

Experts and Politics in Patent Policy: The Final Report of the Expert Group on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering of the European Commission, 17 May 2016

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Abstract The 2016 Report of the “Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering group” is highly contentious. This opinion provides an overview of its content, discusses its relevance, and projects the future of the reform process of the Directive on Biotechnological Inventions 98/44/EC.

Keywords Biopatents · *Brüstle* · Experts · *Monsanto* · Stem cells · *Tomato and Broccoli*

1 Introduction

This article aims at making sense of the “Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering of the European Commission”, submitted on 17 May 2016.¹ The “Expert Group on Biopatents”, so its short title, was set up in 2012 to advise the European Commission on patent law in the field of biotechnology and genetic engineering.²

¹ Download via the European Commission’s DG Growth Webpage: <http://ec.europa.eu/growth/industry/intellectual-property/patents/biotechnological-inventions/>; or directly: <http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/> (first version uploaded 17 May 2016, last update of the report 16 September 2016).

² Commission Decision of 7 November 2012, C (2012) 7686 final.

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According to its mandate,³ its task was threefold: (a) “to provide the Commission with the necessary legal and technical expertise regarding intellectual property [henceforth “IP”] law practice and IP law administration, public and industrial research and development [...] in the context of the application of Directive 98/44/EC, with the exception of ethical issues [...]”; (b) “to assist and advise the Commission in its reporting requirements under Article 16, paragraph (c) of Directive 98/44/EC” of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [henceforth “Biopatent Directive”⁴]; and (c) “to provide the Commission with analysis and position papers [...]” Article 16 Biopatent Directive requires the Commission to report annually to the European Parliament. While the Directive has been in place for 18 years, the current exercise would be the preparation for the Commission’s third report only.⁵ Implicit, however,⁶ was the highly political question of whether the Commission should support a revision of the Biopatent Directive, which has been called for by various actors, including the European Parliament⁷ and the Dutch presidency of the Council in 2016.⁸ Since the European Commission enjoys the exclusive right to initiate a legislative process (Art. 17 Sec. 2 EU Treaty) and since its resistance to a “re-opening” is well documented,⁹ what had appeared to be no more than a technical expert report has turned into a highly political undertaking.¹⁰

The group was composed of 15 members, ten chosen for their individual expertise,¹¹ four for their status as societal representatives,¹² and one to stand for

³ Article 2 of the Commission Decision reads in full: “to provide the Commission with the necessary legal and technical expertise regarding intellectual property law practice and intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, and biotechnology in the context of the application of Directive 98/44/EC, with the exception of ethical issues related to that Directive, which are the mandate of the European Group on Ethics in Science and New Technologies” ... [and] “to assist the Commission in its reporting requirements under Article 16, paragraph (c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.”

⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ (30.7.1998) L 213/13.

⁵ Prior reports COM(2002) 545 final and COM(2005) 312 final; discussed by Schneider (2010).

⁶ Only recital 4 of the Commission Decision of 7 November 2012 (*supra* note 1) says that the group should assist the Commission in preparing a report on the *development* and *implications* of patent law in the field of biotechnology and genetic engineering” (emphasis added by C.G.).

⁷ Various Resolutions of the European Parliament had called on the Commission to act; for a summary see Schneider (*supra* note 5), pp. 602–606.

⁸ Programme of the Netherlands Presidency of the Council of the European Union, 1 January 2016–30 June 2016, p. 19. Download: <https://english.eu2016.nl/documents/publications/2016/01/07/programme-of-the-netherlands-presidency-of-the-council-of-the-european-union>, published 6 January 2016.

⁹ I. Schneider (*supra* note 5), pp. 601 and 609.

¹⁰ This process resulted, after finalising the IIC review process, into the “Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions”, OJ (8.11.2016) C 411/3.

¹¹ S. Bostyn, A. Farquharson, R. Jacob, A. Kamperman Sanders, S. Knuth-Lehtola, P. Pereira, P. Puigdomènech, C. Sattler de Sousa e Brito, I. Schneider and J. Taormino.

¹² S. Csörgő, H. Iserentant, C. Then and P. Würtz Lindum.

one “other public entity”, here the European Patent Office.¹³ Its members were selected upon application in 2013. The selection process appears to be unbiased and guided by proportional selection principles, and provides for the representation of Member States,¹⁴ specific societal groups (industry,¹⁵ non-industry/universities, yet surprisingly, in view of the political pressure,¹⁶ a farmers’ organization is missing), and professions (scientists and IP attorneys, IP lawyers, IP professors, IP social scientists). It met first on 12 December 2013 and delivered the report, after 18 meetings on 17 May 2016.

While the mission was “advice on re-opening”, the Commission had initially requested guidance on two issues: plant patents, and human embryonic stem cells (hESC). On the Commission’s request later on, the group took on a third issue, the question of the patent scope, instigated by the ruling of the Court of Justice of the European Union (CJEU) in *Monsanto v. Cefetra* in July 2010. The group formed three subgroups, chaired by S. Bostyn. In consequence, the report is divided into three parts (A–C). Under its rapporteur H. Iserentant, the subgroup on plants produced the “Subreport on Plant Related Inventions” (A.). The second subgroup under the rapporteur C. Sattler de Sousa e Brito submitted the “Subreport on the patentability of human stem cells” (B.). The third subgroup, to which J. Taormino served as rapporteur, wrote the “Subreport on the Scope of Protection of Patent Claims Directed to Nucleic Acid-Related Inventions” (C).¹⁷ Beyond these general topics, the subgroups were free to set their own foci. The first opted to concentrate on the “essentially biological process” patent exemption, the second broadened this perspective from embryonic to general “human stem cells”. Members of “majorities” and “minorities” remain anonymous, except for cases in which individuals provided dissenting opinions.

The submitted text is a rather difficult read. Beyond the evident tripartite division, the text is structured along “opinions”, marked as unanimous, majority or minority views held in the group. Each opinion is supported by legal arguments. Those again are supported by an interpretation of facts. Thus, the text has a complex horizontal and vertical structure and thus resembles to some extent a court decision. The text of a court decision is horizontally structured by the elements of a legal test which determine a decision (if conditions A, B, C are fulfilled, the result is Y), each element is vertically supported by an analysis of legal principles and contested facts as delivered by both parties of a given dispute, ranked based on the burden of proof or credibility. Here in contrast, the text is not oriented towards a decision, but a recommendation. Horizontally, it is structured along opinions. Vertically, each opinion is supported by contested legal

¹³ S. Yeats.

¹⁴ Belgium, Finland, France, Germany, Netherlands, Italy, Portugal, Spain and the United Kingdom, as required by recital 7 and Art. 4(3) of the Commission Decision 7 November 2012 (*supra* note 1).

¹⁵ EuropaBio (industrial patent policy); European Seed Association (breeders); Flemish Institute of Biotechnology (independent, commercial biotechnological research); No Patents on Seeds! (patent opponent).

¹⁶ This political pressure has built up in the Council of Agricultural Ministers, as recorded by the Luxembourg Presidency: “The impact of a recent decision of the European Patent office (EPO) concerning the patentability of plant traits on the plant breeders’ rights regime” was discussed in the Council (Agriculture and Fisheries) on 22 October 2015 (<http://data.consilium.europa.eu/doc/document/ST-12943-2015-INIT/en/pdf>).

¹⁷ The workshare corresponds to Art. 5(4) Commission Decision 7 November 2012 (*supra* note 1).

arguments. These are in themselves not new. They correspond to the arguments exchanged in the discussed procedures in the EPO and CJEU; for a thorough legal argumentation, one would do better to turn to the standard academic literature. Yet, the function of this text is to prepare legal arguments for a political arena.¹⁸ This is why the style and language absorb a distinct meaning. Beyond that, the report provides information about the state of the art of technological advancement. In addition, it displays how dense the relation has become between the EU's patent law and the EPC patent system (much more than one would expect from a legalistic perspective¹⁹).

The parlance of majority and minority opinions and multiple cross-references make the text a “clumsy read”, and a critical question persists: majority/minority of what? The obvious answer is “the vote of 15 appointed experts”. Yet, the appointees applied on their own initiative.²⁰ The group as such is not, and is not supposed to be, representative. While argumentative dissenting minority opinions of individualized authors are annexed, they are buried amongst documentary evidence, such as national transposition legislation (A2), or the truly superfluous reprint of the Directive's recitals (B1). The texts and annexes deserved more editing.²¹ The argumentative quality of the Subreports is mixed; only the dissenting opinions (in sum 42 pages out of 264) are of very high quality throughout.²² Therefore the question imposes itself: What is the report good for? The produced text as such is unreadable. What function does the report serve? The following article digs into the context of the report (Sect. 3), but first summarizes and reassembles the content of the three Subreports (Sect. 2).

2 The Three Subreports

All three reports organize their arguments in terms of unanimity, majority and minority. The results of seven votes as to how to advise the European Commission to act (take no action, issue clarifying statement or initiate legislative activity) are

¹⁸ In this area of law, even the presentation of the facts mirror the different worldviews. Therefore, majority and minority opinions need to be read side-by-side to reveal the different perspectives, rationales and assessments of the facts and evidence.

¹⁹ The text assembles the situations of connectivity (e.g. Subreport A: pp. 109 et seq.; Subreport B: Annex B4, EPO-guidelines 2015 after *Brüstle*: p. 159); Subreport C, pp. 194 et seq.). The political scientist I. Schneider describes the relation as “co-evolution”, Schneider (*supra* note 5), pp. 608, 620.

²⁰ The European Commission chose from about 90 applications.

²¹ Yet, over the summer 2016 many mistakes were corrected, a proper front page was installed and a table of contents inserted, the structures of the three annexes became aligned – which provide for the overview of also the dissenting opinions. Yet, there is still an “annex” to an “annex” (p. 255); referencing is not impeccable (footnotes refer, e.g. to A III, meaning A3; footnote No. 113 refers to “alternative strategies [...] as shown in Annex I”, but it is B. Annex 1. The text referred to has presumably been inserted into the introduction). Footnote No. 129 is incomplete as to publication years; footnote No. 198 is misleading: the referred *authored* article in the book *edited* by C. Geiger is: Krauss and Takenaka (2013). Also unclear are the references to the contributions in the books edited by Lawson and Charnley (eds, 2015) and Kur and Dreier (eds, 2013). Page numbers are missing for the article by G. Van Overwalle in IIC (2011).

²² Minority opinion held by C. Then as regards part A (pp. 105–120), minority opinion held by S. Csörgő as regards part A (pp. 121–126), minority opinion held by I. Schneider as regards part B (pp. 161–177), minority opinion held by I. Schneider as regards part C (pp. 257–265).

Part II omitted

the legal situation “clear”, and having Member States (as EPO members and as EU Council of Agricultural Ministers) and the Commission refrain from further legislative activity, both in the European Union’s arena and in the EPO. With this result in mind, the following question imposes itself: What is this text good for? What is the reason for the structure chosen?

3 Making Sense of the Report

3.1 Committees in the EU Multilevel System

Expert groups form part of the European Commission’s support structure working towards European policymaking.⁴⁶ However, an “expert group”/“expert commission” should not be confused with a “comitology commission” (formerly “regulatory commission”).⁴⁷ The latter play an integral part in the typically multilevel decision-making of the European Union’s political administration, which delicately balances supranationalism and intergovernmentalism.⁴⁸ These commissions bring together experts from national ministries or specialized agencies. Expert groups, in contrast, supply governmental bodies with expert knowledge in more traditional ways. They serve to enhance the rationality of a political decision-making process.⁴⁹ More recently this expertise has become acknowledged as a central characteristic of modern, de-nationalized decision making aspiring to substitute for legitimacy and aggregate knowledge organized by a parliamentarian discourse.⁵⁰ Expert committees can be formal or informal,⁵¹ temporary or permanent, appointed individually in person or as representatives,⁵² representative

⁴⁶ Technically called “Comitology System”, see *inter alia* Vos (2009).

⁴⁷ The European Commission uses the term “expert groups” and distinguishes these from “comitology committees”; see the Commissions explanation of “expert groups” at: <http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2>.

⁴⁸ Comitology committees are composed of Member States’ delegates who support the European Commission in formal decision-making, legitimized by the EU legislator, which empowers the Commission to adopt implementing legislation subject to the scrutiny of Member States.

⁴⁹ Classically conceptualised as an intended conflict between “truth” and “power”, R. Mayntz, “Speaking Truth to Power: Leitlinien für die Regelungen wissenschaftlicher Politikberatung, der moderne Staat” (dms) – 2(1) Zeitschrift für Public Policy, Recht und Management pp. 5–16, 9: “Der Wissenschaft geht es um wahre Aussagen, der Politik um gestaltendes Handeln. Diese unterschiedlichen Rationalitäten müssen im Beratungsprozess vermittelt werden: Die Qualität der Politikberatung bemisst sich daran, wieweit es gelingt, ein sowohl wissenschaftlich solides wie politisch umsetzbares, kurz ein dem Zweck entsprechend brauchbares Ergebnis zu erzielen.”

⁵⁰ See the joint publication of M. Bartl et al., “Knowledge, Law and Power beyond the State”, Amsterdam Law School Legal Studies Research Paper No. 2016-08.

⁵¹ “Formal” work groups are set up by Commission decision. “Informal” work groups are set up by an individual Commission department that has obtained the agreement of the Commissioner and Vice-President responsible and of the Secretariat-General.

⁵² The European Commission distinguishes five types (A–E) of expert members: Type A – individuals appointed in a personal capacity, acting independently and expressing their own personal views. Type B – individuals appointed to represent a common interest shared by stakeholder organizations in a particular policy area. They do not represent individual stakeholders, but a particular policy orientation common to

of “the population” or just the person of the expert.⁵³ Their input is not binding.⁵⁴ Conceptually, there are two different types of “expertise”, scientific expertise and professional expertise. Scientific expertise maneuvers on the interface of politics and science. Its modern emergence and its inbuilt rationality result in conflicts, which are roughly defined as conflicts involving politics and truth, and have been well researched.⁵⁵ Professional expertise, in contrast, is conceived as complementing existing knowledge inside governmental bodies with outside “real-world” practical expertise or adding knowledge that does not exist inside (e.g. ethical expertise⁵⁶). Especially when private industry is involved in providing expert knowledge, legitimacy stems from the idea of stakeholder participation.⁵⁷ Professional expertise can be selected on the merits of an individual or by way of representation of an institutional policy. Most professional expert groups⁵⁸ have in common with scientific expert groups that the external expectation is for them to deliver an unequivocal report. Underlying both types is the rationale of an epistemic community qualified by “a shared set of normative and principled beliefs, which provide a value-based rationale for the social action of community members”.⁵⁹ While natural scientists presumably agree on facts, in the case of professional experts it is expected that diverging opinions between group members can be calibrated internally, and coalesced into one homogenous position. Yet, experts and science have become demystified, respecting the need for evaluation in interpreting facts. Today’s expert reports, even those produced by natural scientists, often come with a majority and a dissenting opinion, presenting these arguments side-by-side,

Footnote 52 continued

different stakeholder organizations. They may be proposed by stakeholder organizations. Type C – organizations in the broad sense of the word including companies, associations, NGOs, trade unions, universities, research institutes, law firms, and consultancies. Type D – Member States’ authorities (national, regional or local). Type E – other public entities, such as authorities from non-EU countries (including candidate countries), EU bodies, offices or agencies, and international organizations.

⁵³ Being an additional category, most evident with regard to expert committees on ethics, cp. the Federal Belgian Ethics Council representing “the population” (<http://www.health.belgium.be/nl/belgisch-raadgevend-comite-voor-bio-ethiek>) to the Danish Council of Ethics (<http://www.etiskraad.dk/Om-Raadet/Historie.aspx>) and the European Group of Ethics (<https://ec.europa.eu/research/ege/index.cfm>), the latter both representing “experts as experts”.

⁵⁴ Qualified as essential element of expert advice, *see* Mayntz (*supra* note 49), p. 11.

⁵⁵ Recently OECD (2015), “Scientific Advice for Policy Making: The Role and Responsibility of Expert Bodies and Individual Scientists”, OECD Science, Technology and Industry Policy Papers, No. 21, OECD Publishing, Paris. doi:10.1787/5js3311jcpwb-en; and European Commission, Taking European Knowledge Society Seriously, *Report of the Expert Group on Science and Governance to the Science* (directed by Brian Wynne), 2015, <http://www.ec.europa.eu>; academic reflection about the interface has centered around the terms of risk and precaution. A seminal text is Beck (1986); for a primer, *see* Antonsen and Elmkvist Nilsen (2013).

⁵⁶ With regard to the Biopatent Directive, the Commission is complementarily supported by the EGE group, its webpage (*supra* note 53). For an analysis *see* Busby et al. (2008).

⁵⁷ B. Farrand, “Trading Information for Influence: Forms of Knowledge and the Power of Legitimacy”, in: M. Bartl et al. (eds), (*supra* note 50), p. 11.

⁵⁸ This expectation might not be cogent in all cases.

⁵⁹ P. M. Haas, “Introduction: Epistemic Communities and international policy coordination”, 46 International Organization, special edition, “Knowledge, Power, and International Policy”, 1992, pp. 1–35, at p. 3. A seminal work is Holzner and Marx (1979).

thus also acknowledging differences in “institutional knowledge”.⁶⁰ Dissenting opinion often enjoys special appreciation by the general public.

The expert group on biopatents is composed, in the language of the European Commission, of members “Types A, B and E”,⁶¹ meaning that its members are both individually appointed independent experts (Type A) and representational experts (Types B and E). The group does not represent “the population”. The majority are IP practitioners (either appointed on individual merits or as representation); some are IP scholars (appointed on individual merits). The group is installed for its legal IP expertise, not for its natural sciences expertise.⁶² It should complement the Commission’s own expertise⁶³ with regard to “practice”. The group mixes professional IP interests (goal orientation) with academic work ethics (argument orientation). As stated in the introduction to Subreport B, the report “does not represent any individual position of the experts, nor any speakers or position of the Commission itself [...]” The group, as it is composed, is not an “epistemic community” as defined in social science theory. It does not bring together “the epistemic patent community”.⁶⁴ While all group members share profound patent knowledge, they do not share common beliefs. The group brings together passionate advocates for strong patent protection and their critics. The obvious rationale of the group’s composition is the broad and unbiased representation of societal standpoints. Therefore, a uniform opinion of the group was not to be expected. Yet, reading between the lines of the report’s Foreword and the Subreports’ executive summaries reveals that the Commission had made clear that it wished for a consolidated opinion, despite the evident tensions between group members.

3.2 The Interface of Politics and Expert Advice

3.2.1 *The Mandate: Consensus Versus Dissent*

While the expectation of a consensual report was neither explicit in the mandate nor in the public tender, it became required by the Commission and turned into a heavy burden for the group. From the outside, it seems of negligible importance whether an expert group delivers a consensual or a dissenting report. Especially from a legal

⁶⁰ B. Farrand (*supra* note 57), p. 11 observes that “experts” might have “expert knowledge”, but differ with regard to “institutional knowledge, impacting on their ability to be heard”. He distinguishes academics and volunteer staff of NGOs with professional support structures of industry.

⁶¹ <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2973>.

⁶² The subgroup on human embryonic stem cells had “the benefit of having invited” one “external” natural scientist Prof. Peter Andrews, University of Sheffield (UK) (report p. 7), as foreseen in Art. 5(7) Commission Decision 7 November 2012 (*supra* note 1). His expertise was highly valued by the group. Records of the hearing with him were kept (as stated in the minutes of the 8th Meeting of 27 November 2014), but have not been made public.

⁶³ The European Commission attended the meetings as stipulated in Art. 5(3) Commission Decision 7 November 2012 (*supra* note 1). Knowledgeable personnel were sent to the group’s meetings, directed by the head of department responsible for IP. This position was held by K. Jorna, until the European Commission was reshaped in Summer 2015 merging former DG Market and DG Enterprise into DG GROW.

⁶⁴ Described by Schneider (*supra* note 5), pp. 194–199.

scientists' perspective, a legal experts' group, as a matter of principle, *cannot* be expected to concur in policy questions. Yet, the group was set up to serve the Commission. If the expert group had only had the function of providing input for the Commission's task of reporting to the European Parliament, different positions would have been welcome. However, the Commission's main intent was to gain support in its capacity as the formal initiator of legislative action. While being invited to act by the European Parliament for some time (*supra*), the Dutch Council presidency had put the Directive's revision on the political agenda for 2016. The Commission was under political pressure to respond. While the mandate seeks legal patent expertise, the interest of the Commission was not in legal technicalities. It pursued a strategic interest in its support.⁶⁵ The Commission obviously pushed for a unanimous report. The Subreports struggle to make statements which can be portrayed as expressing a unanimous position,⁶⁶ to the extent that they become meaningless.⁶⁷ Acknowledging the Commission's position so far, it most probably expected unambiguous support for its position not to "open up" the Directive unless an unequivocal opinion suggested otherwise. Dissent would not have been helpful; instead, it would have forced the Commission to take a position no matter which stance it had taken. The Commission has pursued this line to the extent that it required a well-known legal academic who was invited as a speaker to the final symposium in which the report was presented (18 May 2016) to suppress his own opinion. It seems that over time the politically desired content had crystallized, and had become known to the members. In turn, representatives in line with the Commission's position apparently closed ranks in their own interest. In turn, other members seem to have felt that they were not respected in terms of their professional credentials (be they scientific or representative), and that they had been instrumentalized in an opaque,⁶⁸ predetermined political process.

⁶⁵ The installment of expert commissions for strategic reasons is not without precedent. The expert group installed in 2002 to support the Commission in preparing the first Art. 16(c) Report to the Patent Directive 98/44/EC served the function of demonstrating that the Commission was aware of the problem (but it opted not to act formally), Schneider (*supra* note 5), p. 598. For a thoughtful analysis of "political instrumentalization" of scientific advice see Mayntz (*supra* note 49), pp. 10 and 14. While she recognizes the underlying problem, she opposes the idea that scientific policy advice should be distinguished from political advice. She aligns the problem with dichotomous opposites, which by their very nature cannot be resolved in one direction only.

⁶⁶ "Where possible, unanimity was sought", Report, p. 11.

⁶⁷ P. 28: "Within the Expert Group, agreement could be reached that Headnote 1 and 2 of G2/07 constituted valuable and valid elements of a definition of what is an essentially biological process." P. 29: "All Experts could agree that natural mutagenesis is a natural process, and that targeted mutagenesis is a technical process."

⁶⁸ On first sight, the Commission's webpage of the group's work provides transparency. It posts all agendas and minutes. However, additional documents which were prepared on request by several members are not posted (*supra* note 32). It is questionable if the non-publication of these documents is in line with good governance norms on expert advice on the side of the advised organization, which shall safeguard against unwarranted instrumentalization of expertise, see Mayntz (*supra* note 49), p. 12.

3.2.2 Decision-Making Versus Expert Advice: Majority/Minority Versus Unanimity

While the inbuilt rationality conflict for (natural) scientists' advisory expert groups is primarily located at the *external* fringe between the group and politics, the rationality conflict in professional expert groups is *internalized*. As a matter of principle, natural scientists are not supposed to disagree on facts.⁶⁹ Typically, the conflict is about precision: "Which standard is 'safe' (enough)?" Since safety is a value decision, scientists give ambivalent answers. It is the task of the political administration to find tools for translation.⁷⁰

Professional expert groups, in contrast, are expected to be able to consolidate. In an "epistemic community", members are expected to find consensus and mimic the societal process. Yet, most members of the biopatent expert group are individually appointed on their personal merits. In addition, "Type B and E" experts are appointed with the expectation that they will represent their organization. In cases where language for a viable consensus cannot be found (thus, "a professional consensus"), it is an open question why professionals should bow to a majority. As far as they are individually appointed on their own merits, experts want to be recognized and heard, regardless of being in the minority. As far as they are appointed as representatives of an organization, it becomes important that the institutional position of the organization becomes identifiable as different. This is the case for both, professional organizations and public interest groups. Unless the task to consolidate was explicit in the public tender or any other reason makes it likely that the group will concur for reasons of their own interest, the chances of consensus are rather low. Thus, professional expert groups are exposed to a profound rationality conflict. On the one hand, they are expected to reassemble reasons around which consensus can grow (but potentially are the basis for dissent); on the other hand, they are expected to wash out dissent and work to find common ground (usually at the expense of sharp argumentation). The conflict is exacerbated when the group is composed of members that represent a broad societal spectrum, as was the case here.

The expert group on biopatents resolved the conflict with a compromise. The overall executive summary presents the "majority" opinion (only). The Subreports diligently reiterate the majority/minority legal arguments. Polls are thoroughly reported which present the different recommendations as to what the Commission should be advised to do. The significance of this exercise cannot be deciphered from the outside. Eventually, the "majority" appears by and large to be composed of members of the "epistemic patent community" (supra). The Chair, a renowned scholar, has published extensively in support of "classic" principles, and made his position known in the annexes (A5, C7). The CV of the rapporteur of Subgroup B, posted on the Internet, reveals that she held a professional mandate in the same discussed case.⁷¹ While from a professional point of view, this special expertise

⁶⁹ No one would expect natural scientists "to consolidate", or to find "consensus".

⁷⁰ E.g. by creating a time-limited permit for emissions or by a safety measure defined by distance.

⁷¹ C. Sattler de Sousa e Brito, rapporteur for Subreport B on stem cells, was part of the attorney's team representing Brüstle in the CJEU's *Brüstle* proceedings.

could, in principle, secure high-quality information, it also implies that the position taken would not contradict earlier argumentation. The rapporteur of Subgroup C is a renowned patent attorney who has held mandates for large industrial undertakings.⁷² Yet, the “majority” report is not and is not supposed to expose “the” industrial position.⁷³ But even the representative of the breeders’ organization found herself in the “minority” (see Subreport A, Annex A4). Agricultural business interests were not represented. The “majority” of the group thus reunites professionals with a “broad patent” stance (not only “pro-patent”). Pressure seems to have been put on dissenting members to write their own texts, which became concealed in the midst of numerous annexes, which is both good and bad. It is bad as far as it impairs the argumentative dissent culture. However, it has also turned out to be for the good, since this personalized public exposure seems to have given an incentive to the dissidents to submit remarkable high-quality opinions which merit attention.

Yet, the argumentative structure often cuts through the pattern of the majority versus minority/expert position, which means that they are placed next to each other, making transparent the dissent while respecting the equal weight of arguments. On several occasions, the majority comments on the minority, either inside the text (p. 38) or outside in the form of additional annexes (A5, pp. 127 et seqq.). The language of the majority is emphatic (“[...] introducing a breeders’ exemption immediately interferes with the patent protection at its heart”, p. 50), sometimes manipulative (describing the minority argument as “objectively speaking appealing” versus describing the majority argument as simply “obvious”), or discrediting the dissenting members (by being somewhat misleading with regard to the content of the dissent: Subreport A, footnotes 55, 61, 83 refer to positions not taken in the dissenting opinion). One may speculate on the reasons for all of this. Either the writer responsible adhered to the normative idea of scientific truth (inducing him/her to insist on being “right”), or that person was politically or personally motivated.

3.2.3 Culture: Consensus Versus Dissent

On top of these two structural rationality conflicts, cultural differences are superimposed. Europe’s history has given rise to either consensual or argumentative societies. Belgium, the Netherlands, and Switzerland are understood to be rather consensual societies; the United Kingdom, Germany, and Italy are portrayed as combative and argumentative. The societal spirit is likely to be imprinted in a person’s value system. Thus, according to this theory, for a Belgian, consensus is primarily a good thing. Finding common ground in a group is an achievement. A group which has arrived at a consensus is attributed high credibility. In contrast, for Italians and Germans, compromise is entangled between good intentions and power relations. That implies that the underlying “give and take” must become visible.

⁷² J. Taormino reveals on his webpage that he has held various mandates in the EPO’s opposition and appeal procedures on the part of the food and pharmaceutical industry.

⁷³ Rapporteur for the Subreport A, Hannes Iserentant, *e.g.* is with the Technology Transfer Institute of the Vlaams Instituut voor Biotechnologie, Ghent. This is a (privatized) TTO, working for the (public) University of Ghent.

Dissent between members of a group as such neither necessarily disrupts the team spirit nor impairs the validity of the groups' appraisal.

It seems that this cultural split burdened the task of the expert group, both internally and externally. Internally, the Chair is a Belgian native, whereas strong-minded "dissidents" are Germans. Without further enquiring into the members' personal backgrounds, it shall be assumed that all were socialized in these respective contexts. It stands to reason that the more the Chair pushed for consolidation, the more the dissidents felt that they were being manipulated and their opinions suppressed. Externally, the respected Belgian IP scholar G. Van Overwalle, who had herself served on prior expert committees, argued that the group's position would have greater impact if it settled for a consensus.⁷⁴ Only then would the report have the chance of attracting the public's attention to the problems discussed. It should not come as a surprise to the reader that the author's intuition, coming from the perspective of a German national, is the opposite.

3.3 Specter: "The Pandora's Box"

The Expert Group's Chair concludes (p. 6):

The overwhelming majority of Experts were not in favor of reopening the Biopatent Directive. [...] even though the Expert Group identified several issues which may not necessarily have been resolved entirely and faultlessly satisfactory by the Biopatent Directive and/or by case law [...], a very solid majority did not see any positive prospect in reopening the Biopatent Directive with a view to resolve some or all of these issues. One of the considerations of the majority was that reopening the Biopatent Directive would be tantamount to opening 'Pandora's Box', and the Experts doubted whether it would be in the interest of research, industry, and society as a whole to plunge oneself into a new and very likely long negotiation process [...].

While the question of "reopening or not" was not the mandate of the expert group, the report focuses only on this issue, qualifying its decision as that of the "overwhelming majority" or "very solid majority". Yet, majority of which constituency? These experts are not representative of the whole of society. The majority opinions mirror the typical belief structure of the "epistemic patent community".⁷⁵ The verb "plunge" insinuates an adventurous and risky undertaking. Yet, all that is at stake is a regular legislative procedure, a possible revision which

⁷⁴ Personal communication, 9 June 2016. Van Overwalle's opinion is based on her membership for many years in the Belgian Advisory Council on Bioethics, the first European Commission's Expert Group on Biotechnological Inventions, the Standing Advisory Committee before the EPO (SACEPO), and the Economic and Scientific Advisory Board (ESAB) of the EPO.

⁷⁵ Some of the fundamental beliefs of this "patent epistemic community" are: (1) patentability requirements are conceived of "rules" which have to be interpreted widely, whereas exemptions are technically "exceptions" which are to be interpreted narrowly (disregarding the fact that patents are exceptions to competition, and the legitimation for the exceptions); (2) the patent scope is defined by the wording of the claim (not by concurring human rights, regulations, and circumstances "upstream"); (3) the principle of absolute product protection is valid and may not be questioned; and (4) "conflicts are taken care of by contract autonomy", and not by statutory licenses.

had already been envisioned by the Biopatent Directive itself. The experts' report now mimics the "voted opinions" of the European Parliament on the Biopatent Directive, which I. Schneider has called the "barometer of public opinion".⁷⁶ In the Commission's eyes, the expert report probably serves to respond to the Council and Parliament in the same language of a "voted majority opinion". And yet, the Commission found a compromise for the time being in drafting a "Commission's notice" which clearly deviates from the majority vote, but does not instigate the process of revision.

Not only should the European Parliament rightfully be concerned by the report, the whole European public should be. The majority texts reflect disrespect of not only the legislative, but also the adjudicative processes. The texts of the majority aim to re-establish principles which had been limited and modified by the Biopatent Directive. It seems that the texts strategically formulate fundamentalist positions, aiming at influencing future deliberations. The majority group reveals itself as one that does not want to be regulated or corrected. It wants to play by its own rules. This result should give the Parliament enough incentive to have a closer look at the report, and take its time to read the (hidden) dissenting opinions with scrutiny. It may thoroughly monitor the effects of the Commission's notice of November 2016 both on the EPO's adjudication and the jurisprudence of the future European Unified Patent Court. Yet, the Commission's notice only opposes the EPO's interpretation of Art. 53(b) EPC/Art. 4 Biopatent Directive ("products obtained by means of essentially biological processes"), and thus takes up only one of the various concerns discussed in the Expert Report. In the past, the European Parliament was particularly engaged in the interpretation of Art. 6 Sec. 2 Biopatent Directive. If the European Parliament comes to the conclusion that the Biopatent Directive continues to be interpreted in a way inconsistent with its regulatory goals, it must repeat its call on the Commission to submit a proposal for its revision.

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⁷⁶ Schneider (*supra* note 5), p. 608 (in the original: "*parlamentarisches Stimmungsbarometer*").

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