post-grant. The missing link in the EU's 'patent package' is the institution vested with the power to grant the European Union Patent with Unitary Effect and this institution is the EPO.

As noted earlier, European patents are currently granted by the EPO on inventions which fulfil the legal requirements of novelty, inventive step and industrial application set out in the European Patent Convention. If the UPC comes into being, the EU Unitary Patent (EUPUE) will also be granted by the EPO in exactly the same way as European patents, in accordance with the requirements of the EPC.<sup>65</sup> This may seem odd, since the EU unitary patent is a legal object of the European Union created by an EU Regulation<sup>66</sup> but stands to be granted and administered by an organization outside the European Union in accordance with the terms of a Treaty (the EPC) to which the EU is not a party. Notwithstanding, the Court of Justice has unambiguously declared that the design of the UPC and the deferral to the EPO for the grant of the EU patent are compatible with the Treaties. So, the EPO's role will be further enlarged through the administration of the EUPUE once the UPC starts to function. At the time of writing, the UPC's future is uncertain due to the UK's Brexit and a pending challenge at the German Constitutional Court. For the purpose of the argument in this paper, it is largely immaterial whether the UK remains in the UPC or not. It is also immaterial whether the UPC is redesigned so as to be directly under the purview of the Court of Justice as many commentators have suggested would be desirable in order to avoid the dilution of the integrity of EU law caused by the current design. The reasons are threefold. First, the legal requirements for the European Union unitary patent are left undefined in European Union law thus leaving the specification of these requirements *de-facto* and *de jure* to the EPO. Secondly, closer integration of the UPC with the Court of Justice will not remedy the dependency of the UPC and EU on the EPO whilst the EPO remains an independent, autonomous organization. Thirdly, the EPO's privileged position as the institution with the exclusive power to grant European patents and the EU unitary patent creates normative path dependencies which are very difficult for courts to resist whether they happen to be a specialist court like the UPC or generalist courts. These path dependencies resulting from the

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<sup>63</sup> On the history of the EU's failure to set up a central court see H.Ullrich, 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' (2002) 8.4 *European Law Journal* 433-491

<sup>64</sup> Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ 2012 L 361 and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements OJ L 361

<sup>65</sup> Case C-146/13 at para. 29 and 30

<sup>66</sup> Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ 2012 L 361, p. 1

hegemony of the EPO are further explored below through the case study of the UK Supreme Court deference to the EPO.

### 3.1 Filling the Gaps

It is well accepted that harmonization of European Union law on patents lags behind harmonization of copyright and trademarks.<sup>67</sup> Substantive harmonization of European patent law was mainly secured outside the European Union with the Council of Europe's adoption of the Strasbourg Convention in 1962.<sup>68</sup> The Strasbourg Convention introduced the three substantive requirements for patentability: novelty, inventive step and industrial application. These requirements subsequently became the European and international benchmarks for the grant of patents in the EPC and TRIPS Agreements. As noted by Wadlow, the adoption of the Strasbourg Convention was thus the most significant step in facilitating a decade later the creation of a centralized administrative institution for the grant of patents in Europe in the form of the European Patent Organization (EPO). This was because the threefold legal requirements cut across the variations in national laws to settle on a common set of substantive legal requirements for patentability. The threefold requirements are thus the legal backbone of the "common" system of patent law in the EPC. These requirements, contained in Article 52 EPC, were also enshrined two decades later in Article 27 of the TRIPS agreement. However, there is no uniform definition of these requirements in the TRIPS agreement or how they are to be interpreted by WTO Members. Indeed, it is well accepted that the absence of a uniform definition is one of the 'flexibilities' enjoyed by WTO Members to implement Article 27 in their national laws to reflect their economic and social priorities.<sup>69</sup> Nor are there legal definitions of these requirements in European Union law. Instead, the European Union's harmonization of patent law has been largely limited to Directives on Supplementary Certificates and the EU Directive on Biotechnological Inventions (1998) which extends patent protection to isolated genes and cells and contains a list of moral exclusions which have given rise to controversial rulings by the Court of Justice.<sup>70</sup> The EPO, though not obliged to, transposed the moral exclusions in rule 28(c) EPC. Notwithstanding, the autonomy of the EPO and EU legal systems was stressed by the Enlarged Board of Appeal in the landmark WARF case.<sup>71</sup> The applicant had requested the EBA to make a preliminary reference to the Court of Justice on the meaning of the specific moral exclusion in the Directive which the EPO had transposed in rule 28(c) EPC.<sup>72</sup> The EBA refused the request on the grounds that "the Boards of Appeal of the EPO are not courts or tribunals of a member state of the EU, and there is no power under the EPC for a

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<sup>67</sup> L. Bently, D. Ganjee and B. Sherman, B. *Intellectual property law* (Oxford University Press, 2018)

<sup>68</sup> C. Wadlow, (2010) 'Strasbourg, the Forgotten Patent Convention, and the Origins of the European Patent Jurisdiction' *IIC* 123–149.

<sup>69</sup> Gervais, D. J. (2003). *The TRIPS agreement: drafting history and analysis*. sweet & maxwell. Ruse-Khan, H. G. (2009). Time for a Paradigm Shift-Exploring Maximum Standards in International Intellectual Property Protection. *Trade L. & Dev.*, 1, 56.

<sup>70</sup> European directive 98/44, See the CJEU's decision in *Brustle v Greenpeace* and its sequel: A. Plomer, 'International Stem Cell Corporation V. Comptroller General of Patents, Designs and Trade Marks (CJEU)' (2016) 55(4), *International Legal Materials* 731-739. A. McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: a Fragmented Future too Far?' (2017) 48.1 *IIC-International Review of Intellectual Property and Competition Law* 42-70.

<sup>71</sup> G 0002/06 (use of embryos: WARF) 25.11.2008

<sup>72</sup> *Ibid.*

Board of Appeal to refer questions to the ECJ”.<sup>73</sup> The EPO thus enjoy exclusive de-jure discretion, authority and power to give detailed, substantive content to the legal requirements and exclusions for the grant of both the existing European patent and the forthcoming European Union unitary patent. In so doing, arguably, the EPO is effectively charged with making economic patent policy and patent law in the European Union. For these reasons, it is far from clear that a re-design of the UPC to bring it directly under the purview of the Court of Justice would alter the existing hegemony of the EPO and the democratic deficit arising from the EU and Members States transfer of power over patents to the administrative machinery of the EPO. According to Prof. Bross, a German Constitutional lawyer and former judge, neither would such a redesign be compatible with the German Constitution because of the EPO’s structure’s failure to respect the separation of powers and the rule of law. At a keynote lecture on 25<sup>th</sup> May 2017, Prof. Bross criticized member states for having created “an almost omnipotent executive with no proper checks and balances by an independent judiciary”.<sup>74</sup>

### **3.2 Judicial deference to the EPO: the UK Supreme Court**

Whatever the shape of the future relationship of the UK with the EU and whether or not the UPC enters into force and the UK remains part of it, judicial cooperation and dialogue amongst European judges and the EPO is likely to continue to shape the legal contours of European patent policy in the future. The approach of UK judges to the jurisprudence of the EPO boards is of particular interest for three reasons. Specialist judges in patent law are rare and generalist judges with specialist knowledge of patent law an even greater rarity. The decisions of UK judges are particularly instructive because the UK is one of the three leading countries with the highest volume of patents in Europe and some of its highly respected senior judges in the UK Supreme Court (formerly the House of Lords) have developed an expertise in patent law. The UK’s common law tradition has also stimulated the writing of judgements which set out in great detail the judges views on issues of principle regarding the EPC and its relationship with national laws. Finally, over the last two decades, development of a common judicial culture and “judge-craft”<sup>75</sup> amongst European patent judges has been encouraged by the regular symposia of European Patent Judges hosted by the EPO.

Notwithstanding, it could be argued that the UK’s approach to EPC decisions may be of limited interest as other generalist, constitutional courts in Europe may adopt a different approach from UK courts. Whilst this is true, the analysis of UK senior judges’ approach to the EPO ‘jurisprudence’ reveals the powerful momentum created by the combination of structural institutional fragmentation, the hegemony of the EPO in the grant of patents and the technical orientation of patent laws hedged in favour of patent holders to defer to the EPO to avoid destabilizing existing commercial interests and investments. The judgments of UK judges evidence the dependency of generalist courts on the prior, supposedly administrative

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<sup>73</sup> Ibid.

<sup>74</sup> Cited in Kluwer’s patent blog: <http://patentblog.kluweriplaw.com/2017/05/25/rule-law-epo-ugly-writing-wall/>

<sup>75</sup> Title of Justice Kitchin’s presentation at the 2015 EPO symposium, <https://www.epo.org/law-practice/judiciary/documentation.html>).



and technically informed decisions of the EPO and the reality of the economic and political considerations which are inherently involved in these decisions. Since many commentators have suggested that the flaws in the UPC and EU's patent-package could be remedied if a revamped UPC or new specialist patent court was brought under the direct purview of the Court of Justice, it is worth reflecting on the issues identified by highly respected judges of other generalist courts in balancing commercial and public interests in patent policy and patent law.

In his Burrell lecture of 2014, Lord Neuberger disclosed that, as a member of the UK Supreme Court delivering the leading judgment in *Human Genome Sciences v Eli Lilly* [2011] UKSC 51, he had been troubled by the decision of two English courts below which had invalidated a patent granted by the EPO because it seemed to him that “that there was a great deal of commercial and public interest policy, as opposed to legal principle” (at para. 21). The “important policy point” identified by Lord Neuberger was whether the claims in a patent application showed a sufficient degree of promise to justify the grant of a monopoly to an applicant. “so that the rest of the pharmaceutical industry is being kept off, for 20 years” or whether it is in the public interest “that there is a free and competitive market in working and experimenting on those chemicals.”<sup>76</sup> This balancing of policy factors, in the case of applications for European patents (and the forthcoming EU unitary patent) is exercised in the first instance by patent examiners at the EPO and its boards of appeal applying and interpreting the requirements for an invention in the EPC. The validity of a patent granted by the EPO may be revisited in invalidity or infringement proceedings in national courts (or by the UPC if it comes into being). All the same, the decision of the EPO boards to grant a patent undoubtedly creates overwhelming path dependencies particularly when the original decision of the EPO examining board is affirmed by the Technical Boards of Appeal of the EPO. The pressure points on generalist courts are evident in the jurisprudence of the UK Supreme Court discussed below. They arise from a combination of factors including the legal openness of national laws implementing the EPC, economic considerations, the cultural nexus connecting the higher echelons of the EPO boards with senior judges in national courts and the self-perceived limitation of generalist courts anxious not to be seen to make law. These pressures and normative path dependencies are illustrated below.

When the UK acceded to the EPC in 1973, the UK Patents Act (the Act) was revised to give effect to the EPC. One of the most significant changes in UK law was the removal of the long-standing statutory definition of an invention dating back to the Statute of Monopolies thus effectively reducing the opportunity for judicial creativity to invalidate patents considered not to be ‘inventions’.<sup>77</sup> The reduction to the three requirements for an invention in the EPC, defining the ‘common law’ of Member States has turned judicial attention instead to the question of whether the interpretation of these requirements by EPO boards is legally binding on the EPO Member States. In the UK, the answer lies in s. 130(7) of the UK Patents which states that since Member States had resolved to adjust their laws relating to patents to bring them into conformity with the corresponding provisions in the EPC the corresponding provisions in the UK Patents Act are “... so framed as to have, as nearly as practicable the same effects in the UK as the corresponding provisions in the EPC...”. In

<sup>76</sup> Lord Neuberger, Burrell Lecture (2014) at para. 21

<sup>77</sup> Instead, Article 1 (1) lists the requirements for an invention mirroring the counterpart requirements in the EPC and Article 1 (2) includes a negative definition mirroring the list of exclusions in the EPC.

short, s. 130(7) of the UK Patents Act provides interpretive guidance for UK courts, enjoining consistency with the EPO but stopping short of stating that UK courts are legally bound by the decisions of EPO boards. For two decades and notwithstanding the changes to the UK Patents Act, English courts continued to review the validity of patents granted by the EPO boards by reference to their own established jurisprudence which also happened to be less generous to patentees than the EPO's. All this started to change in 1996 when Lord Hoffmann in *Merrell Dow Pharmaceuticals, Inc. v. Norton & Co* [1996] R.P.C. 76 (HL), began to call for UK courts to align their decisions to those of EPO boards on the grounds that s. 130(2) imposed a duty on the UK to construe the three patentability requirements having regard to the decision of the EPO.<sup>78</sup>

Lord Hoffmann acknowledged that "These decisions are not strictly binding upon courts in the United Kingdom" but he argued that "they are of great persuasive authority" because they are decisions of "expert courts" involved in the daily administration of patents and secondly because it would be undesirable if national courts were to construe these provisions differently from the EPO. By contrast, the court of first instance and Court of Appeal below had stressed their judicial responsibility and exercise of independent judgment as colourfully put by L.J. Jacob in *Actavis v Merck*:

"In saying our courts would and should normally follow the settled jurisprudence of the EPO it should be understood, of course, that they are not bound to do so. In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away."<sup>79</sup>

Still over a period of fifteen years after *Merrell Dow Pharmaceuticals*, the UK House of Lords and then the UK Supreme Court went much further than taking account the decisions of the EPO boards. In a series of landmark rulings, the UK's highest court overturned the "much stricter" decisions of the Court of Appeal and High Court below whilst acknowledging that UK courts were not legally bound by the decisions of the EPO boards.<sup>80</sup> The rationale, according to Lord Hoffmann, was that whilst courts may differ on the interpretation of factual evidence, the EPC required uniformity on matters of 'principle', as far as possible.<sup>81</sup>

In 2011, the UKSC followed the same approach in *Human Genome Sciences v Eli Lilly* [2011] UKSC 51, and overturned the decision of the courts below on the interpretation of the 'industrial application' requirement prompting numerous criticisms from IP practitioners and law scholars alike, who described the ruling as a bridge too far.<sup>82</sup> Article 57 EPC provides that 'An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture'. The Court of Appeal had suggested that the differences in the decision of the EPO Technical Board of Appeal and the English courts were due to procedural and evidential shortcomings. The High Court hearing in *Eli Lilly* had lasted thirteen days and involved cross-examination of the evidence in adversarial proceedings. By contrast the hearing at the EPO's Technical Board of Appeal had

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<sup>78</sup> J. Watts & T. Alkin, 'A Road to Unification: Patent Litigation in the United Kingdom 1990-2012' (2013) 23:2 *Fordham Intell. Prop. Media & Ent. L.J.* 571

<sup>79</sup> *Actavis v Merck* [2008] EWCA Civ 444

<sup>80</sup> Lord Neuberger, Burrell lecture at para. 20

<sup>81</sup> *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc and another* - [2008] 4 All ER 621 at para. 3

<sup>82</sup> B. Whitehead, S. Jackson. K/ Kempner, J, 'Eli Lilly v HGS: Has the Pendulum Swung Too far?' (2012) 12(3) *BSLR*: 100

lasted one and half-days, was largely paper based and procedurally questionable as Eli Lilly had been allowed by the TBA to submit a 700 pages document to TBA officials three weeks before the hearing without advance notice to the other party.<sup>83</sup> In the UK Supreme Court, Lord Neuberger conceded that the UK adversarial system enables a more thorough evaluation of the evidence, albeit at a higher cost for the parties, but he rejected L.J.Jacob's view in the Court of Appeal that the differences in outcome in this instance were evidential. He insisted that the issue at stake was one of legal principle, regarding the meaning of 'industrial application' in Article 57 EPC. The English courts below, Lord Neuberger said, had erred in setting the bar too high and (mis) applying the principles laid down in the 'jurisprudence' of the EPO boards which had interpreted 'industrial application' to include 'plausible' or 'reasonably credible' applications.<sup>84</sup> Yet, in reality, the so called issues of 'principle' turned out to be inextricably interwoven with policy decisions about the economic implications for the UK bio-industry of the UKSC departing from the standards applied by the EPO. By Lord Neuberger's own admission, the submissions of the UK BioIndustry Association (BIA) to the UK Supreme Court changed his original inclination to affirm the judgment of the Court of Appeal which had revoked the patent granted by the EPO. The UK BIA had intervened after the Court of Appeal ruling, stressing the importance of consistency between UK courts and the EPO, warning of the potential risks to the hundreds of innovative companies in the UK bioscience sector which it represented if the patent was revoked. In 2010, the BIA said, the aggregate turnover of these companies was £5.5 billion and they had around 36,000 employees.<sup>85</sup> This evidence was critical in swaying Lord Neuberger who conceded that "just as it would be undesirable to let someone have a monopoly over a particular biological molecule too early, because it risk closing down competition, so it would be wrong to set the hurdle for patentability too high, essentially for the reasons advanced by the BIA."<sup>86</sup> Lord Neuberger's concluding thoughts acknowledge that where the line should be drawn between commercial interests and the public interest was "a matter of different opinions and debate."<sup>87</sup> Similarly, Lord Walker said that he had been persuaded by Lord Neuberger, against his inclination, to reduce the risk of a chilling effect on the UK bioscience industry and the desirability of consistency with the EPO and other European Contracting States. Thus notwithstanding Lord Neuberger's reservations, the UKSC decided that a departure from EPO standards would might lead to unacceptable economic losses for the UK industry. Legal security and certainty and ultimately the commercial interests of a sector of UK industry prevailed over the interests of other sectors, including the scientific community, researchers and the wider public in the grant of a monopoly over fundamental knowledge originating in the interpretation of the EPC by EPO boards.

It may be argued that the UKSC's approach to the jurisprudence of the EPO boards has been singularly deferential and weighed in favour of commercial interests. After all, two major

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<sup>83</sup> Discussed by Jacob L.J. in the Court of Appeal judgment [2010] EWCA Civ 33 at paragraph 32

<sup>84</sup> Ibid at paragraph 96

<sup>85</sup> Ibid at paragraph 96

<sup>86</sup> Lord Neuberger 100 above. Quite where the line should be drawn in the light of commercial reality and the public interest can no doubt be a matter of different opinions and debate. However, in this case, apart from the fairly general submissions of the parties and of the BIA, we have not had any submissions on such wider policy considerations." At paragraph 130

<sup>87</sup> Ibid.

longitudinal studies of patent litigation in European courts show that between 20% and 50% of patents granted by the EPO are invalidated in national courts.<sup>88</sup> It could thus be that UK senior judges have been singularly willing to actively assist in the political hand-over of power to the EPO and the priority given to protection of commercial interests. It may also be thought that the Court of Justice could offer greater resistance and follow the approach of other generalist higher courts which have rejected the policies of patent offices and weighed the wider interest of the public against the private interests of patent holders. For instance, both the Australian High Court and the US Supreme Court invalidated patents on isolated genes held by the US Cie. Myriad Genetics coding for proteins indicative of Breast Cancer.<sup>89</sup> In so doing, the US Supreme Court in *AMP v Myriad Genetics*, overturned the thirty year long policy of the US patent office, holding that: "... patent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'" However, it is evident from the judgments of these constitutional courts that they are aware that they are being called upon to make decisions of an economic and social nature in the interpretation and application of the legal criteria of patentability. In Lord Neuberger's words, the self-understanding of these generalist courts is that the decisions they are called upon to adjudicate are constitutionally sensitive because they relate to 'policy' rather than 'principle'. Similarly, policy considerations weighed in the Indian Supreme Court's rejection of the ever-greening patent granted by the USPTO which Novartis sought to validate in India for its cancer drug Gleevec. However, in that case, the Indian Supreme Court was able to lean on the statutory limitations on the 'inventive step' requirement adopted by the legislature in section 3(d) of the Indian Patents Act.<sup>90</sup> Such statutory controls are rare in patent laws. There are no similar legislative controls on the 'inventive step' requirement in national laws in Europe or EU law. Finally, whilst it is indeed possible for constitutional courts to exercise some control over the policies adopted by *national* patent offices and the courts below, the structural position of the EPO in the European patent system and its relationship to national courts is quite different from that of national patent offices and national courts. By contrast to the EPO, national patent offices in Europe do not have quasi judicial appeal boards, interpreting the 'common' legal requirements of patentability and building a body of "case law" and 'jurisprudence' on the interpretation of the substantive legal requirements for the grant of patents. Moreover, national patent offices and national courts stand are integrated in a hierarchical legal order with national constitutional courts standing at the apex. By contrast, the EPO is not subject to judicial review by national courts, or the forthcoming Unified Patent Court, itself designed to be at arms length from the Court of Justice.

Notwithstanding the deference of the UKSC to the EPO, as well as other supreme courts in Europe from which the UKSC drew inspiration, it remains true that there is divergence amongst national courts in the interpretation of the 'common law' requirements in the EPC. It is precisely this enduring divergence which underpins the European Commission's determination to eliminate differences and enhance commercial certainty and legal security for investors through the creation of the Unified Patent Court. Lord Neuberger too sees the differences as an obstacle to commercial investment and looks to the informal dialogue between judges at meetings organized by the EPO in the past decades as a valuable method of

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<sup>88</sup> Graham, Stuart JH, and Nicolas Van Zeebroeck. "Comparing patent litigation across Europe: a first look." 17 STAN. TECH. L. REV. 655 (2014) and Cremers, Katrin, et al. "Patent litigation in Europe." *European journal of law and economics* 44.1 (2017): 1-44

<sup>89</sup> *D'Arcy v Myriad Genetics Inc. & Anor* [2015] HCA 35 and *Association for Molecular Pathology v. Myriad Genetics*, No. 12-398 (569 U.S. 576 (2013))

<sup>90</sup> *Novartis Ag v. Union of India*, (2013) 6 SCC 1

judicial rapprochement. Both these perspectives arguably involve an idealized understanding of the role of generalist courts and a narrow understanding of patent law detached from the broader social and political economy in which the patent system sits and the interests which it serves.<sup>91</sup> These socio-legal factors include the powerful pressure exercised by private companies at every single level in the patent system, from the enactment of legislation<sup>92</sup> to the patent friendly approach of patent offices and the EPO beholden to their clients and the self-imposed limitations of senior judges on their role as law-makers in the constitution.<sup>93</sup>

For this reason, calls to rethink the institutional design of the Unified Patent Court as the ultimate gatekeeper of the European patent system should certainly be heeded. Equally, close analysis of the landmark rulings of generalist courts in patent cases reveals that the decisions to invalidate or revoke patents rest on the courts interpretation of the requirements for an ‘invention’ or ‘inventing step’ or ‘industrial application’, presenting as technical, legal criteria but in reality embedding public policy considerations. The UK Supreme Court’s reluctance to depart from the EPO Boards of Appeal interpretation of these requirements in the last two decades provides a vivid illustration of the magnitude of the constitutional, political and economic challenges arising from the accumulated “legal” *acquis* at the EPO. This suggests that the issues presented by the fragmentation of the European patent system are not simply caused by institutional fracture and its exacerbation with the addition of the UPC. Critical adjustments of the substantive law on patent requirements are necessary and have to be effected internally – in order to achieve a fair balance between the interests of inventors/investors and the public interest in the allocation of the powerful monopoly rights created by patents. It cannot be taken for granted that generalist courts can readily assume the main burden of acting as a corrective or as legislators on patent policy. The addition of human rights in the patent law toolkit<sup>94</sup> might have a heuristic value in pointing to the ideal direction of travel - but the critical legal mechanics lie in the specification of patentability standards which in their current level of generality, technicality and lack of specificity have allowed an “almost omnipotent”<sup>95</sup> administrative body in Europe to prioritize the commercial interests of private actors over those of the public with the acquiescence and assistance of some national constitutional courts.

## CONCLUDING THOUGHTS

Despite his reservations on the mix of legal principle and policy considerations in the *Human Genome Sciences v Eli Lilly* case, Lord Neuberger concluded his Burrell lecture with the view that there are two main advantages to harmonization of the European patent system. The first is that cross border judicial cooperation is capable of bringing greater consistency and certainty and secondly that the creation of a body of specialist European judges with expertise in patents is a welcome development “avoiding judges without patent law expertise

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<sup>91</sup> On the administrative reforms to the US Patent system which have led to the USPTO’s dependency on the fees of its clients, see: Jaffe, Adam B. "The US patent system in transition: policy innovation and the innovation process." *Research policy* 29.4-5 (2000): 531-557.

<sup>92</sup> According to G.F. Rich, The (US, 1952) Patent Act was written basically by patent lawyers ... A good 95% of the members (of Congress) never knew that the legislation was under consideration, or that it had passed, let alone what it contained’ ‘Congressional Intent—Or, Who Wrote the Patent Act of 1952’ (1963) *Southwestern Legal Foundation, Patent Procurement and Exploitation: Protecting Intellectual Rights* 61 (

<sup>93</sup> The latter is documented by Peter Drahos in his extensive empirical study of patent offices (op. cit).

<sup>94</sup> Charter of Fundamental Rights of the European Union and the European Convention of Human Rights

<sup>95</sup> Prof. Bross, op. cit. supra

in the CJEU making decisions in the field of patent law”.<sup>96</sup> On this view, patent law is primarily a technical field because determination of whether there is an invention or ‘inventive step’ necessarily requires high levels of technical legal knowledge in highly specialized fields.<sup>97</sup> Judges typically lack such specialist knowledge so they are ill equipped to decide whether a patent should be granted and likely to differ and err. Legal uncertainty is bad for business, so the answer to the commercial imperative for legal certainty is to create specialist patent judges to review the grant of patents and for these judges and the generalist judges which act as ‘watchdogs’ to confer with each other to develop patent law. The argument in favour of a judicial technocracy for patents is also typically accompanied by scepticism as to the competence of generalist courts to intervene in the field. If patent law is intrinsically technical then it is – almost by definition – unsuitable for judicial review by generalist judges. Yet, whilst the examination of a patent application undoubtedly requires judges to evaluate technically complex facts and scientific evidence, the question of whether the application and ‘invention’ reaches the required thresholds of novelty, inventive step and industrial application requirements to merit rights of exclusivity for twenty years ultimately involves the application of legal standards and principles coupled with policy considerations weighing the social and economic impact of granting 20 year monopolies. The applicable standard which decides whether the technical advance is sufficient for the grant of a patent is a legal standard, albeit informed by technical scientific standards. Critically, the specification of the legal standard itself is not readily reducible to technical considerations or legal principle in isolation from policy considerations. Underlying the policy considerations are political and economic assumptions about the goals of the patent system, the best means to facilitate investment and innovation and ultimately the fair and just distribution of property rights and entitlements in democratic societies. These assumptions are rarely brought to light in the hum-drum allocation of patents by patent offices or judicial hearings but they are clearly acknowledged in many of the leading cases reaching the courts. In national legal systems, ‘mixed’ legal/policy decisions typically lie at the margins of justiciability but checks and balances in national constitutional contexts – in theory - allow for judicial overreach in the realm of policy to be corrected by higher courts and ultimately by legislatures. By contrast, notwithstanding the economic and legal centrality of the EPO, there are no equivalent checks and balances on the EPO and only a weak and complex nexus of checks on the UPC itself dependent on the EPO. Against this background, as argued by many scholars, the Court of Justice and constitutional courts in particular have a critical function to play in judicial oversight of patents granted by the EPO. Equally, this paper has argued that the role of courts and the judiciary in orienting and developing patent law and their ideal vision of moving towards a specialist club needs to be reviewed to gain a deeper understanding of judicial power in advancing the relative interests of multiple actors in democratic societies. The UKSC’s deference to the EPO is particularly striking because of the resistance and hostility that Lord Hoffmann and other former members of the House of Lords have shown to deference to the European Court of Human Rights. This brings us back to the initial thoughts in this paper regarding the role of courts in liberal democracies. The European patent system is undergoing a profound transformation. Hitherto, the scholarship on the current system and its future has primarily been the preserve of (private) IP lawyers or

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<sup>96</sup> Lord Neuberger, Burrell Lecture (2014) at para. 28

<sup>97</sup> WIPO study of 101 national patent laws: Certain Aspects of National/Regional Patent Laws: Inventive Step [http://www.wipo.int/scp/en/annex\\_ii.html](http://www.wipo.int/scp/en/annex_ii.html)

EU Constitutional lawyers exploring means to enhance institutional integration of the UPC into the EU and the incorporation of EU fundamental rights protection into patent law. This paper has suggested that the decisions on which patents should be granted critically depend on administrative and judicial interpretation of the legal thresholds for an invention. The risk posed by the EPO, specialist patent courts and the UPC is that they are structured and operate on the assumption that patent thresholds are technical and detached from the public purpose of the patent system. The technocratic, specialist vision of patents obscures their inherent political and economic dimensions. For this reason, the extension of the EPO's 'technocratic' orientation through the addition of a specialist patent court in the form of the UPC, signifies the rise and entrenchment of a patent juristocracy in Europe. The literature on global constitutionalism and the rise of juristocracies thus provides an important complementary lens through which to take a fresh look at the governance of the European patent system. It also provides a template through which to raise new and under-explored research questions about the theoretical foundations of the jurisdiction of patent offices and courts and their role in liberal democracies. It highlights the need for systematic empirical and comparative studies of these courts and an exploration of normative questions of how to enhance democratic governance of the patent system.