PATGOV

The Governance of the European Patent System

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BACKGROUND ON THE PROJECT: FROM CRITICAL DIAGNOSIS TO POSSIBLE REFORM

The multi-level and fragmented European patent system has been criticized for a number of reasons. Some authors have addressed *performance deficiencies* of the system, emphasizing the decreasing quality of patents (including back-logs in patent assessment) and/or the –high- level of the patent fees in Europe, often from the perspective of increased global competition between the so-called IP5 offices (USPTO, EPO, JPO, KIPO, and SIPO)[1].

Another issue is the link between *innovation and patenting*. The traditional patent paradigm is that inventors need to be rewarded for their R&D efforts by creating a long-term, enforceable, exclusive right to the use of that invention. Such exclusive rights thus create an incentive for R&D; the requirement to publish the invention further stimulates the diffusion of ideas. Within this paradigm the role of the patent system is straightforward. i.e. to establish whether the basic requirements for patentability (novelty, inventive step, and industrial applicability) are met. The links between patenting and innovation are however much more complicated than this basic reward idea presupposes. The downside of exclusive rights is that monopolies are created which by definition distort markets. Patents furthermore impede the combination of new ideas and inventions and raise transaction costs[2] (the anti-commons problem). In that sense patents may be detrimental to innovation rather than promote it. The empirical evidence about the link between innovation and patents is far from

[1] See for example N. van Zeebroeck et al. (2008), `Patent inflation in Europe', *World Patent Information* 30: 43-52; B. van Pottelsberghe (2009), *Lost property: The European patent system and why it doesn't work*, Bruegel Blueprint Series, Brussels: Bruegel; G. Scellato et al. (2011), *PATQUAL. Study on the quality of the patent system in Europe*, commissioned by EC DG MARKT, Torino/Enschede: Politecnico di Torino/University of Twente; G. de Rassenfosse & B. van Pottelsberghe (2013), 'The role of fees in patent systems: Theory and evidence, *Journal of Economic Surveys* 27(4): 696-716.

[2] B. Hall (2007), `Patents and patent policy´, *Oxford Review of Economic Policy*, Volume 23(4): 568–587.

conclusive[3]. More generally, the OECD observed a striking paucity of economic evaluation of the patent system[4].

From a (*bio-)ethical* angle, others have questioned the patentability of inventions in specific areas such as stem cells, human embryos, and genetically modified organisms. Such patent cases have also given rise to fierce opposition from civil society/NGOs[5]. Criticism from the perspective of ethics is however not limited to such 'patents-on-life' issues, but also involves questions regarding broad and upstream product patents (that hinder rather than foster innovation), the importance of openness and of sharing of knowledge, specific medical concerns, and the global justice dimension of patenting[6]. The extent to which the European patent system takes on board such ethical and societal considerations is however very limited.

In defence of the patent system, some scholars have argued that patent systems are not meant to evaluate broader societal issues[7]. In this view, exceptions to patenting should be designed to demarcate clear instances of technologies that do not comply with the basic patent criteria of novelty, inventive step, and industrial applicability. Patent law and its application should not involve other considerations; such considerations should be dealt with outside of the patent system. The latter position is however challenged by authors that argue that patent systems are part of larger innovation and governance systems within society and should be assessed accordingly. From the perspective of governance studies, focusing on *accountability and legitimacy*, it has been argued that the European patent system is in fact a very closed system, a technocracy made up of legal and technical experts who at best interact with only those stakeholders directly involved in patenting practices (i.e. patent applicants) but hardly beyond the patent system as such[8]. The European Patent Office (EPOff), as the supranational agency of the European Patent Organisation (EPOrg), has a high degree of autonomy and combines executive, quasi-jurisdictional, and tacit legislative powers. This self-governance raises questions about transparency, accountability and democratic control[9]. The system has insufficient formal and informal mechanisms that provide for `checks and balances' by means of broader networks for dialogue and learning, which creates problems of democratic legitimacy[10]. It has distinct characteristics of a so-called epistemic community[11]: a network of professionals with shared normative

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[3] See for example European Parliament/STOA (2007), *Policy options for the improvement of the European patent system* (IP/A/STOA/FWC/2005-28/SC16); S. Borrás & C. Edquist (2014), *Institutions and Regulations in Innovation Systems: Effects, Problems and Innovation Policy Design*, Papers in Innovation Studies, Paper no. 2014/29, CIRCLE, Lund University.

[4] OECD (2004), *Patents and innovations: Trends and policy challenges*, Paris: OECD.

[5] See N. Rigaud (2008), *Biotechnology: Ethical and social debates*, OECD International Futures Programme, Paris: OECD. See http://no-patents-on-seeds.org/en/information/patent-cases for an overview of NGO-involvement in opposing the patentability of plants/animals.

[6] See for a recent overview of ethical concerns surrounding (biotech) patenting: E.-M. Forsberg et al. (2018), `Patent Ethics: The misaligned view from inside and outside the patent system', *Science and Engineering Ethics*, 24: 1551-1576.

[7] See for example R. Crespi (2005), `Ethico-legal issues in biomedicine patenting: a patent professional viewpoint', *Science and Engineering Ethics* 11(1): 117-136.

[8] E. Kica & N. Groenendijk (2011), `The European patent system: dealing with emerging technologies', *Innovation – The European Journal of Social Science Research* (24(1-2): 85-105.

[9] I. Schneider (2009), `Governing the patent system in Europe: The EPO's supranational autonomy and its need for a regulatory perspective', *Science and public policy* 36(8): 619-629; A. Plomer (2019), "The EPO as patent law maker in Europe", *European Law Journal* 25(1): 57-74.

[9] I. Schneider (2009), "Governing the patent system in Europe: The EPO's supranational autonomy and its need for a regulatory perspective", *Science and public policy* 36(8): 619-629.

[10] S. Borrás (2006), 'The governance of the European patent system: effective and legitimate?', *Economy and Society* 35(4): 594-610; S. Borrás , Ch. Koutalakis & F. Wendler (2007), `European Agencies and Input Legitimacy: EFSA, EMeA and EPO in the Post-Delegation Phase, *Journal of European Integration* 29(5): 583-600.

[11] P. Drahos (1999), `Biotechnology patents, markets and morality', *European Intellectual Property Review*, 21(9): 441–449; L. Davies (2002), `Technical cooperation and the international coordination of patentability of biotechnological inventions', *Journal of Law and Society* 29(1): 137-162; P. Drahos & J. Braithwaite (2002),

principles and beliefs, shared causal beliefs, a shared notion of what constitutes valid knowledge, and with a common policy enterprise[12].

From the perspective of *epistemology and science models*, the patent system has been criticized for not being able to deal with new modes of knowledge production ('mode2') and/or with technologies, such as large parts of biotechnology, that show characteristics of post-normal science (i.e. high levels of uncertainly, value disputes, high decision stakes, and high societal urgency). Given these characteristics knowledge production and exploitation (of which the patent system is part) is inherently linked to policy making (and to politics), and both should take place within extended societal communities.

Finally, from the *perspective of RRI* the patent system has also been criticized for lack of inclusion of and responsiveness to societal stakeholders. RRI is a research and innovation strategy that highlights the importance of research and innovation contributing to societal goods, not creating undesirable side effects, and being developed in dialogue with society and in line with societal values. It implies that –through inclusive participatory approaches- societal actors work together during the whole research and innovation process in order to better align both the process and its outcomes, with the values, needs and expectations of European society[13]. Several approaches to RRI exist[14], but with clear commonalities: for research and innovation to be responsible, it needs to address significant societal needs and challenges, it needs to actively engage and respond to a range of stakeholders, in order to anticipate potential problems, identify alternatives, and reflect on underlying values[15]. Because patents are part of the overall research and innovation process, these requirements also apply to patent systems. The PatentEthics project, run by Oslo and Akershus University College of Applied Sciences (HiOA, now Oso Metropolitan University) from 2013-2017, critically assessed ethical implications of current legislation and institutional practices for patent protection (both in Norway and in the larger frame of the European patent system), focusing on non-human biotechnological inventions, more specifically aquaculture biotechnology[16]. This included an assessment of biotech patenting within the European multi-level patent system from the perspective of Responsible Research & Innovation (RRI). One of the main findings of the project was that the European patent system is currently not aligned with major RRI-principles such as addressing significant societal needs and challenges, engagement with and responsiveness to stakeholders, and reflexivity on underlying values[17].

The PATGOV project built this and similar diagnoses, but took the analysis an important step further by looking at **changes needed in the governance of the European patent system in order to**

Information Feudalism. Who owns the Knowledge Economy?, London: Earthscan Publications Ltd; Borrás (2006, ibid).

[12] P. Haas (1992), `Introduction: Epistemic Communities and International Policy Coordination', *Intern. Organization* 46(1): 1-35.

[13] https://ec.europa.eu/research/swafs/index.cfm?pg=about

[14] R. Von Schomberg (2013), `A Vision of Responsible Research and Innovation', in: R. Owen, J. Bessant & M. Heintz (eds.) *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, London: John Wiley & Sons (chapter 3); J. Stilgoe, R. Owen & P. Macnaghten (2013), `Developing a framework for responsible innovation', *Research Policy* 42: 1568-80; K. Jacob et al. (2013), *Options for Strengthening Responsible Research and Innovation: Report of the Expert Group on the State of the Art in Europe on Responsible Research and Innovation*, Brussels: European Commission.

[15] F. Wickson & E.-M. Forsberg, 'Standardizing Responsibility: The Significance of Interstitial Spaces', *Science and Engineering Ethics* 21(5): 1159-1180.

[16] *Final Report to the Norwegian Research Council for project 22069 – PatentEthics: Ethical dimensions of patent law in non-human biotechnology*, Oslo: HiOA, 2017. See also E.M. Forsberg & N. Groenendijk (2019), RRI and Patenting: A Study of European Patent Governance, *NanoEthics* 13(2): 83-101.

[17] *Final Report PatentEthics project* (ibid); *Report on the project workshop (Munich, 2016)* on the responsiveness of the patent system to stakeholders (https://responsivepatenting.wordpress.com/).

substantially align it with RRI-principles, more specifically to enhance its responsiveness to societal stakeholders, or -put more simply- to open the system up.

The multi-level/dual European patent system

The European patent system consists of a multi-level dual framework for patent assessment, granting and litigation. It involves the European Patent Organisation (EPOrg, based on the European Patent Convention, EPC, of 1973), an international organisation with 38 Member States, including all 27 EU Member States. It is located in Munich, The Hague, Berlin and Vienna, and employs about 6.700 staff members. It is the third largest international organization (IO) in the world.

Patent applicants currently have the possibility to file for a national patent with validity in their home country only, or for a European patent granted by the European Patent Office (EPOff). In the national route, the National Patent Office (NPO) deals with the examination and granting process (although some countries have out-sourced the examination process to the EPOff also in the case of national patents). In the European route, the EPOff deals with the examination and granting of the patent, but the patent claim has to be formally validated and maintained in each EPOrg contracting state the applicant wants the patent claim to be valid for. In that way patent protection can be sought by the patentee in up to 44 European countries (in addition to the 38 EPC contracting states there are so-called extension and validation states). Applicants also have the possibility to start the national route (1st filing) and then upgrade to the European route (2nd filing).

For European patents, the EPOff also handles opposition to granting of patents, and appeal cases. Patent litigation (i.e. the legal process to enforce the exploitation of patent claims) is currently handled by national patent courts, and not at the European level.

Patent assessment and granting follows patent law as laid down in the EPC and in national patent law, and the EU is not involved in (harmonisation of) patent regulation. However, in one specific area the EU has adopted legislation that is relevant to patenting. The 1998 Biotech Directive includes clauses that limit the patentability of certain biotechnological inventions; these clauses have later been incorporated into the (working rules of the) EPC.

The EPC and the EPOrg deal with patents, for a large group of European countries, including all EU Member States. Within the EU other important intellectual property rights are the domain of specialized EU agencies. The European Union Intellectual Property Office (EUIPO, formerly OHIM: Office for Harmonization in the Internal Market) deals with trade marks and industrial designs; the Community Plant Variety Office (CPVO) deals with plant variety rights.

The project had **six specific research objectives**:

1. To develop an **analytical framework** to assess the feasibility of such changes, and to make the necessary methodological preparations for the actual analyses;
2. To explain the limited use of **mechanisms that are currently available in the European patent system** to involve societal stakeholders and/or to address societal issues (such as third party observations, *amici curiae* briefs, ethics advisory committees, compulsory licensing, and outreach activities by the EPOff and by national patent offices);
3. To map and assess similar **mechanisms that are used by other regional patent systems** and could potentially be transferred to the European patent system (such as the USPTO peer-to-patent initiative, and the use of Boards of Ethical Review);
4. To map and assess (the feasibility of) **changes needed in the institutional set-up** of the European patent system in order to enhance responsiveness. This concerns especially the role of the EPOff as a highly autonomous entity within the system, fully funded by applicants, and subject to minimal political control;
5. To map and assess (the feasibility of) **changes needed in European patent law** in order to open up the patent system to more inclusive intellectual property rights (restrictions on broad patents, countermeasures against patent trolls, and promotion of collaborative patenting schemes such as patent pools, patent clearing houses, open source models and restricted liability regimes);
6. To assess **the likely impact the Unitary Patent will have** on the responsiveness of the European patent system.

These six research objectives were linked to six research Work Packages (WPs).

During the implementation of the project, an additional (7th) research objective was set, linked to a specific WP: which **similarities and differences** can be discerned **between the institutional set-up of the three main bodies that deal with intellectual property rights in Europe**: the EPOrg, the European Union Intellectual Property Office (EUIPO) and the Community Plant Variety Office (CPVO)?

ANALYTICAL FRAMEWORK & METHODOLOGY (WORK PACKAGE 1)

Central to the project is the RRI-concept of responsiveness. Responsiveness builds on (or: presupposes) other dimensions of RRI, such as (1) a specific focus on addressing significant societal needs and challenges, (2) active engagement of stakeholders, and (3) anticipation of potential problems, identification of alternatives and reflexivity on underlying values. Responsiveness is about the actual steps taken by actors, based on openness towards and engagement of stakeholders, and on reflexivity, i.e. the subsequent change and adaptation. It goes beyond mere strategic reaction to events in the organisation's environment[18].

Application of the concept of responsiveness first requires identification of actors (i.e. those who respond) and of stakeholders. In the project the following key actors have been identified:
- The European Patent Organisation (EPOrg), consisting of its executive body, the European Patent Office (EPOff) and the Administrative Council (AC);
- National patent offices (NPOs);

Relevant primary stakeholders are:
- Patent applicants (such as businesses and research institutes);
- Patent lawyers representing patent applicants;
- Competitors of patent applicants and patent holders.

Relevant secondary stakeholders are:
- The contracting parties to the European Patent Convention (EPC);
- The European Union (EU) and its institutions (and agencies); this stakeholder has been treated as a key actor in the analyses that looked at the Unitary Patent;
- Other regional patent systems;
- WIPO;
- NGOs;
- Individual citizens;
- Society at large.

In the different work packages, the focus was on different secondary stakeholders: societal stakeholders were central to work packages 2, 3 and 5, whereas the institutional stakeholders (contracting parties, the EU) were more prominent in work packages 4, 6 and 7.

The analytical framework for the project built on (historical-)institutionalist literature. Based on earlier diagnoses of the system, the main premise, used as starting point for the analyses, was that the responsiveness of the main key actors to stakeholders beyond the group of primary stakeholders currently is (very) low. The analytical framework then used a simple distinction between willingness and capacity to explain such (low) responsiveness:
- "Willingness" refers to interests of actors: low responsiveness is due to the fact that taking into account (secondary) stakeholders' positions goes against the interests of the key actors, who have a high level of relative bargaining power in decision-making;

[18] E.M. Forsberg & N. Groenendijk (2019), RRI and Patenting: A Study of European Patent Governance, *NanoEthics* 13(2): 96.

- "Capacity" refers to lock-in effects. Low responsiveness is caused by high change costs, and as a result, actors are locked-in into a sub-optimal situation[19].

For each of the partial analyses linked to the various research objectives, elements have been added to this basic framework.

Methodology

In the project, various research methods were used:

- Analysis of academic literature (articles, research reports);
- Analysis of secondary statistical data (mainly from the EPOrg, WIPO, Eurostat);
- Analysis of websites, policy documents and legislation (mainly from the EPOrg and the European Commission);
- Interviews with key actors.

Application of the latter method was not without problems. The Data Management Plan, drawn up at the start of the project, in line with the requirements (regarding consent, data storage) of the REA and the Norwegian NSD, included the use of semi-structured questionnaires, with a guarantee of anonymity while reporting findings from the interviews. It has however proven to very difficult to engage respondents from within the patent system (especially from within the European Patent Office) in such interviews, even though considerable time and energy was spent in contacting potential interviewees. Those who wanted to cooperate in most cases insisted on full confidentiality. It was therefore decided to replace the semi-structured interviews with more informal talks based on Chatham House Rules. 17 of such talks were held (by Skype or by telephone), with 12 different informants. The information provided in these talks has been used as research input/findings only if it could be substantiated by means of triangulation with other research methods.

CURRENT MECHANISMS FOR (ENHANCED) RESPONSIVENESS (WORK PACKAGES 2 and 3)

These two work packages focused on (a) the **mechanisms that are currently available in the European patent system to involve societal stakeholders and/or to address societal issues**, and (b) **similar mechanisms used by other patent systems** that could potentially be transferred to the European patent system. These mechanisms were first mapped and then critically assessed.

[19] Lock-in effects related to the patent system have been described in the literature before in various ways. For example, S. Thambisetty (2013), The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies like Synthetic Biology, LSE Law, Society and Economy Working Papers 18/2013, London School of Economics and Political Science, Law Department has argued that actors within the system are preoccupied with managing uncertainty through sticking to existing legal doctrines and rules in patent law, as providing new optimal patent standards is resource intensive; the temptation to rely on analogy and incremental solutions that satisfice is therefore very high. Substantive goals are sacrificed for short term gains in certainty. L. Vertinsky (2010), *Comparing alternative institutional paths to patent reform*, Alabama Law Review, 61(3): 501-552 has -for the US case- pointed to the transition costs that come with patent system reform, focusing on the users of the patent system (in institutional-theoretical terms: costs associated with micro adaptation).

Responsiveness mechanisms at the institutional level

At the institutional level, stakeholder involvement is largely limited to the group of primary stakeholders: patent applicants and the patent legal community[20], through observer status in the Administrative Council (AC) and its various committees, membership of the EPO Standing Advisory Committee before the European Patent Office (SAPECO), and membership of the EPO Roundtable on Patent Practice (EUROTAB).

As far as involvement of secondary stakeholders is concerned[21], such involvement seems to have been more extensive in earlier years. In 2007, the EPOff engaged in a scenario process (Scenarios for the Future), involving a large group of experts and stakeholders. From 2012 to 2015, the EPOff had an Economic and Scientific Advisory Board (ESAB). This board consisted of independent academic experts and practitioners, supported and coordinated by the EPO Chief Economist. Its activities were however not continued.

The EPOff still does organise relevant stakeholder events, but these are not very frequent and again largely target the group of primary stakeholders (businesses, national patent offices and the legal profession). In addition, since 2012, it uses consultation procedures.

In its Strategic Plan 2023, the EPOff has announced it will establish an Observatory, which will serve as an inclusive platform that brings together public and private stakeholders from across civil society (including non-governmental organizations) to discuss and debate developments in innovation and patents.

Responsiveness mechanisms at the patent processing level

At the patent processing level, the EPC provides for two mechanisms through which secondary stakeholders can be involved: third party observations (art. 115 EC) and oppositions (art. 99 EPC). Additionally, under art. 112 EPC proceedings (i.e. referrals to the Enlarged Board of Appeal), third parties can issue so-called *amicus curiae* briefs. Third party observations and *amicus curiae* briefs have relatively low thresholds as no fees are involved (as is the case with opposition procedures). Finally, the EPOff has a system (SECa) in which (ethically-)sensitive cases are singled-out during the examination procedure.

Similar mechanisms, used in other patent systems

The project tentatively looked into the potential use of other responsiveness mechanisms, by focusing on two cases: the USPTO and IP Australia. This work package did not entail a full-fledged comparison of patent systems but was meant to see if other patent systems provide useful responsiveness mechanisms, that are currently not used by the EPOrg. As such, no `new´ mechanisms were found. By and large, the USPTO and IP Australia engage in similar activities at the institutional level as the EPOrg: consultations, stakeholder events and advisory bodies. The same is true for the level of patent processing, where we also find third party observations, oppositions and *amicus curiae* briefs. In the case of the USPTO the so-called peer-to-patent (P-2-P) pilot was looked into in some more detail, but it was found that this pilot is strictly about third party observations on prior art[22].

Finally, this work package tried to establish whether and to what extent patent systems use Boards of Ethical Review or similar ethics boards in their patent examination and granting processes. It

[20] Forsberg & Groenendijk (2019, op. cit).

[21] Involvement of contracting parties has been dealt with as part of work package 4, on institutional issues.

[22] The art. 115 EPC mechanism was originally also meant as such (i.e. to let third parties reflect on issues of novelty), but the use of the term `patentability´ in art. 115 EPC has broadened its scope (see Forsberg & Groenendijk, 2019, op. cit., p. 92).

turned out that in that respect the Norwegian case, which was central to the earlier PatentEthics project, was quite unique[23].

Critical assessment

Regarding outreach activities to stakeholders, the focus of the EPOrg (in close cooperation with the NPOs) is on its primary stakeholders, i.e. its clients. Engagement with and responsiveness to secondary stakeholders is limited, as is the range of mechanisms used. Following the logic of the analytical framework briefly outlined above this can be due to (a) limited differences in interests between the key actors and these stakeholders, (b) a relatively weak bargaining position of these secondary stakeholders, and (c) high change costs of moving from a state with low responsiveness to a state with high(er) responsiveness.

It seems unlikely that all key actors and (primary and secondary) stakeholders in the system have similar preferences. For that, the patent system is too much contested, for example (but not only) by third party observations, oppositions, and by -critical- *amicus curiae* briefs. If, for example, third parties question the patentability of certain inventions, this is directly at odds with the interests of the EPOrg: in the long run limited patentability means less clients. The problem here is that with third party observations and *amicus curiae* briefs, neither the EPC nor the EPOff implementation guidelines provide any rules on substantive follow-up or debate. These instruments are therefore rather non-committal, even when, as is possible in the case of *amicus curiae* briefs, they are invited by the EPOff itself. This severely limits the power of secondary stakeholders to influence the system. Finally, change costs may be a hindrance. Higher engagement of secondary stakeholders at the institutional level and/or in the patent granting process comes with extra costs, not only direct financial costs, but also costs in terms of (cultural) adaptation of the key actors involved. Still, the earlier experience under the Pompidou (2004-2007) and Brimelow (2007-2010) presidencies shows that such enhanced engagement is possible, and therefore not primarily a cost issue. Pressures to keep patent fees low and more generally to work as efficient as possible existed also under these presidencies.

A post-patent granting mechanism: compulsory licensing

In their national patent legislation, a large number of EPC member states provide for the possibility for government and/or third parties, under certain circumstances and conditions, to use a patented invention without the authorization of the patent holder. In most countries the competent authority to decide on compulsory licensing are NPOs and/or courts, in some cases ministers and/or competition authorities.

Such compulsory licensing provisions aim at balancing the patent holder's interest and other, wider interests, in other words they aim to ensure a fair exercise of patent rights. As part of the so-called TRIPS flexibilities, article 31 TRIPS (non-exhaustively) lists the possible grounds for compulsory licensing: non-working or insufficient working of the patented invention; anti-competitive practices and unfair competition; public interest, including public health, national security, national emergencies and other circumstances of extreme urgency; failure to obtain a voluntary license under reasonable terms within a reasonable period; and dependent patents and other titles that relate to the protection of inventions. Moreover, certain conditions have to be met: the entity applying for a compulsory license should have been unable to obtain a voluntary license from the right holder on "reasonable" commercial terms; if a compulsory license is issued, adequate remuneration must be

[23] The Norwegian Patent Law (§15a Patentloven) requires the national patent office to consult an independent ethical board in case it doubts whether an application is at odds with *ordre public* and morality clauses. See M. Tvedt & E-M Forsberg (2017), The room for ethical considerations in patent law applied to biotechnology, *The Journal of World Intellectual Property,* 20: 160–177.

paid to the patent-holder; and a compulsory license must be granted mainly to supply the domestic market (i.e. it is possible to export products manufactured by using a compulsory license as long as the core function is to supply the domestic market)[24].
Generally, within the EU compulsory licensing practices are subject to the general provisions on competition policy (articles 34, 36, 101, and 102 Treaty on the functioning of the European Union), in the sense that compulsory licensing may not distort the proper functioning of the internal market. As documented by Tudor[25], in several cases the European Court of Justice (ECJ) has taken a firm stance against compulsory licensing practices by EU member states that were considered to be discriminatory. On the other hand, EU competition policy provisions allow the European Commission and the ECJ to impose compulsory licensing as a remedy to anti-competitive practice by a patent holder (i.e. if it abuses its dominant position by refusing to voluntarily license its patent). Moreover, some EU directives (such as the Biotechnological Patent Directive and the Community Plant Variety Right Directive) explicitly provide for compulsory licensing by EU member states, but this possibility is limited to the case of a plant breeder that cannot use a plant variety without infringing a patent.

In practice, compulsory licensing is not very common in Europe in the domain of patents[26]. Various reasons for this lack of use can be mentioned:

- Ignorance and unfamiliarity;
- The existence of the possibility of compulsory licensing as such has a positive effect on the willingness of patent holders to engage in voluntary licensing (the so-called hidden power of compulsory licensing);
- Compulsory licensing procedures can take long (also due to EU medicines regulations on data and market exclusivity), which creates a significant threshold for potential licensees;
- Requests for compulsory licensing are more often denied than honored by the relevant authorities/courts;
- Fear of economic reprisals by other countries;
- Fear of breach of EU competition law.

Still, some European countries have used compulsory licensing, and recent development might even indicate renewed interest in this mechanism[27]. In the pre-EPC era compulsory licensing was far more common, for example in Germany[28]. In Denmark there were three cases of compulsory licensing in

[24] In the domain of pharmaceutical products, the latter condition created a problem for especially developing countries that lack domestic production of pharmaceuticals. In 2003 this problem was tackled within the framework of the WTO Doha Declaration (the so-called Paragraph 6 Decision) by providing for a waiver for those countries, who may now import a specific patented pharmaceutical product. The Doha Paragraph 6 Decision has been implemented in the EU by means of Regulation (EC) 816/2006, which regulates the use of compulsory licensing for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.
[25] J. Tudor (2012), Compulsory licensing in the European Union, *Geo. Mason J. Int'l Com. Law* 4(2): 222-258.
[26] See for instance the overviews provided by Knowledge Ecology International (KEI) on EU compulsory licenses (http://keionline.org/publications). See also WIPO Secretariat (2011), *Survey on compulsory licenses granted by WIPO Member States to address anti-competitive uses of intellectual property rights*, CDIP/4/4/REV/STUDY/INF/5, and European Patent Academy/European Patent Office (2018), *Compulsory licensing in Europe. A country-by-country overview*. R. Beall & R. Kuhn (2012), Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, *PLoS Med* 9(1): 1-9 show that all compulsory licensing cases regarding pharmaceuticals (mainly: HIV/AIDS drugs) have occurred outside of Europe.
[27] P. Cappuyns & J. Vanherpe, A Licence! And Quick! Recent Developments Concerning Compulsory Licences For Patented Pharmaceuticals In The European Union, *Les Nouvelles*, June 2018: 184-188.
[28] Ph. Maume (2014), Compulsory licensing in Germany, in: R. Hilty & K.C. Liu (eds*), Compulsory Licensing*, MPI Studies on Intellectual Property and Competition Law, Springer, vol. 22.

earlier times (1943, 1966 and 1972). Later there were two in France (1983 and 1997)[29]. Italy granted compulsory licences in 2005 against Merck for a number of antibiotics containing the active compounds *imipenem* and *cilastin* (based on abuse of market position), and in 2006 against Glaxo for refusing a licence for *sumatriptan* for treating migraines. In 2007 Italy demanded Merck to issue licences free of charge for *finasteride*, a drug against (inter alia) prostate cancer. France imposed compulsory licences in 2004 for diagnostic tests for breast cancer[30]. In July 2017 the German Federal Court of Justice confirmed a compulsory license granted for *Isentress* (an AIDS drug, containing the patented substance *raltegravir*)[31]. In the Netherlands, following expert advice[32], the minister of Health Affairs announced his intention to further explore the possibility to use compulsory licensing of patents of highly expensive medicines. The use of compulsory licensing is also frequently advocated by international organizations such as the WHO, UN and OECD. Finally, the coronavirus pandemic has created a new momentum for the use of compulsory licensing.

CORE ISSUE 1: THE EPO AS AN AGENT WITHOUT PRINCIPALS (WORK PACKAGE 4)

In this part of the project, the focus turned to the institutional set-up of the European patent system and the EPOrg. **The main question addressed here was in what way the institutional set-up contributes or hinders responsiveness, and -in the latter case- to map and assess (the feasibility of) changes needed in the institutional set-up of the European patent system in order to enhance responsiveness.**

In addition to the basic analytical framework and the idea of interests, bargaining power and lock-in, a dedicated framework was developed[33], based on principal-agent theory and the literature on delegation to international organizations (IOs). This contributed significantly to the state-of-the-art, as to date the EPOrg has not been analysed from the perspective of scholarship on delegation to IOs and principal-agent theory. In addition, the analytical framework developed in this part of the project has potential wider significance for application to delegation to IOs (and to agentification in the EU). It differs from traditional principal-agent models in the sense that it provides a more balanced treatment of principal and agent behaviour as sources of agency problems; in traditional models the root cause of the agency problem is agent behaviour only. This is in line with recent literature, in which the common thread is the idea that delegation to and principal-agent relationships within IOs should be `unpacked´, by looking at delegation chains, at the different and varying role of actors, by not only focusing on A but also on P, and by looking at the dynamic character of delegation (delegation phase, post-delegation, feedback loops). The framework used in the project therefore revolved around various elements:

- The delegation logic;
- Agency slack;
- Complex agencies;

[29] See the overview in European Patent Academy (2018, op. cit.).
[30] The Italian and French cases mentioned here were not reported in European Patent Academy (2018, op. cit.).
[31] The patent in question was however revoked by the EPOff in October 2017, which means that the case never came before the highest German Court (the Federal Constitutional Court).
[32] Raad voor Volksgezondheid en Samenleving (2017), *Development of new medicines. Better, faster, cheaper*, The Hague.
[33] Building on N. Groenendijk (1997), “A principal-agent model of corruption”, in: *Crime, Law & Social Change*, 27: 207-229; D. Hawkins, D. Lake, D. Nielson and M. Tierney (2006), "Delegation under anarchy: states, international organizations, and principal-agent theory", in: D. Hawkins, D. Lake, D. Nielson and M. Tierney (eds), *Delegation and agency in international organizations*, New York: Cambridge University press, 3-38.

- Incentive schemes;
- Principal behaviour;
- Agent behaviour.

In the application of this model the EPOrg was regarded as the agent and the contracting parties to the EPC were seen as its principals.

Delegation logic

Underlying any principal-agent relationship is delegation of tasks. The two main common reasons for delegation are: (a) delegation as division of labour and gains from specialization[34], and (b) delegation for credible commitment[35]. In addition to these main logics of delegation, there may be reasons for delegation that refer to the possibilities that the delegation provides (post-delegation) for certain - strategic behaviour by the principal(s). These possibilities fit in with a more dynamic, and less static, view on principal-agent relationships[36]. Delegation for blame shifting[37] refers to the possibility that the principal delegates tasks, that are prone to policy failures and/or involve unpopular decisions, in order to let the agent carry the consequences and to escape electoral punishment. Other reasons refer to the use of post-delegation actions by individual principals, given the constraints that collective principals face in decision-making. Collective principals may delegate agenda-setting tasks, not for reasons of use of specialized expertise, but because they cannot reach a common position on the policy agenda themselves[38]. Other possibilities are delegation for consensus building[39] and delegation in order to lock-in distributional effects[40]. One-step further is delegation to create a policy bias or lock-in[41]: delegation to policy-biased agents that serve an individual state's (or a group of states´) interest in the future. What all these possibilities have in common is that they facilitate decision-making by collective principals, and that the delegation involves strategic considerations on the level of the individual states that make up the collective principal.

The preamble of the EPC provides some clues about the logic behind delegation to the EPOrg. It states that contracting states have the desire to strengthen cooperation between them in respect of the protection of inventions, and that such protection may be obtained in those states by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted[42]. Early EPOff documents mention reduction of duplication of work, cooperation on patent documentation and more effective patent law through harmonization of domestic patent law with the EPC[43]. This is all very much in line with the first logic of delegation: delegation for gains of specialization, with the underlying cooperation logic of providing a single procedure and more harmonised patent law for applicants, thereby reducing their transaction costs.

Although slightly speculative (for lack of official sources to refer to), it can be argued that the second delegation logic, credible commitment, is also relevant in the case of the EPOrg. One could argue that patent granting by national patent offices (NPOs) provides an opportunity for states to discriminate against foreign inventors, and that granting patents on a European level, by an independent agency,

[34] Hawkins, Lake, Nielson and Tierney (2006, op. cit.).
[35] Majone (2001, op. cit.); Tallberg (2002, op. cit.); Thomson & Torenvlied (2011, op. cit.).
[36] Tallberg (2002, op. cit.).
[37] Tallberg (2002, op. cit.).
[38] Hawkins, Lake, Nielson and Tierney (2006, op. cit.).
[39] Thomson & Torenvlied (2011, op. cit.).
[40] Kassim and Menon (2003, op. cit.).
[41] Hawkins, Lake, Nielson and Tierney (2006, op. cit.).
[42] Convention on the Grant of European Patents (EPC) of 5 October 1973. This preamble has not been changed by the 2000 revision of the EPC.
[43] See G. Doern (1997), "The European Patent Office and the political economy of European intellectual property", in: Journal of European Public Policy 4(3): 388-403.

creates credible commitment to absence of such bias. The dual set-up of the whole system with a national route through NPOs and a European route through the EPOrg, at least suggests that the contracting states may have had two types of applicants in mind. On the one hand national inventors that did not operate outside their own country (simply put: SMEs) and on the other hand inventors that operated across borders (larger, multinational companies), and for whom a level playing field is especially important.

The third logic, strategic delegation, may have been relevant if we look at the way that participation in the EPC has developed. The idea originated in France; already in 1947 did France propose to the Council of Europe (CoE) to create a European Patent Office (the Longchambon Plan). The idea was developed, over a long period of time, through work of CoE committees, in which France and Germany took the lead. The EPC/EPOrg started with a relatively small group of countries: Belgium, Germany, France, Luxembourg, Netherlands, Switzerland and the United Kingdom, and over the decades developed into the current group of 38 countries. The founding countries have been able to decide upon the content of the EPC, and on the way the EPOrg operated; to countries that joined later this represented an *acquis*, to which they were locked-in. Given the composition of the group of founding states (with –language wise- the Netherlands being the only odd one out), the choice of the three working languages (English, German and French), is an example of such a so-called first mover advantage. In addition, it also means that these states have been able to adopt content (in terms of substantial patent law) that must have been relatively close to their preferences, but not necessarily close to the preferences of states that joined later.

Agency slack

The agency problem commonly is conceived as the problem of agency slack. In the case of the EPOrg, agency slack can occur in two ways:

- Shirking: patents are granted in a way that is not in line with the principal´s preferences, in terms of the quality of the patent that is granted. The quality of a patent involves different dimensions: (i) the performance of the product provided to customers (i.e. does it stand up in opposition, appeal and litigation cases?), (ii) the costs incurred, and (iii) the timeliness of the service provided[44];
- Slippage: patents are granted by the EPOrg that the (collective) principal would not have granted if the decision had been handled by the principal itself (reversely: patents have been denied by the EPOrg, whereas the principal would have granted them).

The project looked into the possibility of empirical measurement of agency slack in the case of the EPOrg but found that not to be straightforward. The first aspect (quality) can be measured, as empirical material on patent quality is sufficiently available. However, such material is not available over a period of decades (as the EPOrg became operational in 1977), and, moreover, patent quality has increasingly become a relative issue, i.e. it is assessed by stakeholders in comparison with other economic blocks, and with the performance of their patent systems. The second aspect of agency slack is actually very difficult to measure. One way is to assume that slack exists when principals have to spend additional resources to regain control of their agents. These control efforts then serve as proxy for slack[45]. Another way would be to look at extreme cases, where the granting (or non-granting) of patents by the EPOff has led to fierce societal debate and see what the positions of contracting parties have been in these cases. Such an analysis was beyond the scope of the project.

[44] G. Scellato et al. (2011), *PATQUAL. Study on the quality of the patent system in Europe*, commissioned by EC DG MARKT, Torino/Enschede: Politecnico di Torino/University of Twente.

[45] This is the approach used by E. Heldt, "Regaining control of errant agents? Agency slack at the European Commission and the World Health Organization", in: *Cooperation and Conflict* 52(4): 469-484.

The EPOrg as a complex agent: symbiosis and ignorance

Many authors have pointed out that delegation in the context of IOs is significantly different from delegation on the national level. First, delegation to IOs involves a multitude of principals, as IOs are often made up of a relatively large number of contracting states, acting as a collective principal. Secondly, most IOs are set-up in such a way that they are complex agents, with intermediate principals (representing the contracting states, in a board or council) and an ultimate agent (an office or secretariat, or agent in the narrow sense). That means we have a delegation chain that runs from the contracting states (primary principals) to their representatives in the IO (intermediate principals) and from them to the ultimate agent (the IO secretariat or office).

Figure 1 outlines the main actors and relationships involving delegation to the EPOrg[46].

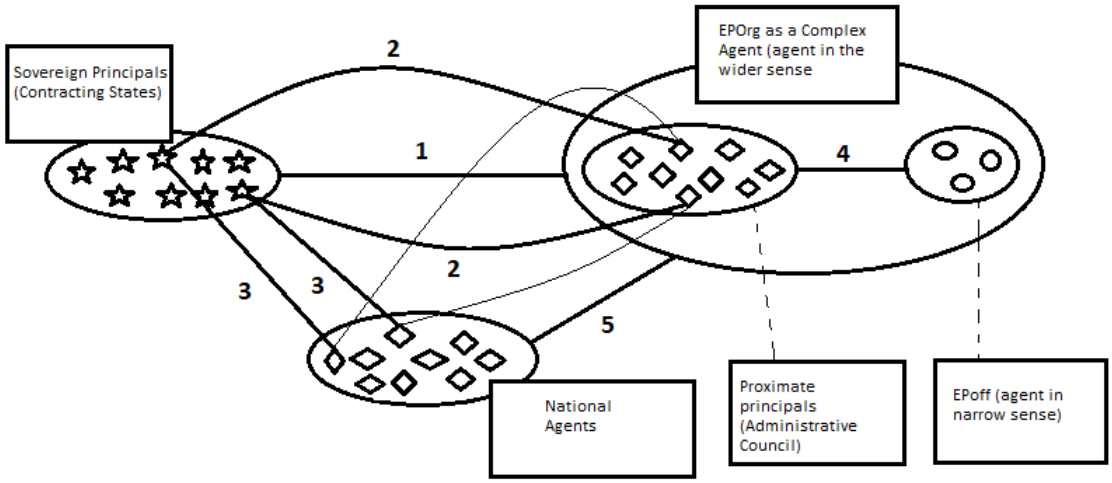

Figure 1: Delegation to the EPOrg: actors and relationships.

Relationship (1) is the basic delegation relationship from the Contracting States to the IO. The Contracting States are the Sovereign Principals (SPs), the EPOrg is the Complex Agent (CA), or agent in the wider sense. `Complex´, as within the EPOrg there is further delegation, with representatives of the SPs acting as the Proximate Principals (PPs), gathered in the EPOrg's Administrative Council (AC). Relationships (2) denote these representations, where the PPs are actually agents, serving their principals at home. Relationship (4) is the delegation relationship between the AC and the EPOff, in which the PPs are principals and EPOff is the agent in the narrow sense.

Relationships (3) also involve delegation, but on the domestic level, from central government to specialized agencies (national patent offices, or dedicated units within the responsible ministry): the NPOs. In the EPOrg context, representation in the EPOrg (as PPs in the AC) in most cases involves heads of these NPOs. This is shown in figure 1 by the identical shapes (the diamonds) and by the thin lines running from the NPOs to the AC. Finally, there is a multi-level relationship (5) between the EPOrg and the NPOs, with a certain division of tasks, and with intense cooperation. In that sense the EPOrg has developed, from an initial add-on to NPOs, for patent applicants that wanted to follow a European route, to the current umbrella under which NPOs function in the multi-level patent system.

[46] Inspired by a similar figure, used by M. Elsig (2010), "Principal-agent theory and the World Trade Organization: Complex agency and `missing delegation´, *European Journal of International Relations* XX(X): 1-23, applied to the WHO.

Based on a detailed analysis of legislation, EPOrg documents, the EPOrg/EPoff website and auxiliary sources, the following conclusions were drawn regarding the two bacis relationships in this complex agency.

The relationship between the AC (PPs) and the EPOff (ultimate agent) is **highly symbiotic**. As such, the EPC provisions seem to bring a clear division of labour between the PPs and the agent (EPOff). The PPs make the rules (building on the EPC), and the EPOff uses these rules in patent granting. The PPs appoint and supervise the EPOffP, who has to report to the PPs. There is also delegation of agenda-setting power (with both AC members and the EPOffP being able to set the AC agenda), which is common in principal-agent relations. In practice however, the EPOffP is the main provider of documents when it comes to AC meetings. This signals the information a-symmetry inherent to principal-agent relationships. However, is goes a bit further than that, in the sense that most of the *de facto* legislative power of the AC (as PPs) seems to build on what the EPOff proposes. Moreover, the division of labour between the AC and the EPOff is much less clear than the EPC suggests. The EPOrg and the AC do not have their own website but are embedded into the EPOff website. On this website, and in many communication channels, a distinction between EPOrg and EPOff is not made, and reference is made only to the `EPO´, which –on second reading- turns out to be the EPOff rather than the EPOrg. Another tell-tale is the background of EPOff presidents. The current president, António Campos, was executive director of the EUIPO from 2010-2018 (observer in the AC), and before that he worked at the Portuguese NPO, where he became president in 2005. In that capacity, he represented Portugal in the AC. The previous EPOffP, Benoît Batistelli, whose term ran from July 2010-June 2018, was AC deputy chair from December 2006-December 2009, and AC chair from March 2009-June 2018, prior to his appointment as EPOffP. Previous EPOff presidents show similar career paths (i.e. a path from AC to EPOffP)[47]. The EPOffP seems to be more of a *primus inter pares* than an actor that is distinctly separate from the group of principals. Also, there have been only a few cases where the AC and the EPOffP seem to have come into conflict, even under Batistelli's term, who had a very coercive management style.

Ignorance is the keyword when it comes to describe the role of the SPs vis-à-vis the EPOrg; that role is also not very well detailed in the EPC. The contracting states are mentioned in the preamble, and additionally there is exactly one article that deals with the SPs, which was introduced by the 2000 EPC Revision. It states that a conference of ministers of the Contracting States responsible for patent matters shall meet at least every five years to discuss issues pertaining to the EPOrg and to the European patent system. There is no evidence in EPOrg documents that such a conference has taken place since 2000. That means that the only involvement of the SPs is through their representatives in the AC, with the SPs acting as multiple principals for multiple agents (PPs). Direct involvement of ministers with the EPOff (bypassing the PPs) is scarce.
What is behind this lack of involvement is not clear. It could be that the SPs, in their relationship with the PPs, do not perceive any slack. Another possibility is that the SPs are simply not able to act as a collective principal because of heterogeneity of preferences (which renders conferences of ministers, which aim at consensual outcomes, useless to start with). We know that within the EU (which represents a large number of EPC contracting states) decisions on intellectual property rights are very difficult to take.

[47] Alain Pompidou (EPOffP from July 2004-June 2007) was the exception.

Incentive schemes

PAT assumes that some sort of funding or payment scheme is part of the contract between principal and agent, and that that funding is based on performance (regarding the outcomes). In practice, such incentive schemes are not always in place or are not that well developed. Agencies are often largely funded by user charges; IOs are often mainly funded by contributions from the contracting states (based on general parameters such as GNP or number of inhabitants). Such absence of performance-based incentive schemes is detrimental to the principal, and beneficial to the agent.

Contracting states have to pay an initial contribution to the EPOrg when they join. In terms of the operating budget, patent applicants pay for the EPOrg, not the principals. The EPOrg budget has to be balanced (expenditure has to be covered from applicants´ fees), and only in special circumstances do contracting states provide contributions to achieve such a balance[48]. Annual revenue from patent and procedural fees makes up 1.885 mln euro (2018), which is 99.3% of overall revenue[49]. This scheme could be an incentive for shirking, but at the expense of the applicant (as expenditures go up, fees can be increased), and not at the expense of the principal.

A recurrent issue is the revenue of renewal fees for European patents. As validation takes place on the national level, such fees are paid to NPOs. Both the EPOff (examination and granting) and the NPOs (validation and renewal) make costs for European patents. The AC (i.e. the NPOs …) decides on how these renewal fees are split between the NPOs and the EPOff. This provides the PPs with some leverage vis-à-vis the EPOff. However, the budgetary arrangements can hardly be called a performance-based incentive scheme.

Principal behaviour

Contrary to most initial research that used principal-agent theory, and which focused mainly on negative (i.e. agency cost increasing) behaviour of the agent, the literature on IOs increasingly pays attention to behaviour of the principal that result in higher overall delegation costs. Such behaviour comes in various forms[50]: (a) principal shirking, (b) principal-induced drift, (c) principal subversion, and (d) collusion.

With principal shirking, the principal fails to provide adequate resources to the agent to effectively carry out its tasks. In the case of EPOrg, it was found that the SPs and PPs do not provide the EPOff with any financial means, apart from the initial contribution, and a split part of renewal fees, but at the same time allow the EPOff to fully fund its activities through fees.

Principal-induced drift results from a lack of consensus and unclear mandates by the collective principal. The mandate given by means of the EPC in 1973 was clear, rule-based and detailed. Changes in the environment (e.g. emerging technologies) have however created gaps in the mandate. These gaps have not been filled by the SPs, except for the EU intervention by means of the Biotech Directive. Here, the PPs have done the lion's share of the work, by (re)interpreting rules and *de facto* rule making. On the one hand, for the complex agency (of which the PPs are part), this is a clear example of principal-induced drift. On the other hand, one could argue that the PPs have prevented drift by the EPOff (the ultimate agent) by constantly updating and detailing the agent's mandate. We should however keep in mind that the rule making by the PPs is in practice largely initiated and prepared by the EPOff itself.

With principal subversion, individual members of the collective principal undermine the proper execution of tasks by the agent, to their own benefit. The mirror image of principal subversion is

[48] EPC, Articles 37, 38 and 42.

[49] European Patent Organisation (2017), *Comprehensive Summary 2018 budget; Estimates for 2019-2022*, Munich: European Patent Organisation.

[50] See a.o. A. Thompson (2017), *Principal Problems: UN Weapons Inspections in Iraq and beyond*, paper Annual National Conference of the Midwest Political Science Association, Chicago, 12-15 April 2017.

collusion, when individual or groups of states team up with the agent (secretariat) to achieve outcomes on the expense of other states. Principal subversion and collusion thus occur when states individually and directly interfere with activities of the agent. In the case of the EPOrg, such behaviour has not been documented in the literature or in other sources.

Agent behaviour

Whereas the initial PA model focused on shirking and bonding as the main types of behaviour of agents, and as the main elements of agency cost, a more elaborate picture has emerged of the efforts of the agent in dealing with the principal, and especially with the monitoring done by the principal[51].

First, the agent can resist such monitoring by means of buffering. Buffering comes in two types: (a) dualism, and (b) ceremonialism. Dualism is the loose coupling of core tasks (what the agent actually does) and those practices that please other powerful players in the institutional environment (what others like it to do). Ceremonialism is superficial reporting designed to satisfy monitoring without revealing too much information. When it comes to dualism and reporting, it is not clear whether the annual reports provided publicly by the EPOff are identical to the management reports of the EPoff to the AC (as mentioned in EPC Article 10(2)e). If these are separate documents, then these management reports are not publicly available. The annual reports are supplemented by various other public reports, such as Quality Reports, and Social Reports. The common thread of these reports is provision of a lot of numbers and graphs, and very little reflection, let alone critical self-reflection. The focus is especially on how the EPOff performs towards its customers and the wider patent community; it does not seem to report with the AC (or the contracting states) in mind. The EPOff does not systematically and regularly reflect on developments in patent law and technology; such reflection is limited to special events (workshops, conferences), again targeting the patent community rather than principals.

In terms of ceremonialism, the EPOff has engaged in various activities, such as the European Inventor (of the Year) Award (as from 2006). In addition, and less ceremonial, it has set up the European Patent Academy (in 2004) which provides training, in cooperation with other regional patent offices, NPOs, and the EUIPO. It is also heavily involved in cooperation, by means of such training activities and exchange of best practices, with countries outside of the EPC territory (in Asia, Africa, and Latin America). These activities are not the core business of the EPOff, but they strengthen its position and autonomy.

In addition to buffering agents have a variety of behavioural means to increase their autonomy, beyond what was –initially- regarded as sufficient for the execution of their tasks. Agents have the possibility to interpret and reinterpret rules[52], even to the extent that they *de facto* create new rules. They can do so in in gradual incremental ways, which are visible to the principal, but do not provide the principal with an incentive to act and control. They can also (re)interpret rules in such a way that it splits the collective principal, making it unlikely that the principal will act. They can behave in accord with substantive preferences of the principal but develop procedural innovations (which deviate from what the principal prescribed) which also gives a low incentive for the principal to act, but which creates precedent. They can also ask the principal to formalize practices that the agent has developed informally. As far as rule making in the European patent system is concerned, we can refer to the *de facto* rule making role of the AC described above. In addition, it is important to mention the significance of the so-called Guidelines for Examination in the European Patent Office, a 985-page

[51] The overview is based on D. Hawkins and W. Jacoby (2006), "How agents matter", in: in: D. Hawkins, D. Lake, D. Nielson and M. Tierney (eds), *Delegation and agency in international organizations*, New York: Cambridge University press, 199-228.

[52] Hawkins and Jacoby (2006, op. cit.).

handbook for patent examiners. This rule-/handbook is not a product of the AC, as part of its rule-making powers, but is produced by the ultimate agent (the EPOff) based on the management competencies given to the EPOffP in Article 10(2) EPC. It adds an additional layer of (re)interpretation of rules, and of *de facto* rule-maki g, to the EPOrg.
In addition, the agent can use third parties (TPs): IOs and interest groups that prefer strong IOs can collude against states. Agents can increase the permeability to TPs, i.e. allow non-principals with similar preferences to be involved in the agents´ decision-making process. The most obvious type of TP to involve is the agent´s clientele, as well as like-minded NGOs. Regarding the EPOrg, as far as TPs are concerned, the AC and the EPOff always involve the same TPs: the patent profession, and BUSINESSEUROPE. In 2012, the EPOffP set up the Economic and Scientific Advisory Board (ESAB) to address important economic and social issues relating to the patent system and to support the EPO with evidence-based policymaking, this time involving experts from outside of the usual group of suspects. This Board was active from 2012-2015, by means of workshops and – a limited number of-external studies. They also provided expert statements, which in the EPOrg context could be labelled critical, or at least uncommon, as they addressed system aspects, rather than technicalities of patent law. The ESAB somehow ceased to exist in 2015; information on the ESAB on the EPOff website is provided in the past tense.

Treaties as incomplete contracts with high revision costs: lock-in
Principal-agent contracts, as all contracts, are in practice incomplete contracts, which do not specify what is to be done in every possible contingency. On the contrary, if such contracts would be complete, there would not be delegation and no discretion for the agent. Incomplete contracts can be made more complete at the post-delegation stage, but at some cost. Delegation to IOs involves international treaties; preparation, adoption and revision of international treaties is very demanding, as in almost all cases revision of international treaties requires unanimity (and sometimes ratification at the domestic level). International patent law (both substantial and institutional) is therefore hardly ever changed, amended or updated. Whereas the SPs were able to reach consensus on the original 1973 EPC (with a relatively small group of founding states) and on its procedural/technical update in the 2000 revision, any other, and more substantial changes have not been possible. The notable exception is the 1998 EU Biotech Directive (the content of which was implemented into the EPC and the EPC's Implementing Rules), which puts limits on the patentability of some biotech inventions, for ethical reasons. The EU Biotech Directive can be seen as a corrective measure, initiated by a sub-set of EPC contracting states, but through the framework of the EU. The substantive content of the Biotech Directive has however not been incorporated into the EPC by means of the route of Article 33(5), which would require unanimity in the AC, but through Implementing Regulations (that require three-quarters majority).
The AC, with its far-reaching *de facto* law making powers, especially through the Implementing Regulations, has used these powers to provide *de facto* updates of the EPC. This practice obviously results in a situation where important political questions about patentability of certain inventions, as well as important institutional issues, are dealt with as implementing issues, on a technical/executive level.

Conclusion
The EPOrg is a so-called complex agent, with delegation taking place from a multitude of principals (the contracting states) to an agent in a wider sense (the EPOrg), followed by further delegation within the IO, by the representatives of the contracting states (AC), to the agent in a narrow sense (EPOff). These representatives come from NPOs, which are (a) domestic agents in national patent granting procedures vis-à-vis their domestic principals, and (b) operate in the multi-level European

patent system as co-agents with the EPOff. A proper incentive scheme between the contracting states and the EPOrg is missing; clients fund the EPOrg. As a result, the EPOrg's interests and those of its clients (who finance the EPOrg) coincide. Contracting parties (SPs) do not interfere with the EPOrg. Within the EPOrg, the relationship between the PPs and the ultimate agent (EPOff) is highly symbiotic. This system thus suffers from multiple agency issues, which have resulted in too much autonomy for the ultimate agent (EPOff) and an overall lack of political guidance. The European patent system consists of a power block of the EPOff, NPOs and clients, with shared interests, which is hardly controlled by the contracting states (SPs). Overall, the set-up severely hinders responsiveness.

Potential changes

Change is very unlikely, as the system is locked-in to the EPC; multilateral treaty change probably comes with unsurmountable high costs. However, if EPC change would be possible at reasonable costs (or: if the contracting states would be willing to accept significant change costs), the following institutional changes should be considered:

- Replacement of the current EPOrg AC by:
    - a Management Board (MB) in which the EPOff and the (heads of) NPOs are represented, and which is embedded in the EPOff organization. The EPOff president can however not be chair or vice-chair of this MB;
    - a Governing Council (GC) made up of ministerial representatives from the contracting states;'
    - an Assembly made up of representatives from national parliaments and the European Parliament.
- Appointment of the EPOff president and vice-presidents by the GC;
- Separate status within the EPOrg for the Boards of Appeal (i.e. no longer embedded within the EPOff). Members of the Boards of Appeal are appointed by the GC. Decisions on suspension of members of Boards of Appeal are also made by the GC;
- Separate status within the EPOrg of the Board of Auditors. Members of the Board of Auditors are appointed by the GC. Decisions on suspension of members of the Board of Auditors are also made by the GC;
- Transfer of the (*de facto*) law making competencies of the current AC to the GC;
- Annual reporting from the MB to the GC, as well as regular external independent reviews/benchmarks of the EPOff;
- The Assembly has a deliberative and an advisory role; it makes recommendations to the GC on issues of patent law and on institutional issues;
- Limiting the financial dependency of the EPOrg on its clients, by letting the contracting states provide more base funding;
- The GC decides on fee levels and fee splitting between the EPOff and NPOs;
- Explicit and binding rules on participation of third parties in GC, MB and committee work, emphasizing the need for broad involvement and representation of such parties;
- Legal independent status for a Scientific Advisory Board, which advises the GC on broader issues relevant to the functioning of the patent system;
- Introduction of a simplified EPC revision procedure.

A COMPARISON OF THE EPOrg, EUIPO AND CPVO (WORK PACKAGE 7, extra)

In the era that the EPC was adopted (the early 1970s), the governance dimension of IOs, with its current focus on issues of accountability, transparency, and legitimacy, was not well developed (and even within that context the EPC Treaty was rather minimal concerning governance issues). Moreover, the EPOrg is no longer an add-on to national patent systems for users that want to follow the European route but has become the umbrella under which NPOs operate.
To supplement the analysis of the work package 4, it was therefore decided to look at two organizations similar to the EPOrg, that were established at a later stage: the European Union Intellectual Property Office (EUIPO, established in 1994) and the Community Plant Variety Office (CPVO, also established in 1994). The EUIPO deals with trademarks and designs, the CPVO with plant variety (or: plant breeder's) rights.

Obviously, there are important differences between on the EPORg on the one hand and the EUIPO and CPVO on the other hand, beyond the obvious difference in formal status (IO versus EU agency). Firstly, sizes differ. The EPOrg involves 38 member states and thus reaches beyond the EU geographically. It is the third largest IO in the world, with about 6.700 staff. EUIPO has 1.000 staff and is the largest EU agency in staff size. The CPVO has only 44 staff and belongs to the smaller EU agencies. Secondly, patents have a much higher political salience than trademarks, designs, and plant variety rights.
Importantly, the governance structures of the two IP EU agencies have been subject to revision by means of revision of the underlying regulations. Such revision is far less costly than treaty revision. The expectation was therefore that -in spite of differences in context- these governance arrangements are state-of-the-art, in comparison to the outdated arrangements of the EPOrg. The main question in this extra work package was therefore: **which similarities and differences can be discerned between the institutional set-up of the three main bodies that deal with intellectual property rights in Europe: the EPOrg, the EUIPO and the CPVO?**

This work package added value to the overall project, but is also relevant as a stand-alone research activity: even though research into EU agentification has boomed over the last decade, and although these two agencies are (often) included, as cases, in research on EU agencies, dedicated research on the EUIPO and/or the CPVO has so far been missing.

To start with the most important **similarities**, the basic set-up of the two EU agencies echoes to a large extent the set-up of the EPOrg. This is in line with earlier observations, that point at the similarity between the governance structure of EU agencies and certain IOs, as a case of isomorphism[53]:

- the EUIPO has a management board, similar to the EPOrg AC; in the case of the CPVO this body is also called the administrative council;
- in both cases the Boards of Appeal are embedded into the agency, just as the Boards of Appeal are part of the EPOff in the case of the EPOrg;
- the chair and vice-chairs of the MB/AC are chosen from among the MB/AC members, just as is done within the EPOrg AC;
- the two agencies are primarily funded by user fees and do not receive funding from the EU budget.

[53] See J. Tallberg (2002), "Delegation to Supranational Institutions: Why, How, and with What Consequences?", in: *West European Politics*, 25(1): 23-46, and H. Dijkstra (2014), "Approaches to Delegation in EU Foreign Policy: The Case of the Commission", in: M. Wilga and I. Karolewski (eds), *New Approaches to EU Foreign Policy*, London: Routledge, 38-56.

The main **differences** are as follows:

- appointment of the executive director (EUIPO) and the president (CPVO) is done not by the management board (MB, EUIPO) or administrative council (AC, CPVO), but by the EU Council. Removal from office also requires a Council decision;
- this is also true for the president/chairs of the Boards of Appeal. They can be removed from their position only after an EU Court of Justice decision;
- In the case of the EUIPO, the representatives in the MB are largely the same (people) as those that are part of the EPOrg AC: representatives/heads from the national IP offices. But we see slightly more representatives from ministries here, compared to the EPOrg. In the case of the CPVO most representatives come from ministries, especially ministries of agriculture and/or health;
- given the nature of the two EU agencies, the European Commission is a member of the MB/AC (a non-voting member in the case of the CPVO). EP also has a representative (with voting rights) in the MB of the EUIPO;
- both agencies have permanent observers to their MB/AC, representing client groups or organizations they cooperate with (such as the EPOrg, WIPO), but the EUIPO also uses a system of rotating observers to widen the group of involved stakeholders;
- both organizations, and especially the EUIPO, are networking agencies; they have well-defined plans for cooperation between their agency and the national offices, and earmark part of their finances to that end. The EPOrg is also heavily involved into such cooperation and networking, but in the case of (especially) the EUIPO the financial arrangements are much more explicit;
- fees for applications for trademarks, designs, and plant variety rights are set externally from the agencies, i.e. by means of the relevant EU regulations.

The analysis of the governance arrangements of the two agencies, in comparison with those of the EPOrg, then focused on the **three different dimensions of agency (or IO) governance**: control, network management and accountability.

In agentification and IO literature, governance of agencies is often framed as a *control* issue, within the standard principal-agent framework. Given the entanglement of EU agencies and national counterparts, another frame is that of *network management*. This governance dimension is not based on a delegation logic, but on a cooperation logic. It is about adequately involving all relevant cooperation actors, both in terms of interests and in terms of the resources they bring to the network ("pooling")[54]. The third frame is *accountability*. Accountability is not about delegation, but about giving account on the organization's mandate, to various fora of interested parties, i.e. societal groups, who have an interest in the way the mandate is performed, because they are impacted by that. They are parties that have a "stake" in the organization's actions (stakeholders), but do not necessarily contribute to these actions.

Unfortunately, accountability and control are sometimes conflated; ex post oversight or budgetary control mechanisms are then presented as accountability mechanisms[55]. For example, the external budgetary control of agencies by the European Court of Auditors (ECA) is not about accountability, as the ECA is not a stakeholder. The ECA is an agent that performs monitoring activities on other agents (such as the Commission and EU agencies), on behalf of a principal (Council/European Parliament).

[54] Egeberg, M. and J. Trondal (2017), 'Researching European Union Agencies: What Have We Learnt (and Where Do We Go from Here)?', *Journal of Common Market Studies* 55(4): 675-690

[55] See for example Vos, E. (2018), *EU agencies on the move: challenges ahead*, Stockholm: Sieps; Buess, M. (2014), 'European Union Agencies' Vertical Relationships with the Member States: Domestic Sources of Accountability?', *Journal of European Integration* 36(5): 509-524.

Another common mix-up is that of `stakeholder´ involvement and accountability. Involvement of a network partner, for example of users/clients through advisory committees or consultations is a matter of management (i.e. bringing their interests and expertise into the network), not an accountability mechanism.
Regarding these three dimensions, the following findings could be presented:

- The control governance dimension was found to be not very well developed in the case of the EUIPO/CPVO. Given the low level of political salience of the IPRs involved, this situation may however present acceptable risks for the principal. In the case of patents, and the EPOrg, the formal governance arrangements are largely identical to those of the CPVO, and control mechanisms are very limited (see work package 4), but here decisions are regularly taken that are contested politically;
- If we look at the governance arrangements from the perspective of network management, they make much more sense. They arrange the main features of multi-level networks, with the EPOrg/EUIPO/CPVO as main hubs, and involvement of the main other actors in the system, including observers and user groups. However, network management is commonly not based upon formal decision-making rules and procedures, with decision-making powers in the hands of those actors that are active in the spokes of the network, upon proposal by the hub. Network decision-making is often consensual, more informal and more fluid;
- Apart from the general EU rules for transparency and access to documents, there are no legal arrangements for accountability of the EUIPO and CPVO; neither does the EPC contain clauses on accountability for the EPOrg. It is up to these organizations themselves to define fora and mechanisms for accountability. But in doing so they hardly arrange for accountability (to societal actors). They rather provide lots of information on what they are doing to primary stakeholders (clients).

To conclude, in all three cases control mechanisms and bodies are used for network management (i.e. the symbiotic relationship discussed previously). This not only implies use of suboptimal means from the perspective of network management (for which better means are available), it also renders these mechanisms and bodies useless for proper control. Accountability lacks legal basis and the relevant mechanisms are limited to providing information to primary stakeholders. This also is detrimental to proper control, as accountability to a wider public can be used by principals as a fire-alarm monitoring mechanism. The various governance arrangements are conflated and therefore do not adequately cover the three governance dimensions.

CORE ISSUE 2: THE EXCLUSIVITY OF PATENT RIGHTS (WORK PACKAGE 5)

The purpose of this work package was to map and assess (the feasibility of) **changes needed in European patent law** in order to open up the patent system to more inclusive intellectual property rights.

In this work package, attention was first paid to the -normative- question of what could currently be defined as the core logic underpinning the European patent system. Following conventional wisdom, a patent system's task is to provide incentives to innovate and diffuse knowledge, by means of issuing exclusive property rights, but for a limited period, under the condition of detailed disclosure of the invention, and with the possibility for compulsory licensing of these rights in well-defined

circumstances[56]. In line with this logic, the EPOff states in its Guidelines (G.II.4.1.3): "The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject matter accordingly". Patentability as such is regulated by means of (a) the requirements of novelty, inventive step and industrial applicability, and (b) the morality clause of art 53(a) EPC (and the specific exceptions to patentability of certain biotechnological inventions brought in by means of the EU Biotech Directive). The EPO guidelines for examination say about article 53(a) EPC: 'The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour [...] This provision is likely to be invoked only in rare and extreme cases´. Art. 53(a) EPC thus does not request any ethical impact assessment but simply gives the EPO a possibility to deny extremely controversial patents.
Another possibility is to see patents as regulatory interventions by the state on behalf of society that should be in service of society's interest[57]. The latter view makes it very clear that granting patents comes with (economic, ethical) trade-offs and is essence a balancing act: patents are privileges, not rights. Currently, patents are often viewed as legal entitlements rather than economic tools with costs, benefits, and relationships to other aspects of innovation. Despite its purpose, the patent system therefore remains virtually unconnected to other technology and innovation policies[58] and operates from a rather broad and vague conceptualization of innovation. However, the patent system should not go for `any innovation as such´, and especially should not prioritize outdated vertical integration (`silo´) approaches to innovation but should promote open innovation as much as possible. The patent system is a vehicle for knowledge diffusion and not for innovation *per se*[59]. Taking this view on the European patent system as a starting point, the work package then analysed possible changes in -substantive- patent law that would provide for more balanced patents.

A three-pronged approach

In this work package, a three-pronged system of patents was developed:

- Traditional patents, based on exclusivity (property-rule), but with enhanced countermeasures in order to rebalance the system;
- Inclusive patents, based on liability-rules, with an obligation for inclusive voluntary licensing;
- Patents with compulsory licensing.

1-Traditional patents: enhanced balancing measures

Staying within the current patent paradigms, a number of changes are possible.
The first change is to enhance the patentability requirements for patents in emerging technologies, by means of explicitly addressing the *ordre public* and morality clause of art 53(a) EPC as a patentability requirement in well-defined cases. This should be done by applying a precautionary method of independent risk assessment by the patent examiners, rather than by using a plausibility approach based on the patent application (such as is used with the other -technical- requirements of novelty, inventive step and industrial applicability)[60].

[56] Cf. European Parliament/STOA (2007), *Policy options for the improvement of the European patent system* (IP/A/STOA/FWC/2005-28/SC16).
[57] J.Pila (2020), Adapting the *ordre public* and morality exclusion of European patent law to accommodate emerging technologies, *Nature Biotechnology*, 38: 546-558.
[58] S. Borrás & B. Kahin (2012), Patent reform in Europe and the US, *Science and Public Policy*, 36(8): 631–640.
[59] European Parliament/STOA (2007; op. cit.).
[60] See Pila (2020, op cit.), according to whom this would involve creating a special morality and public policy triage system within the EPO and domestic patent offices to screen all patent applications for a predefined class of emerging technologies for certain threats, and subject them to full precautionary risk assessment. In principle,

Another, related change is the introduction of a general proportionality requirement to counter overly broad patent claims. Currently, in the European patent system, the issue of the broadness of the claim is treated as a matter of insufficient disclosure of information in relation to the claimed subject-matter, not as an issue of claimed subject-matter in relation to the detrimental effect of the patent blocking further (downstream) innovation. The privilege should be proportional to the welfare losses it incurs on other actors[61].

A third change is differentiation in patent protection length, taking into account that different technologies have different life cycles: short for, for example, software; long for, for example, medicines[62]. This fits in with earlier observations of the OECD[63] on the uniformity of the patent system ("one-size-fits-all"), understood as equal treatment for all inventions within the subject matter, as a prominent example of a principle which should be reviewed.

Finally, in the post-granting phase, renewal of previously unused patents should be allowed under specific conditions only. Moreover, alienation of patent rights to parties that do not commercially use these patents (NPEs, non-practising entities) within a certain period of time, should render these patents invalid by law.

2-Inclusive patents

Patent holders currently have various possibilities to share their patent rights, by means of contracting. Such arrangements come in different sorts, ranging from basic licensing of rights to one or more parties, to more complicated schemes such as open source licenses (permissive licenses, patentleft schemes), creative commons, defensive patent licenses, cross-license networks, patent clearing houses, and patent pools. In this work package, such schemes were mapped and classified according to several dimensions.

Building on the seminal work of Calabresi & Melamed[64] on entitlements protected by property, liability or inalienability rules, some authors argue that such contracting arrangements (should) build on the strong property rights traditional patents provide. Merges[65] has argued that especially repeat players can arrange such schemes (voluntary organizations, in his words) at acceptable transaction costs, even in the context of patent thickets (overlapping set of patent rights which requires innovators to reach licensing deals for multiple patents from multiple sources). Liability rules, on the

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such a system could be introduced administratively, without change of substantive patent law, but it would be desirable to provide a strong legal basis.

[61] See also, for the US case: D. Karshtedt (2014), *Upstream inventions*, presentation IPSC - UC Berkeley School of Law August 8, 2014, who argues for completeness as an explicit condition for patentability.

[62] Hall (2007, op. cit.), referring to the seminal work on optimal patent design by Nordhaus, points out that the length and breadth of patents (the two main issues in optimal patent design) are likely to depend on the nature of the product market and the technology, which is inconsistent with long-standing practice and policy in most patent systems of having uniform rules for patents across technologies..

[63] OECD (2004, op. cit.). Another possibility mentioned by the OECD is differentiation in patent fees according to the breadth of the patent.

[64] G. Calabresi & A. Melamed (1972), Property Rules, Liability Rules, and Inalienability: One View of The Cathedral*, Harvard Law Review*, 85(6): 1089-1128. The important distinction here is between (a) property, where no one can take the entitlement from the holder unless the holder (by negotiation) sells it willingly and at the price at which he values the property, and (b) liability, where entitlements are sold according to an external, objective standard of value. Liability rules can be more efficient if there are high costs of establishing the value of the entitlement by negotiation (for example if there are many parties involved), i.e. if transaction costs are high, and a Coasean solution is unlikely.

[65] R. Merges (1996), Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations, *California Law Review*, 84: 1293-1393; R. Merges (2004), Compulsory Licensing vs. the Three "Golden Oldies". Property Rights, Contracts, and Markets, *Policy Analysis*, 508: 1-15.

other hand, involve collective valuation, legislative wrangling and legislative lock-in, and are less cost-efficient. Two counterarguments can be put forward here. First, in the current context of innovation (especially in emerging technologies) and given the relevance of open innovation, the patent thicket issue is probably more significant now than it was earlier. Secondly, Merges (and others) equate liability-rules based entitlements with compulsory (i.e. non-voluntary) licensing and assume collective rules on valuation and inclusion. This is not necessarily true, as liability rules can go hand-in-hand with voluntary licensing schemes. Compulsory licensing can have two forms: (a) the -inclusive- licensing is compulsory, but the way this is done is up to the rights holder, and (b) the licensing scheme is compulsory and predefined (in the UK context: statutory licensing).
Other authors have therefore advocated the use of liability rules in combination with inclusive schemes, either to replace traditional (property-rule based) patents[66] or to supplement them[67]. The basic difference between traditional patents (with the possibility of voluntary licensing schemes) and inclusive patents is that with inclusive patents inclusion is obligatory; with traditional patents the right holder is not obliged to include. With inclusive patents FRAND rules provide the bottom-line for such inclusion, but the right holder is free to choose other schemes (patentleft, permissive licenses, or waivers). Schemes are negotiated but conflicts over inclusion are ultimately subject to litigation.

Van Overwalle has argued that such inclusive patents might be subject to simplified application procedures (registration patents, but with full examination upon request) and with the possibility in the application phase to change an application for an inclusive patent into an application for a traditional patent (or vice versa). Obviously, such changes are not allowed after the patent has been granted. Antonellii[68] has advocated a differentiation between using the property rule (traditional patent) and the liability rule (inclusive patent), depending on the type of knowledge spill over involved. Exclusive protection based on the property rule should be used in case of intra-industry spill overs (i.e. vis-à-vis competitors in the same product market). Non-exclusive patents based on the liability principle should be used in the case of interindustry spill overs (i.e. vis-à-vis users of patented knowledge in other product markets). Karshtedt[69] has argued to use liability patents for research patents, i.e. for inventions that have large upstream significance, but -if granted as traditional patents- could stifle downstream innovation. Another possibility would be to use this type of patent for standard essential patents (SEPs), although the problem here is that it is often not possible to foresee at the application and granting stage if a patent will become a SEP or not.

3-Patents with compulsory licensing

Currently compulsory licensing is used as a countermeasure in the context of traditional patents, in the post-granting phase, on a case-by-case basis, if certain criteria are met. As such this mechanism, even though not commonly used, should remain in place, but harmonisation of compulsory licensing rules (in the EPC and/or EU context) is called for to reduce legal uncertainty and to prevent potential unfair competition.
In addition, the third prong of revised European patent law could be made up of generic compulsory licensing of patents (i.e. statutory licensing) for specific types of inventions, such as medicines, according to conditions set by the relevant authorities (and not by the right holder(s)).

[66] J. Reichmann (2000), Of Green Tulips and Legal Kudzu: Repacking Rights in Subpatentable Innovation, *Vanderbilt Law Review*, 53: 1743-1798.
[67] G. Van Overwalle (2015), Inventing Inclusive Patents. From Old to New Open Innovation, in: *Kritika: Essays on Intellectual Property,* vol. 1, P. Drahos, G. Ghidini & H. Ullrich (eds.), Edward Elgar, 206-277.
[68] C. Antonelli (2019), A reappraisal of the Arrovian postulate and the intellectual property regime: user-specific patents, *European Journal of Law and Economics*, 47:377–388.
[69] Karshstedt (2014, op. cit.).

THE UNITARY PATENT AND COMPETITION FOR IPRs (WORK PACKAGE 6)

In 2012/2013, through the mechanism of enhanced cooperation, EU Member States and the European Parliament reached agreement on the so-called patent package, which consists of three parts:

- a regulation creating a European patent with unitary effect (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). This UP involves 26 EU Member States, with Croatia and Spain opting-out;
- a related regulation establishing a language regime applicable to the unitary patent (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 requirement);
- an agreement between EU countries to set up a single and specialised patent jurisdiction (Agreement of 19 February 2013 on the Unified Patent Court). The UPC involves 24 EU Member States, with Croatia, Poland and Spain opting-out.

The final work package addressed **the likely impact the Unitary Patent (UP) and the Unitary Patent Court (UPC) will have** on the responsiveness of the European patent system.

History and state-of-play

The project first took a broader and historical perspective on how patents in Europe have been governed in relation to the process of European integration.

In the context of European integration, a common system for patent rights was proposed already in 1949, within the Council of Europe (the so-called Longchambon plan, named after French senator Henri Longchambon). His idea was to set up a European Patent Office that would deal with registration of patent applications and examination of the main patentability elements. National IP authorities would grant and administer the actual patents. A Committee of Experts of Patents (CEP), made up of representatives from national IP bodies, discussed the Longchambon plan, and focused on two main elements[70]: (a) harmonisation of search/examination procedures and of patentability requirements and exclusions (given the huge differentials between the systems of the countries involved), and (b) the relationship between a European Patent Office and the national IP bodies.

The CEP focused on the first issue in its Preliminary Comparative Study on Novelty and Patentability (April 1951). It went on to work on the basic harmonisation of substantive patent law, resulting first in the 1963 Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, and later in the 1973 Munich Convention on the Grant of European Patents (EPC). Progress on this substantive harmonisation had been good enough to go one step further than the original Longchambon plan: the EPOff would not only register and examine applications, but would also grant the European patent, made up of a bundle of potential domestic patent rights, to be validated by national IP bodies in those countries that the applicant wants patent protection. The governance structure (the second issue that the CEP looked at) followed from this division of tasks, with the national IP bodies represented in the Administrative Council (AC) of the EPO.

The EPOrg was thus conceived by the Council of Europe and its Member States, and the groundwork was done before the Treaty of Rome was signed and before the start of the EEC. Whereas the main aim of the Council of Europe had been to create legal certainty for companies, the EEC approached

[70] Partasarathy, S. & A. Walker (2014), 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe', in: R. Okediji & M. Bagely (eds), *Patent Law in Global Perspective*, Oxford: OUP, p. 321-343.

the patent issue from the perspective of the core objective of the Treaty of Rome, the single market. It started to develop its own plans for an EEC patent system, i.e. it aimed for a unified EEC patent, centrally examined and granted, with immediate validity throughout the entire EEC territory. In 1962 an EEC Committee of Experts proposed such a single patent, also to be managed by a European Patent Office, with oversight by an Administrative Council made up of representatives from EEC Member States. It proposed that patent litigation for these EEC patents should also be unitary and done by a specialised chamber of the European Court of Justice. Interestingly, this EEC Committee was made up of the same group of people (heads of national IP bodies) as the Council of Europe CEP, that proposed a non-unitary system.
The main strategic hurdle that the EEC had to take was the position of the UK, an issue that significantly delayed the EEC's plans. It was proposed that the EEC patent would be open to participation by non-EEC members, upon approval by the AC. Non-EEC members would be involved in the management of the European Patent Office, but could not be involved in the decision-making and legislation on the (EEC) patent system. For the United Kingdom this was acceptable only if it was a EEC member. If not, it preferred to have a common system of registration, examination and granting of the patent, but with validation (within the framework of their own patent law) on the domestic level for non-EEC (EFTA) members (and unitary for EEC members). After the negotiations on UK EEC membership broke down in 1963, and with the Council of Europe 1963 Strasbourg Convention in place, the case for such a two-tier system within the EEC framework lost momentum. An Intergovernmental Conference, made up of –again- the heads of national IP bodies and a large group of observers, discussed all options and decided to go for the EPC/EPOrg option, even though the United Kingdom joined the EEC in 1973. The EPC was signed in 1973 and entered into force (in 1977) for a group of countries that was made up of six EEC Member States (Belgium, France, Germany, Luxembourg, the Netherlands and the newly joined UK) and one EFTA member (Switzerland; Sweden followed in 1978). It has been highly successful in terms of membership, going from seven contracting parties at the start to the current 38 contracting parties.
In 1975 (two years after the EPC was signed) the –then- nine Member States of the EEC (the six founding countries and Denmark, Ireland and the UK) also signed the Community Patent Convention[71] which however never entered into force[72].
Arguing from the perspective of a well-functioning single market, the EC has never given up on the idea of a unitary EU patent, on which it finally reached agreement in 2012/2013 (50 years after such a unitary patent had first been proposed). Registration, examination and granting of UP applications will be done by the EPOff[73], but the UP puts an end to a number of disadvantages of regular EPC patents. First, as opposed to the EPC patents, validation in individual EU Member States is no longer required. An additional advantage is that an application can be made in English, German or French (just as with EPO patents), but granted UPs do not have to be translated in all official EU languages; with EPC patents such translation is still required for validation purposes. Secondly, patent litigation will take place on the EU level as well, through the UPC.

Ratification of this third part of the patent package (on the UPC) is however still pending, blocking the entry into force of the UP/UPC. Currently, of the 24 EU Member States involved in the UPC, 9 have not ratified, including Germany, where the Federal Constitutional Court has questioned the constitutionality of the UPC. Moreover, following Brexit, the UK has officially withdrawn its

[71] Convention for the European Patent for the Common Market (76/76/EEC).
[72] Pitkethly, R. (1999), *The European Patent System: Implementing Patent Law Harmonisation*, paper International Symposium on Innovation and Patents, Hitotsubashi University Japan, 12-13 February 1999.
[73] To that end the involved EU Member States have established a common system of patents for Parties in the EPC, an enhanced cooperation procedure that the EPC allows for (Art. 142 EPC).

ratification, effective from July 20, 2020. Apart from the fact that this means that UP/UPC-system will not cover the UK, it also poses legal problems in terms of the validity of the UPC ratification procedure as the UPC Agreement included a Central Division section of the UPC in London. For the second time around the position of the UK thus presents an obstacle for the introduction of a unitary patent.

Institutional issues

The institutional set-up of the European patent system will become even more labyrinthine with the introduction of the UP/UPC. Relevant institutional arrangements concern: (a) embedding the UP into the EPOrg structure, and (b) the institutional set-up of the UPC.

Based on Part IX of the EPC the UP Member States have delegated all administrative task to the EPOff and, in order to ensure the governance and supervision of these activities, form a select committee (SC) within the EPOrg AC. The set-up and working rules of the SC follows the set-up of the (general) AC in detail, including all the flaws relating to inclusion of societal partners and lack of principal steering, identified in work packages 2-4:

- observer status only for the European Commission; no involvement of European Parliament;
- observer status for BUSINESSEUROPE and *epi*;
- observer status for the other EPOrg contracting states.

The main difference is that the UP regulation (and the rules made by the SC) are very detailed when it comes to fee (sharing) issues. Furthermore, the European Commission has been given an important rule (within the EU framework) to evaluate the proper implementation, within the EPOrg framework, of the UP.

When it comes to the UPC, its institutional set-up follows the same format, with representation of the EU Member States in an Administrative Committee, and an observer status for the European Commission (and no involvement of European Parliament).

From an institutional perspective, the introduction of UP/UPC has thus not been used as a vehicle to open up the system, as the institutional arrangements mimic the existing unresponsive set-up of the European patent system and are fully imbedded into the EPorg structure.

Patent law change

The UP Regulation and the UPC Agreement introduce some substantial changes to patent law, relevant for UPs only:

- explicit progressivity of renewal fees throughout the term of patent protection, as well as differentiation according to business size and size of the market covered;
- the possibility for UP holders to file a statement with the EPOff that the holder is prepared to allow licenses of right (art. 8 UP-regulation), in which case renewal fees will be lowered;
- art. 27 of the UPC agreement introduces some exceptions to patent rights. The most important one is the breeder's exception. This provision limits the effects of patent rights for "the use of biological material for the purpose of breeding or discovering and developing other plant varieties". The breeder's exception has already been incorporated into the national patent laws of France, Germany, the Netherlands (and Switzerland), but the UPC will extent that exception to all UPC contracting states.

These changes are interesting as they might signal an opportunity for the UP/UPC states to circumvent the problem of patent law changes in the context of costly EPC revision. In terms of policy instruments, the UP Regulation allows the UP/UPC states to use the fee instrument more directly to advance to objectives of the patent system. The UPC Agreement directly introduces new patent law and changes to this agreement might be used in the future to the same end. This will still come with considerable costs, but these costs are lower than those associated with EPC revision.

The potential role of the UPC

The UPC introduces some major changes to the judicial part of the European patent system. It explicitly recognizes the primacy of EU law (art. 20 UPC Agreement) and seems to suggest a further hierarchy in sources of law to be applied by the UPC (art. 24 UPC Agreement): EU law, the UPC Agreement, the EPC, other international agreements, and national law. It also states (art. 21 UPC Agreement) that the UPC shall cooperate with the CJEU to ensure the correct application and uniform interpretation of Union law (through requests for preliminary rulings). Furthermore, CJEU decisions are binding on the UPC. The UPC also means a higher level of specialization in patent law of judges compared to the current national courts.

It is clear that this system with multiple sources of law and involvement of multiple courts will give rise to potential frictions[74]. The CJEU has, for example, no jurisdiction over the UPC Agreement as it is not part of EU law. The UPC has no jurisdiction in the granting phase. Forum shopping is yet another potential risk[75]. The enhanced cooperation format (within both the EU and the EPOrg) adds to the overall fragmentation of the system.

From a legal certainty perspective, this fragmentation seems undesirable. On the other hand, a "new kid on the block" brings certain dynamics to the system. The UPC will be a court with more weight than national courts. It has the potential to be better linked to the CJEU as (some) national courts currently are, with more cooperation and more inclination to request preliminary rulings on matters of Union law. The question is what the UPC could mean for inclusion of the two main counter elements to patent law: competition law and compulsory licensing[76]. The UP Regulation, in its preamble, explicitly states that compulsory licences for European patents with unitary effect should be governed by the laws of the participating Member States as regards their respective territories, indicating a lack of willingness to harmonize in this field. The UPC Agreement however explicitly lists national law (i.e. including national law on compulsory licensing) as a source of law. This is also true for EU competition law. Whether the UPC will really incorporate these sources or whether it will restrict itself to hard core patent law, remains to be seen.

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[74] J. Alemeida & G. Oliviera e Costa (2018), From the Unitary Patent Package to a Federal EU Patent Law, *Perspectives on Federalism*, 10: 125-145. See in detail, with an application on the morality provisions: A. McMahon (2017), An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: a Fragmented Future too Far?, *IIC* 48: 42-70.

[75] K. Glazer (2015), Advantages and Disadvantages of the Single European Patent, NAŠE GOSPODARSTVO OUR ECONOMY, 61(2): 24-34.

[76] J. Schovsbo, T. Riis & C. Salung Petersen (2015), The Unified Patent Court: Pros and Cons of Specialization – Is There a Light at the End of the Tunnel (Vision)?, IIC, 46: 271-274; idem (2014), The Unified Patent Court (UPC), Compulsory Licensing and Competition Law. Nordiskt Immaterieelt Rättskydd (NIR).

PROJECT PUBLICATIONS

In print

N.S. Groenendijk (2020), *The Governance of the European Patent System – Final Research Report*, Oslo: Oslo Metropolitan University; available at the project website https://www.oslomet.no/en/research/research-projects/patgov

N.S. Groenendijk (2020), *The Governance of the European Patent System – Policy Brief*, Oslo: Oslo Metropolitan University; available at the project website https://www.oslomet.no/en/research/research-projects/patgov

Conference papers

N.S. Groenendijk (2019), «The European Patent Office: Agent without Principals?», working paper ECPR General Conference, Wroclaw, Poland, 4-9 September, 2019; under submission

N.S. Groenendijk (2019), «Agentification & the governance of European intellectual property rights: Competition, cooperation, and conflated agency governance», working paper presented at the TARN Conference "EU Agencies as `Inbetweeners´? The relationship between EU Agencies and Member States", Maastricht, 4-5 December 2019; under revision for the TARN working papers series

Journal articles in progress/under submission/revision

N.S. Groenendijk, «Principal-agent theory and delegation to IOs revisited: Towards a more balanced treatment of principals and agents»

N.S. Groenendijk, «Three dimensions of agency legitimacy»

N.S. Groenendijk, «Proportionality and inclusivity of patent rights»

N.S. Groenendijk, «The long and bumpy road towards unitary patents and unitary patent protection in the EU: How UK accession in 1973 and Brexit in 2020 threw spanners in the works»

N.S. Groenendijk, «Re-assessing compulsory licensing of patents in light of the coronavirus pandemic»

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