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ARTICLE

Technology, Patents and Markets: The Implied Lessons of the EU Commission's Intervention in the *Broccoli/Tomatoes* Case of 2016 for Modern (Plant) Genome Editing

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Abstract The article deals with plant patents and examines the interplay between technology, patents and markets from a twofold perspective, a legal–technical and a conceptual one. On the legal–technical level, it raises the question whether the Commission's Notice of 8 November 2016 on the EPO *Broccoli/Tomatoes* constellation and the novel Rule 28 EPC-IR (2017) have an impact on the patentability of modern genome editing techniques. It argues that these affect patentability and limit the available protection scope to bare process claims. On the conceptual level, the article is interested in the role of patent law in structuring primary and secondary markets. It submits that in the face of modern biotechnology's challenges, patent law cannot restrict itself to the classical principles of patentability, dependency and exhaustion, which disconnect patentability requirements and scope. It argues that the EU Biotech Directive is to be interpreted as a relinking of patentability and scope in order to also serve the freedom to operate on secondary markets.

Keywords Product protection · Plant patents · Native traits · Process claim · Biotechnology · *Broccoli/Tomatoes*

1 The Issue

Modern genome editing and mutagenesis techniques have prompted the development of the next generation of biotechnology. Labeled as "game

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changer[s]"[1] and as heralding a "new era",[2] these techniques allow for precise alterations of cell DNA. Regardless of the way in which the DNA has been changed, whether by introducing foreign or the species' own DNA, the result almost always qualifies as "non-transgene". The integration of "foreign" DNA is not the central goal. In most cases, the existing DNA is changed in such a way that the resulting product cannot easily be distinguished from either naturally occurring point mutations, or chemically or radioactively induced mutagenesis. DNA sequences might be deleted, suppressed, multiplied, reduced, or moved to a different location of the DNA.[3] Or, genetically modified and biological material is coupled together without having an impact on products. Yet, many related patents have already been issued.[4] While the potential of these techniques is under universal discussion for medical purposes,[5] agriculture and chemistry, this article focusses exclusively on plants, and deliberately puts aside all questions involving human genome editing and possible medical applications, from genomic therapy to the transplantation of pig livers.

1.1 Legal–Technical Level: Focus on Patentability

On the legal–technical level, the discussion concerning gene editing is strongly influenced by two famous cases *Broccoli/Tomatoes I* (2010)[6] and *II* (2015) decided by EPO's Enlarged Board of Appeal[7] (EPO-EBA) concerning marker-assisted breeding. The central question draws on the interpretation of the patentability *exclusion* under Art. 53 lit. b EPC. With the second procedure (*Broccoli/Tomatoes II* – 2015), the EPO-EBA held that product and product-by-process (pbp)[8] claims were allowable for products even when obtained by processes excluded from patentability. In an unparalleled move, the European Commission opposed this interpretation on 8 November 2016.[9] In response, the Administrative Council of the EPO adopted

[1] Ledford (2015).

[2] Andolfo et al. (2016). The various techniques encompass zinc finger nucleases, CRISPR (clustered regularly interspaced short palindromic repeats), TALEN (transcription activator-like effector nucleases), ODM (oligonucleotide-directed mutagenesis), and the like.

[3] A publicly discussed example is the suppression of three genes in wheat resulting in a resistance to blight, Sentker, (2017), p. 31. "Unser bedrohtes Gold", Die Zeit, 20 July 2017

[4] Instructive for the plant-breeding sector: Parisi (2013), Parisi et al. (2013). For a legal analysis of modern breeding techniques under European GMO-regulation: Callebaut (2015).

[5] Controversially discussed by academic institutions, *see* ALLEA (2016).

[6] EPO-EBA G1/08 (*Tomatoes I*) and G2/07 (*Broccoli I*), 9 December 2010, OJ EPO 2012, 130.

[7] G 2/13 (*Broccoli II*) and G2/12 (*Tomatoes II*), both 25 March 2015, OJ EPO 2016, 17, download: http://www.epo.org/law-practice/legal-texts/official-journal/2016/03/2016-03.pdf.

[8] Pbp-claims aim at a product protection via a process description since the product cannot be described otherwise. While the EPO accepts these claims, under the two conditions that the product cannot be described otherwise and that the product itself meets the patentability requirements (*see* § 4.12 EPO Guidelines for Examination, http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_4_12.htm), their exact scope is contested and varies between EPO member states; Krasser and Ann (2016), § 14, para. 110.

[9] European Commission (2016b). It was adopted by EU Member States in February 2017. The Commissions Notice, as a matter of law, has no legal effect on the EPO. However, if the same EU Member States agree with others in the EPO Administrative Council on changing the EPC Implementing Regulations, it would be a surprise if the EBA-EPO did not respect the organization's vote for change,

an amendment to Rule 28 EPC Implementing Regulation (EPC-IR 2017), clarifying that "patents shall not be granted in respect of plants and animals exclusively obtained by means of essentially biological process".[10] This decision leaves many questions open. Will the term "exclusively" differentiate Rule 28 para. 2 EPC-IP from Art. 53 lit. b EPC? What about the problem that rights may refer to characteristics and DNA which naturally occur in plants and fruits ("native traits"[11])?

1.2 Conceptual Level: Focus on Markets

This article aims at taking the debate beyond the legal–technical level, and is interested in exploring the more fundamental level, in particular, the triangle of technology, patent law and markets, taking modern plant biotechnology as an example. Common wisdom holds that the cornerstones of the triangle influence each other as follows: technology structures markets; legal rules frame markets. However, technology does not influence the law; it is neutral and markets may only indirectly influence technology and law. Recent studies in sociology, however, show that markets indeed influence technology.[12] The current paper explores the relationship of (patent) law to markets and to technology: Does the law give structure to (technology) markets via patentability requirements (here Art. 53 lit. b European Patent Convention [EPC] and Art. 5 European Biotechnology Directive [Biotech Directive] 98/44/EC) and principles of scope interpretation? How does the law adjust to technology, and vice versa? To what extent does patent law consciously shape the relations of primary and secondary markets? By granting a privileged position in competition, patent law's eminent task is to structure the relationship between direct competitors (the primary market). In theory, the impact of patents on secondary markets (vis-à-vis non-competitors) is limited: Beyond the patent's scope, market actors are free, dependency rules balance the interests of improvers and pioneers, the principle of exhaustion secures trade freedoms,[13] and competition rules limit the exclusive patent power[14] and overly restrictive

Footnote 9 continued
especially after a decision which requires a three-fourths majority and which was carried with 35 votes for, 1 against and 1 abstention.

[10] Decision of 29 June 2017, revised rule in force since 1 July 2017; *see* https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/r28.html.

[11] It must be acknowledged that the term can have a number of meanings. *Cf.* Metzger (2017), p. 214 "new properties resulting from classical breeding methods of crossing and selecting"; *cf.* Lawson (2015), p. 99: "Limited nature of genetic traits and their limited substitutability"; and *cf.* Kock (2017), p. 132 "plants exclusively consisting of naturally occurring plant genetics, which is combined in the plant by sexual crossing. The genetics can include natural mutants such as somaclonal variations. One example is the trait in the 'Broccoli patent'".

[12] Heidenreich and Mattes (2018, forthcoming).

[13] For biotechnological inventions, the exhaustion principle is concretized by Art. 10 Directive 98/44/EC – and its respective national transpositions, *e.g.* Secs. 9b and 9c of the German Patent Code.

[14] The hottest current issue is access to standard essential patents based on misuse of a dominant market position under competition law (Art. 102 TFEU), *see* C-170/13, CJEU of 16 July 2015, ECLI:EU:C:2015:477.

licenses.[15] Thereby, illegitimate control over subsequent productions chains is supposed to be prevented. Yet, despite the extensive economic literature and a long-lasting judicial debate, the impact of patent law on control over secondary markets has remained contested and is conceptually underdeveloped.[16] This became evident in the deliberations before the European Court of Justice (CJEU) in the *Monsanto v. Cefetra* case (2010).[17] One year prior to the famous *Brüstle* decision of 2011,[18] the CJEU seized the opportunity to comment on the Biotech Directive 98/44/EC.[19] The historian Stefan Hubicki documents a puzzling uncertainty about the reach of plant patents,[20] and about the actual meaning of the text of the Biotech Directive 98/44/EC for (patentable) transgene plants. It is not clear whether patents extend to secondary markets such as foods (polenta made from GMO maize[21]) and textiles (clothes made of Bt cotton[22]). The problem is exacerbated if, after genome editing, genetically altered products cannot be distinguished from products that have not been modified.

The uncertainty is partly due to a mismatch between the economic conception of patents as means for control and management, and the legal discourse which focusses on the technicalities of patentability.[23] Whereas economists focus on behavior and growth impacts, legal debates revolve around the owner to whom the property paradigm assigns an all-encompassing right. The underlying rationale is that strong patent protection stimulates innovation. Yet, innovation as a social phenomenon is more complex and emerges from the right mix of protection, freedom and competition. Competitive markets are structured horizontally (by products which may substitute each other), and vertically (by subsequent levels of the market with non-interchangeable goods and services). Is seems that the legal patent discourse avoids a discussion of the vertical effects of patents. According to the actual state of the art, these depend primarily on the patent claim: The point of

[15] Most noteworthy stipulated by the EU Block Exemption on Research and Development Reg. 1217/2010), Off. J. EU 2010 L 335, 36, and Block Exemption Technology Transfer Reg. 316/2014, Off. J. 2014 L 93, 17.

[16] A problem early raised by Dreier (2001), p. 60, and discussed with regard to "absolute product protection" by Godt (2007), p. 107 ff, p. 619 ff.

[17] C-428/08, *Monsanto Technology LLC v. Cefetra BV* [2010] ECR I-6761. Technically, the case revolves around determining the meaning of Art. 9 Directive 98/44/EC ("contained and performs its function") vis-à-vis the principle of absolute product protection.

[18] C-34/10, *Brüstle* [2011] ECR I-9821.

[19] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions 98/44/EC, OJ L 213, 30.7.1998, p. 13–21: Art. 8(1) Biotech Directive 98/44/EC: "extend[s] to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics", and Art. 9 Biotech Directive 98/44/EC "performs its function".

[20] Hubicki (2015), pp. 27–80.

[21] Example discussed by Straus (2008), pp. 653–656 who distinguishes polenta made from herbicide-resistant/drought-tolerant maize (non-infringing) from polenta made from taste/nutritional value-improved maize (infringing), for a discussion on this distinction: Hubicki (2015), p. 69, fn. 176.

[22] Example given by Christopher Heath, cited by Hubicki (2015), p. 78.

[23] On the relationship between economics and law in IP, and the tasks of law, *see* Van Overwalle (2013), p. 361.

departure is its wording (Art. 69(1) EPC). Courts incrementally derive the scope of the legal title and a respective violation from the quality of the violation material (facts) and from legal principles, most importantly claim interpretation[24] and absolute product protection.[25] Competition law, on a secondary level, may remedy misuse and define limits.

The problem of determining the scope of patents is particularly pressing with regard to plants.[26] Production chains are long and deeply stratified. Yet, plant patents attract less public attention compared to human genome patents. Ethical concerns seem less pressing; therefore, national regulation[27] and constitutional oversight, both in the US[28] and in Europe,[29] is less prominent. Until the *Monsanto* ruling of the CJEU in 2011,[30] the scope of plant patents had remained in the slipstream. Although limitations were discussed as early as the WIPO deliberations in 1983,[31] only few were introduced by the European Community's (EU) Biotech Directive (Arts 4, 8 and 9[32] Directive 98/44/EC) and those were only incompletely transferred to the EPC regime.[33] Plant-related patent law evolved primarily through internal review procedures of the European Patent Office (EPO), which focused on patentability exclusions,[34] relied on a narrow interpretation of those,[35] and allowed

[24] A body of rules determines the interpretation of "the" claim. Claims, for example, may not be interpreted in such a way as to subvert the original meanings of the terms used. Claims are divided into "types" which imply the specific scope, for example there is a basic differentiation between "product claims" and "process claims". The scope of the latter process type, for example, is restricted to the use of the process itself but extends to the products *directly obtained* by such a process (Art. 64(2) EPC); first judicial decision of 14 March 1888 by the Supreme Court of the German Empire (Reichsgericht) of 14 March 1888, RGZ 22, 8 – *Methylenblau.*

[25] As a principle, "absolute product protection" secures two extensions: (1) the patent scope will not be limited to the disclosed industrial applications (provided that the national law does not stipulate otherwise, as does § 1a Secs. 3 and 4 German Patent Code – for human genomic inventions); (2) any other mode of production beyond the disclosed production process is also protected.

[26] For various restrictions to the "freedom to operate" in modern plant breeding *see* Parisi (2013).

[27] For emblematic examples (although ineffective in practice due to the EPC system), *see* § 1a(4) German Patent Law; Art. L613-2-1 French Patent Code.

[28] *Mayo* (decided 20 March 2012), and *Myriad* (decided 13 June 2013). These decisions have been implemented by the USPTO "Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena and Natural Products", USPTO of 4 March 2014, download https://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

[29] *Brüstle*, *supra* note 18.

[30] *Supra* note 17.

[31] Particularly instructive are the diverging answers from jurisdictions at that time on case scenarios concerning the distinction between production and sale, and between primary and secondary markets. This variation prompted the WIPO position of harmonizing protection and extending it from primary products ("consisting/containing") to secondary products ("containing"); Hubicki (2015), at p. 44.

[32] Complementing "contained" by "and performs its function".

[33] On the complex relationship between the EU and the EPO system after the transposition of the EC Biotech Directive 98/44/EC into the EPC system in 1999, *see* Schneider (2010), p. 394.

[34] *E.g.* "plant varieties" in Art. 53b EPC, G 1/98, EPO Enlarged Board of Appeal (EPO-EBA), 20 December 1999, Off.J. EPA 2000, 545 – *Novartis.*

[35] Applied, *e.g.* in EPO-EBA G1/08 (*Tomatoes I*) and G2/07 (*Broccoli I*), 9 December 2010 (*supra* note 6). Even more articulated in G 2/13 (*Broccoli II*) and G2/12 (*Tomatoes II*), both 25 March 2015 (*supra* note 7); for a critical discussion *see* Dolder (2017).

a broad patent-claims language.[36] Legislative safeguards, such as compulsory licenses schemes, turned out to be too strict to be operable.[37] Against this background, it does not come as a surprise that the CJEU used *Monsanto* to clarify the limitations to the patent's scope, which the Directive sought to implement. The Court identified the disclosed function as the central *raison d'être* of the Biotech Directive. It ruled that *meal* from GMO soy does not infringe the patented Bt resistance since it does not fulfill the claimed modified EPSPS[38] function. On the factual level, the Court's decision in *Monsanto* was limited to ground meal. However, the legal debate revolved around the fundamental question whether the decision discards or modifies the principle of absolute product protection.[39] As far as the decision was read as abolition, it met with strong opposition from the professional community.[40] Yet, the lively initial debate quickly died away when the meaning of the justices' words become more and more unclear in the course of the unfolding discussion.

1.3 Interplay Between the Legal–Technical and Conceptual Level

These two parallel developments linked to the *Monsanto* and *Broccoli/Tomatoes* cases shed light on the triangle of technology, law and markets. They illustrate how law reacts to technology, and raise the question of how the recent re-interpretation of Art. 53 lit. b EPC impacts modern genome editing of plant genomes and mutagenesis (and associated techniques). On the legal–technical level, the EPO/Commissions' dispute is confined to marker-assisted breeding. Therefore, the question remains whether genome editing techniques escape the exclusion of Art. 53 lit. b EPC/Art. 4 Directive 98/44/EC or qualify as "essentially biological processes for the production of plants". On a more conceptual level, the link between law and markets emerges from the legal technicalities on patentability: What will be the effect of the potentially granted patents on markets downstream, and which patent strategies will follow?[41] Does the idea of subsequent markets play a role in determining the patent scope?

It is evident that expanding patent protection narrows down other parties' freedom to operate. Yet, the conceptualization of those freedoms enjoys very little

[36] Parisi (2013), p. 130, p. 134.

[37] The industry's proposal for a digital licensing platform has been highly controversial. For an opposing view, *see* Girard (2015), p. 14; for the views of those in favour, *see* Allred 2017; also Melullis, in: Benkard (2015) § 2a, para. 9.

[38] EPSPS (5-enolpyruvylshikimate-3-phosphate) synthase is an enzyme produced by plants and microorganisms. It catalyzes a central chemical reaction which is the biological target for the herbicide glyphosate.

[39] Van Overwalle (2011); Lamping (2010).

[40] Adding to the persistent resistance to judicial patent oversight on the part of the CJEU, *see* Godt (2018, forthcoming). Yet, the *Monsanto* decision is not far stretched: It only reiterates the three cumulative conditions as required by Straus (2008), p. 649 ("the patented genetic information must be incorporated in that [sic. the infringing] material, must still be in that material, and must perform its 'inventive' function".

[41] "Using biology to improve IP", *see* Hubicki and Sherman (2005), p. 740.

constitutional recognition[42] and academic attention.[43] In contrast, the overwhelming majority of patent lawyers take for granted that "absolute" protection is legitimate, in line with the patent paradigm, and economically reasonable: Conflicts are to be resolved by contracts.[44] The idea of "all or nothing" prevails: Once a claim is granted (for a technical step), any subsequent products resulting from crossing and selection are always and in any form protected and patentable in themselves.[45] Inversely, crossing and selection might "contaminate" patentable processes which include transgene plants.[46] The only residual measure which seems to effectively restrict the scope of patents is competition law via its misuse doctrine (Art. 102 TFEU).[47] However, competition expert Hanns Ullrich has insisted for years that competition law cannot make up for failures of patent law[48]: It is the preeminent task of patent law itself to limit the scope of patents for the sake of novel innovations. Competition law comes too late, and investigates only singular cases. The misuse standard, both under national law and Art. 102 TFEU, is too high to properly regulate markets.[49]

This article aims to revive the discussion on the relation of technology, patents and markets, exemplified by the case of genome editing. On the legal–technical level, the following Sect. 2 will revisit the EPO's *Broccoli II/Tomato II* decisions (marker-assisted breeding). It thus focusses narrowly on the relation of law and technology. Section 3 extrapolates the findings: first, to the patentability of randomly induced mutagenesis, and second, to novel gene-editing techniques. The question is how the Commission's Notice of 8 November 2016 and the new Rule 28 EPC-IR 2017 will influence their qualification under Art. 53 lit. b EPC as processes and respective product claims (mutants, native traits). The impossibility to distinguish infringing material using a patented method and non-infringing material opens the discussion on the conceptual level on the relation of law and markets: Which task has patent law to fulfill as a hinge joint between technology and markets? A respective task description with regard to market ordering is discussed at the end of this Sect. 3.3.3. The implications of these insights will be tested under Sect. 4 under three yardsticks of patent doctrine, the disconnection of patentability and scope, adequate property protection and specific rules for chemical patents. We conclude with Sect. 5.

[42] Also acknowledged by Dreier (2001), pp. 60 and 70.

[43] A noteworthy exception is Hubicki (2015). An emblematic example is the narrowing of the competition law-rooted exhaustion principle by the CJEU decision in *Greenstar v. Kanzi* (C-140/10, decision of 20 October 2010). The decision rejects a market-based, objective standard of exhaustion, but overly respects the contractual duties, which the CJEU extends (against the basic principle of contract law) against third parties.

[44] European Commission (2016a), p. 197 commented on by Godt (2016b).

[45] A presumption strengthened by the wording of Art. 8 Directive 98/44/EC.

[46] Thus formulated by Krauss (2011), p. 283.

[47] The most recent decision of the CJEU, C-170/13, *Huawei*, ECLI:EU:C:2015:477 of 16 July 2015, digital publication only.

[48] *See* the seminal work by Ullrich (1995); equally Wolf (2009), p. 263: "Die genaue Justierung der vertikalen Kontrolle kann nicht nur schutzrechtsextern durch Kartellrecht erfolgen".

[49] Léonard (2016); Ullrich (2013).

2 Exposition: Patentability After *Broccoli II/Tomato II*

Non-transgenic biotechnological processes came to the forefront in 2002/2003 with the issuance of the famous patents on tomatoes[50] and broccoli[51]; previously, transgene plants had been the focus of bio-patenting.[52] Fifteen years of litigation and public debate followed: In 2010, the EPO-EBA decided that marker-assisted breeding techniques in plant production do not escape the patent exclusion under Art. 53 lit. b EPC (*Broccoli I/Tomatoes I*).[53] If no foreign traits are introduced into the genome, and the breeding process is based on the mixing of the whole genome of cells,[54] the production process is to be qualified as "essentially biological".[55] The process only escapes this exclusion if the change to the genome is not only the result of the crossing process.[56] In 2015, the EPO-EBA concluded that product protection (formulated as pbp-claims or as product claims) should be available,[57] even if the process by which the product was produced is excluded from patentability under Art. 53 lit. b EPC (*Broccoli II/Tomatoes II*).[58] The EPO-EBA 2015 based its decision essentially on two arguments: (1) exclusions were to be interpreted narrowly[59]; and (2) the examination of patentability requirements were to be separated from the patent's scope.[60] The latter *formal* argument goes parallel to the

[50] EP 1211926, claiming a tomato plant with a low water content which ripens at the shrub.

[51] EP 1 069 819, for a broccoli plant with a higher than usual glucosinolate level which is supposed to be beneficial in inhibiting cancer cells.

[52] Whereas the patentability of transgene plants (genetically modified [GMO] plants) has not been in question since 1995 (EPO – Boards of Appeal of 21 December 1995, T-0356/93 – 3.3.4), and since 1999 has not been excluded by the breeders' rights exemption (EPO – Enlarged Board of Appeal of 20 December 1999, G 1/98), research has shifted towards other improvement techniques as in Europe, GMO food and feed are not marketable.

[53] A minor technical a process "technical", EPO-EBA of 9 December 2010, G 2/07 – *Broccoli I/Tomatoes I* (*supra* note 6).

[54] Defined as "sexually crossing the whole genomes of plants", *cf.* Art. 53 lit b EPÜ, Art. 2 II, Art. 4, recital 32 Biotech Directive, § 2a German Patent Act.

[55] Considering the closeness of the process in this description to the production of hybrid seeds, one may wonder if the EPO decision on hybrid seeds of 2010 needs to be reconsidered. In its *Lubrizol* decision of 10 November 1988, the Technical Board of Appeal argued that the definition of "essentially biological" has to be judged on the totality of human intervention (mirroring the "surprising effect" jurisdiction, Melullis, in: Benkard (2015), § 2a, para. 49). This reasoning reappears in the EPO-EBA decision in *Broccoli/Tomatoes I* (2010). The hybrid-seed decision of the TBA in T 2362/10- *Monsanto* of 21 January 2014 rejected pbp-claims on transgenic corn plants.

[56] The standard example, which the EPO accepts for patentability, is mutagenesis as a process distinct from crossing and selection. Krasser and Ann (2016), § 14 para. 9 clarify that it is the quality of the process not the result which matters (regardless of whether the quality of a mutation is spontaneous or a point mutation).

[57] Thus rejecting the considerations of the submitting judge, *see* Sterckx and Cockbain (2015), p. 195. The opinion was also in opposition to several Member States which had, in the meantime, included these products into the process exclusion, such as Austria, Germany, the Netherlands, and France. The German patent law was revised in 2013, introducing § 2a(1) No. 1, last part of the sentence.

[58] G2/12 and G2/13. EPO-EBA of 25 March 2015 (*supra* note 7).

[59] G2/12 (*supra* note 7), p. 36.

[60] G2/12 under VIII. 2. (6) (b) (*supra* note 7), p. 55: "Whether a product claim or a product-by-process claim is patentable is to be examined irrespective of the extent of protection that is conferred by it after grant".

substantive spirit of the decision, which credits Art. 64(2) EPC as a general principle that product protection for plants is deserved even if products derive from processes that are excluded from patent protection under Art 53 lit. b European Patent Convention (EPC).[61]

Prior to the commencement of this procedure, EPO examiners had not paid much attention to the choice of process or pbp-claim language.[62] Pbp-claims were accepted,[63] and their scope of protection was considered to be governed by Member States' laws which differ widely.[64] Since 2015, claim formulation has shifted in practice towards the description of a rather small number of phenotypic traits (product claims) and to specifying the protected plants by reference to deposited material used in breeding.[65]

On 8 November 2016, the European Commission opposed the EPO-EBA's interpretation of Art. 53 lit. b EPC in the light of Art. 4 and recital 32 Biotech Directive 98/44/EG.[66] In its Notice, the Commission reiterated the legislative history and came to the conclusion that both history and the intention of the legislator demand a wide interpretation of Art. 4 Directive 98/44/EC.[67] It starts with Art. 2 Directive 98/44/EC which defines "essentially biological process" as "natural phenomena such as crossing and selection". And "biological material" is qualified as material "capable of self-reproduction or of being reproduced in a biological system". The core of the Commission's notice is the argument of the broad interpretation of patent exemptions. The consequence is a legal link between excluded processes and products derived thereof (be it by derived protection for process claims, pbp-claims or product claims). Thus, the proposition of separateness is rebutted. Two weeks later, the Director of the European Patent Office stayed all respective examination processes.[68] A reformulated Rule 28 EPC-IR has been in force since 1 July 2017.

[61] Technically, the EPO-EBA refers in G2/12 to the statement in G 1/98 ("plant varieties") that Art. 64 II EPC "is not to be taken into consideration". In both cases, this argument serves the same strategic function: Any patentability exclusion for processes does neither block patents on products nor claims which create product protection (pbp). This argumentative structure preserves the (presumed) rationale of Art. 64 II EPC as a general rule that process patents deserve derived product protection.

[62] Walter (2010), p. 329.

[63] Submitted that all other patentability requirements were met.

[64] Walter (2010), p. 331, Krasser and Ann (2016), § 14 para. 114.

[65] Metzger (2017).

[66] European Commission (2016b).

[67] Therefore, transposing the reading of Art. 6 para. 2 lit (c) Directive 98/44/EC by the CJEU in *Brüstle* (C-364/13, dec. of 18 December 2014, *supra* note 18) to Art. 4 Directive 98/44/EC.

[68] EPO decision of 24 November 2016 (https://www.epo.org/news-issues/news/2016/20161212.html).

3 Extrapolation: Mutagenesis and Novel Gene-Editing Techniques

3.1 Distinguishing?

Does this interpretation of Art. 53 lit. b EPC ("essentially biological process for the production of plants") have an effect on modern genome editing? The *Broccoli-Tomatoes* dispute is limited to a marker-assisted selection *without* mutagenesis (claiming a result of a "natural" mutation [syn. "native trait"]). Is this a basis on which to distinguish (essentially biological) *Broccoli-Tomatoes* and Rule 28 EPC-IR from (technical) mutagenesis and genome editing?[69]

The issue is complicated for two reasons. First, plants obtained by genome-editing techniques cannot, or not easily, be distinguished from plants which mutated "naturally" and have identical characteristics. Where plants could be distinguished biologically on the genomic level, the characteristics as claimed cannot be distinguished in the context of patent law. This is why, based on the legal EPC-situation in mid-2016 (whereby product claims are deemed allowable for plants derived from "essentially biological processes"), Axel Metzger argues that material obtained by other material than referred to in the claim lies beyond the patent's scope.[70] In the light of the Commission's interpretation of 8 November 2016 and the new Rule 28 EPC-IR, the question shifts to one of whether these techniques are excluded from patentability under Art. 53 lit. b EPC *ad initio*.

Secondly, the distinction between "biological" and "technical" with regard to genome editing is contested also in the adjacent area of administrative GMO regulation. On 3 October 2016, the French Conseil d'état submitted the question to the CJEU[71] as to whether mutagenesis is covered by the EU's GMO Directive 2001/18/EC.[72] Industry and science wish an exemption of mutagenesis and genome editing from State oversight based on the argument that these are "only" biological. The preliminary ruling is expected to provide a reasoning along the binary code of "natural" or "technical". While the outcome of a decision on administrative law has no direct effect on patent law, and different interpretations of one term may well coexist in different regulatory contexts,[73] the submitted

[69] A problem discussed in EPO Dok. CA/PL 4/17 of 23 March 2017, p. 36; here a possible alternative is suggested, that of defining excluded plants and animals not by reference to the process that has been applied but rather to the resulting genetic composition. Since "it is unclear, though, how the skilled person could ascertain this feature in the final product without having to resort to the process used", this alternative was rejected.

[70] Metzger (2017); also Metzger (2016) – thus transposing the rationale of "derived of" varieties under Art. 13 paras. 5a and 6 Reg. 2100/94 (EU Plant Breeders' Rights system) to the patent system; Godt (2016a), p. 214 et seq.

[71] http://www.conseil-etat.fr/Actualites/Communiques/Organismes-obtenus-par-mutagenese.

[72] Directive 2001/18/EC Annex I B No. 1, OJ EC L 106 of 17 April 2001, 1–39; a concern that has long been the subject of discussion in the breeding sector, *see* Parisi (2013), p. 216.

[73] Schneider (2011), pp. 475–510; Godt (2015), p. 79.

distinction of "genetic alteration"[74] (y/n) would contradict EPA's reasoning with regard to mutagenesis. It has accepted all types of mutagenesis, regardless of whether random or induced, as "technical". In contrast, non-governmental organizations distinguish "non-technical" random mutagenesis (which might also be induced) from "technical" genome editing.[75] The argument is twofold: (1) the process inside the cell remains "purely biological"; and (2) the man-made technical application lost its novelty years ago. Only when the process inside the cell is altered, is the process to be qualified as "technical".

Considering that the president of the EPO reaffirmed the EPO's position on mutagenesis on 6 June 2017[76] in the context of the revision of Rule 28 EPC-IR, it is clear that the review process is not limited to non-mutagenesis processes only. It affects modern breeding techniques in general. It is therefore necessary to examine the following two cases separately: randomly induced mutagenesis by (rather old) techniques of chemical treatment or radiation (resulting in an "accidental" mutation) (see Sect. 3.2); and targeted mutagenesis by modern gene-editing techniques (resulting in an "induced" mutation) (3.3).

3.2 Random Mutagenesis

In principle, mutagenesis has been a traditional, well-known way to induce mutations.[77] An early example is a light-altered poinsettia,[78] a more recent one is a light-mutated petunia.[79] Today, established techniques employ chemical stress or radiation.[80] For the purpose of plant production, the biological process of "sexually

[74] This decision could overturn the position of the German government [and may have an effect on US practices as well]. The German "Bundesamt für Verbraucherschutz und Lebensmittelsicherheit" stated on 31 October 2016: "... Plants with punctual mutations induced by [...] CRISPR/Cas9 techniques are not 'genetically modified organisms' in the sense of Directive 2001/18/EC"; the US Department of Agriculture's agency "Animal and Plant Health Inspection Service (APHIS)" decided on CRISPR/Cas9-engineered mushrooms on 13 April 2016, Waltz (2016) p. 293, based on the argument that they do not contain foreign DNA. This was the first CRISPR/Cas9 decision. Another 30 altered organisms were previously exempted from administrative oversight for other reasons (*ibid*). A US patent for the said mushroom was filed in September 2015 (*ibid*).

[75] Then and Tippe (2014), p. 20. They qualify random mutagenesis as "low-level" technology, and qualify respective techniques as "essentially biological", therefore non-patentable, like the patent on sunflowers (EP0965631). *See also* Then and Tippe (2017).

[76] President of the EPO, "Exclusion from Patentability under Art. 5(b) EPC of Plants and Animals Produced by essentially biological processes – amendment of Rules 27(b) and 28 EPC", Doc. No. CA/56/17 of 6 June 2017, p. 14: "Some forms of mutagenesis occur in nature (usually called spontaneous mutagenesis). However, whether a specific mutation indeed would occur as the result of spontaneous mutagenesis is entirely speculative. [...]".

[77] Mellulis, § 2a, in: Benkard (2015), para. 10; Krasser and Ann (2016), § 14, paras. 1–2.

[78] Issued by the German Patent Office in 1956. Its reasoning and the diverging decisions in the UK and the Netherlands (both of which denied protection) are discussed by Schippel (1958), p. 333.

[79] EP 0799 564 B1, filed 1996, published 2000. As a consequence, product claims, such as petunia patent EP0719080, which claims the mutant allele induced by mutagenesis, would then be invalid.

[80] EP2374349, a patent filed in 2011 on Osteospermum was put on hold until the EPO's EBA decision in *Broccoli/Tomatoes II*, since it contains product claims, pbp-claims and process claims on (induced) mutagenesis. It is still in the process of negotiation and has not been issued.

crossing of two whole genomes" is not changed, and no trait is introduced or modified. These techniques are thus not novel. Indeed, the EPO issues respective patents based on the (novel) result. However, it is highly questionable if these plant products derive from a non-biological process. The central mechanism is the random process of meiosis (triggered by a non-novel technique). The production of the plant is thus "essentially biological". It is submitted that it should therefore be excluded under Art. 53 lit. b EPC. Induced random mutagenesis in today's practice is simply an alternative or complement to marker-assisted selection, and usually involves little technical expertise. Unless a technical process in isolation triggers mutagenesis in a novel way,[81] random mutagenesis, as a matter of law, should be considered as an "essentially biological process" excluded from patentability under Art. 53 lit. b EPC, and the products thereof as excluded under the Commission's rationale spelled out in its Notice of 8 November 2016.

This argumentation can be aligned with the US Supreme Court's reasoning in *Myriad* (2013),[82] and the subsequent USPTO Guidelines of 2014.[83] Acknowledging that the *Myriad* case is different as far as its reasoning revolves around the isolation paradigm,[84] the reasoning is comparable as far as the "threshold" of patentability is concerned. The Supreme Court held that neither the isolation of a gene sequence nor of a mutant of a named sequence, by identifying the genomic DNA (g-DNA),[85] is enough to constitute patentable subject matter. Only the synthesized complementary DNA (c-DNA)[86] (in that case identical to the naturally occurring DNA but for the fact that only the exons and not the introns are synthesized) qualifies as "man-made" under the Chakrabarty test.[87] Transposed to the plant-production cases at hand, the rationale implies that the mere identification of induced (random) mutations by modern screening processes does not meet the patentability standard. The invention which is worth having a patent granted is determined by positive or negative requirements (patentability requirements or exclusions). The identification of genomic mutants is, under modern PCR screening methods, no longer inventive. In addition, it should be kept in mind that the identification of a (phenotype) mutant is the essential starting point for the development of plant *varieties*. This activity is closer to a discovery than to an invention. For their societal value, these discoveries are protected by a distinct system, the breeders' rights system.

Reflecting these considerations in the context of the legal exclusion of "essentially biological processes for the production of plants", random mutagenesis

[81] And the method claim does not simply refer to identifying mutants: the US Supreme Court decided in *Myriad* that this was ineligible patent matter as it refers to an abstract mental process only, 133 S.Ct. 2107, 2111 (at 2116) (2013) – *Association for Molecular Pathology v. Myriad Genetics.*

[82] *Association for Molecular Pathology v. Myriad Genetics*, 133 S.Ct. 2107, 2116.

[83] US PTO Guidance Document (*supra* note 28).

[84] The "paradigm of isolation" renders the discovery of a natural substance an "invention", and is central to the distinction between "biological" and "technical" (*infra* 4.3); for a condensed analysis of the "Myriad" case *see* Murray and Zimmeren (2011), Godt (2015).

[85] Genomic DNO (g-DNA) is chromosomal DNA in the cell.

[86] Complementary DNA (c-DNA) is synthesized DNA (almost identical to g-DNA) which is produced from RNA by using the Enzyme Reverse Transcriptase.

[87] Nicol (2015), pp. 123–142; Dreyfuss (2013), pp. 7–53.

appears merely preparatory; it does not interfere with the biological process and does not affect or improve the production of a plant itself. The process itself is governed by the "mixing of whole genomes"; the technical step is subservient. Read in this light, the process does not escape the exclusion of Art. 4 Biotech Directive/Art. 53 lit. b EPC.

3.3 "Targeted" Mutagenesis/Genome Editing

3.3.1 Description

Compared to randomly induced mutagenesis, "targeted" mutagenesis processes add more technical and scientific sophistication to the process.[88] Despite the fact that many genome-editing techniques and resulting plants have already been patented,[89] and have become standard techniques in modern laboratory plant breeding,[90] the question imposes itself whether – or under which conditions – the processes and plants produced by using these techniques are excluded under Art. 53 lit. b EPC/ revised interpretation of Art. 4 Biotech Directive 98/44/EC as of 8 November 2016. *E contrario* to marker assisted breeding (*Broccoli/Tomatoes I* 2010), the EPA has obviously not considered "targeted mutagenesis" to be a case of Art. 53 lit. b EPC. Likewise, it seems that the European Commission qualifies genome editing as a technical process since something (a nuclease, an oligonucleotide) always has to be inserted into the cell in order to overcome the plant's own gene regulation. As the current practice stands, this technical step renders the whole subsequent process "technical", therefore patentable, including product protection. It is inferred from Art. 8 and 9 Biotech Directive 98/44/EC that further steps, like crossing, have no relevance for Art. 53 lit. b EPC.

3.3.2 Reasons for Differentiation

Three arguments suggest a more complex approach.

First, the EPO-EBA in *Broccoli/Tomatoes I* (2010) required a comprehensive evaluation of the *whole* process. No single technical step which forms part of a process renders the whole process technical for it to escape the exclusion "essentially biological". Yet, the text of Art. 53 lit. b EPC consists of two elements "essentially biological" and "for the production of plants". It seems that commentators have considered that both parts are congruent,[91] and that the various language versions correspond to each other.[92] This is also suggested by Rule 26(5)

[88] The term is used for oligonucleotide-directed mutagenesis (ODM), zinc finger nuclease (TFN), meganuclease (MGN), Transcription Activator-Like Effector Nuclease (TALEN) (C. Parisi 2013, pp. 123–132), and recently CRISPR-Cas.

[89] An overview and some interesting case studies are provided in Parisi (2013).

[90] Evidenced by the contributions to the "Second Symposium Zierpflanzenzüchtung" organized by the Julius-Kühn-Institut, Quedlinburg 2017, published in "Julius Kühn Archiv" 2017 (download via: https://ojs.openagrar.de/index.php/JKA).

[91] *Inter alia* Melullis, in: Benkard (2015), § 2a.

[92] Metzger (2016).

EPC-EPC-IR. It reads: "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."

The problem of the diverging language versions of Art. 53 lit b EPC/Art. 4(1) lit. b Directive 98/44/EC was already discussed in *Broccoli/Tomatoes I* (2010). The English version reads "for the production of plants", the German version speaks of "*Verfahren zur Züchtung von Pflanzen*", the French version of "*obtention de végétaux ou d'animaux*". The term *Züchtung/obtention* refers to breeding which is defined as crossing and selection,[93] whilst the term "production" essentially means the multiplication of plants, a business which in many sectors[94] has become distinct from "breeding". Breeding and production are two subsequent, separate markets. While it was submitted that the term "production" is broader than *Züchtung*, the EPO-EBA held this differentiation as "not relevant" for the case at hand.[95] Rule 26 EPC-IR was initially included in the list of definitions in Art. 2 Directive 98/44/EC, but later deleted. In retrospect, it appears that Rule 26 reacted to this problem by defining "production" as "breeding". However, "breeding" in the German and French versions implies a narrower exclusion.[96] If the words "for the production" in Art. 53 lit. b EPC have to be interpreted in the sense of the ordinary meaning of "production" in contemporary English, the exclusion could be wider. If the broader definition widened the scope of the exclusion, it would have an impact on the determination of "technical steps": The wider the definition of the process, the smaller the impact of one (technical) step. The respect of both elements could, however, inversely narrow the exemption, if the two elements were separate and additive. More importantly, the final goal would be different: "crossing and breeding" aims at a new plant itself; "production" opens the perspective towards subsequent downstream markets. This raises the question of what the relation is between the exclusion of Art. 4 and the patent scope of Arts 8 and 9 Biotech Directive 98/44/EC. If one accepts a broader reading of "production" in the exclusion of Art. 4, the tension in a scope of protection as defined by Art. 8 and 9 Biotech Directive 98/44/EC becomes evident which read "protection [...] shall extend to any biological material derived from that biological material through [...] multiplication"; and "protection [...] shall extend to all material [...] in which the product is incorporated [...]". If Art. 4 is construed broadly, the scope of Art. 8/9 Biotech Directive 98/44/EC becomes narrower.

Second, European law is an autonomous order distinct from those of its Member States. This implies that there cannot be an "authoritative-language version". EU law requires a uniform interpretation, independent from national Member State

[93] In this, the author disagrees with Sterckx 2010, "Amicus Curiae Brief to G2/07 and G-1/08" ("Addendum" 24 June 2010). She states that the German word *Züchtung* "also means growing and cultivating, or with bees, keeping". Retrieve via: http://www.epo.org/law-practice/case-law-appeals/eba/pending/g2-07_de.html (accessed 8 November 2017).

[94] Not in all, but in many, such as potatoes and wheat.

[95] G 1/08, p. 53.

[96] Faithfully to the German-language version, German commentaries focus on "crossing and selection", *cf.* Melullis, in: Benkard (2015), Art. 53b, para. 89.

preconceptions,[97] including languages. Decisive is the legislative intent as expressed by the European Council and the Parliament. Where doubts remain, it is up to the CJEU to find an authoritative interpretation of EU law, Art. 267 TFEU.[98] Thus, the point of departure is that the exclusion cannot only be determined by what "essentially" means for the qualification of the whole "biological process", but also by the nexus to the "production of plants". The Directive itself does not give a definition for "production". However, the meaning can be inferred from the CJEU *Brüstle* judgement that exclusions in the Biotech Directive have to be interpreted "widely" since they embody important values on which the political compromise for the Directive rests.[99]

Third, the exclusion of Art. 4 lit (b) and the scope of Arts 8 and 9 Directive 98/44/EC are based on both ethical *and* economic-policy considerations. Besides ethical reasons, the exclusion of Art. 4 Biotech Directive is to perform a function of economic ordering in two dimensions. *Upstream*, it aims to keep naturally occurring genomes in the public domain, thus securing free access for scientists and breeders, and freedom to operate for competitors and suppliers. *Downstream* – and this is the core argument of this article – Art. 4 Directive 98/44/EC aims at structuring subsequent markets. It actualizes the specific characteristics of natural biological material as compared to chemicals: Plants reproduce (almost) identically and by themselves. Therefore, safeguards are needed for the trade of plants (especially in cases of exhaustion, Art. 10 Directive 98/44/EC), and for the subsequent market segments for the processing of plants. This is how Art. 4 and Arts 8 and 9 Biotech Directive play together: Art. 4 excludes "essentially biological processes for the production of plants", whilst Arts. 8 and 9 Directive 98/44/EC delineate the scope of patents for violating products which "contain" the patented "genetic information" and in which the "function" is performed.

These considerations are of specific importance for genome edited plants, since, often and typically, individual plants cannot be distinguished from naturally occurring or naturally mutated plant material. If a genome-editing process is to be qualified as "technical", derivative (violating) material cannot be distinguished from (non-violating) "naturally" mutated DNA with certainty. This is also true for CRISPR/Cas technologies which use "guideRNA" to introduce a protein or DNA into a cell. A potential patent claim puts everyone at risk who uses the "same" natural plants. Already the mere threat of a violation would severely restrict the freedom to operate for all who produce and use plants for various purposes. The problem is similar to the famous neighbor cases where field crops became contaminated by the neighbour's GMO plants (known as "Schmeiser constellation"[100]). In a situation when violating material is found, the burden of proof reverts

[97] Only transposing national legal acts may diverge where directives allow leeway, Art. 288 para. 3 TFEU.

[98] For a parallel reading of Art. 4 Biotech Directive with regard to plant varieties *see* Krasser and Ann (2016), para. 231 who argue that (in principle patentable) processes *become* excluded from patentability when falling under Art. 4 Biotech Directive.

[99] Prior to the Commission's Notice, Krasser and Ann (2016), § 14, para. 112.

[100] The facts of the case are highly contested, *see* Hubicki (2015), pp. 70–71. In Germany, the contamination constellation is exempt from patent protection under § 9c(3) of the German Patent Act.

to the defendant (unless a State stipulated a clause similar to § 9a(3) German Patent Code). In other words, the defendant has to prove that he/she did not use the patented material. If the same general rule would apply in cases of genome editing, the freedom to operate is fully laid in the hands of the claimant. This argument goes beyond the *problématique* that plant patents are often too broad and overly-reward the patent holder. The central point here is that the patent holder's range of control too far through the production chain.[101]

3.3.3 Consequences

The consequences of this reasoning are twofold. On the one hand, it must be examined if some forms of genome editing are excluded under Art. 53 lit. b EPC with the argument that this type of interference with natural products is captured by a broadly understood patent exclusion. Where mutations appear to be the normal result of meiosis and sexual crossing ("crossing of whole genomes"), the process as a whole is to be considered "essentially biological". Article 4 lit. b Directive 98/44/EC requires a re-reading of Art. 53 lit. b EPC with regard to the meaning of "for the production". It broadens the exclusion to the research stage *upstream* and the subsequent markets for plants and plant products *downstream*. The legislators of the Directive 98/44/EC did not content themselves with trusting that infringement courts would find appropriate "cut-off-points" for patent claims. The Directive opts for a straightforward, broad exclusion of "essentially biological processes for the production of plants". In this regard, Art. 4 precedes Art. 10 Directive 98/44/EC.

Thereby, the European legislators aimed to uphold an incentive to invest in truly valuable biotechnological plant-engineering techniques. The exclusion takes preference over the examination, if the submitted inventive step is in itself patentable (new, inventive, industrially applicable). It is the task of the patent examiner to scrutinize the respective claim language and distinguish patentable technical steps from non-patentable inventions which extend to the biological process of reproduction. This reading of Art. 4 Directive 98/44/EC is, however, inconsistent with Rule 26(5) EPC-IR. As is widely acknowledged, there is no hierarchy between these norms that could determine invalidity or non-applicability. The law of the European Union and that of the EPC are two distinct bodies of law. Rule 26 EPC-IR was, however, installed with the intention of transposing the European Directive 98/44/EC. Thus, it is safe to say that Rule 26 EPC-IR does not transpose the Directive correctly. An autonomous interpretation of Art. 53 lit. b EPC in parallel with Art. 4 lit b Directive 98/44/EC trumps the words of the legally subordinated rules of EPC-IR, and blocks the patentability of "essentially biological processes for the production of plants".

On the other hand, where general patent eligibility is given ("threshold met"), limitations need to be considered to secure subsequent market freedoms. This argument refers to product claims – derived product protection under Art. 64(2)

[101] This argument was already forwarded by Sterckx (2008), pp. 15 et seq. as a critique of the "reach-through-claims" of the tomato patent in G1/08.

EPC and pbp-claims.[102] In all cases, the patent scope in genome editing might extend to material undistinguishable from patent-protected material. The potential threat of violation severely restricts the freedom to operate as protected by Arts. 28 and 56 TFEU. This problem was contemplated by the EPO member states during the consultation process in 2017. They discussed whether the problem could be resolved by reference to the resulting genetic composition (instead of reference to the process).[103] Since it was "[...] unclear, though, how the skilled person could ascertain this feature in the final product without having to resort to the process used", this alternative was rejected. Thus, the problem remained unresolved. However, Art. 4 lit. b in conjunction with Art. 9 Directive 98/44/EC demand protection for market freedoms. It is therefore submitted that these norms require *de lege lata* a restriction of the patent scope to process protection only. This implies that product claims for genome editing cannot be accepted.[104] Also, pbp-claims cannot be allowed.[105] As far as a process claim can be granted, its scope is limited to the process only (modifying Art. 64(2) EPC).[106]

Again, a reference to US law supports this line of reasoning. In *Mayo*,[107] the Supreme Court discussed the patentability of a test kit that helped to identify the relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Thus, in contrast to the genetic test kit in *Myriad*, the test kit in *Mayo* concerned the physical state of the patient. The court held that "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately". The USPTO transposed this reasoning *inter alia* for "process claims involving a natural principle" (pp. 15 et seq.) which stresses that natural phenomena in and of themselves do not qualify for patentability and that the whole process is to be weighted.

[102] In Germany, absolute product protection is also granted to pbp-claims: German Federal Supreme Court (BGH), decision of 30 March 1993, 1993 GRUR p. 651 – *Tetraploide Chamomille.*

[103] EPO Doc. CA/PL 4/17 of 23 March 2017, p. 36.

[104] What happens, however, when only a product claim is filed? The submitted solution then amounts to a "no" patent result. This suggestion might appear hypothetical considering how modern patents are drafted. However, EPC-IR should give guidance for patent claims language in this regard.

[105] Where pbp-claims were (or have already been) granted, the scope of the patent is to be judicially restricted to the scope of the process only, by Member States' courts.

[106] This fine-tuning is to be executed cooperatively by the administrative and judicial institutions managing the patent system (the EPA as granting institution and the national [and future EU] judiciaries as institutions responsible for horizontal dispute settlement). If these institutions are not able to install the proposed restrictions, it is time to finally submit the Biotech Directive to a legislative review process.

[107] *Mayo Collaborative Services v. Prometheus Labs. Inc*, 132 S.Ct. 1289, 1296–1298 (2012).

4 Conceptualization: From Protection to Market Ordering

This result (*de lege lata* process restriction of the scope of gen-editing patents) demands a discussion on whether the denial of product protection is in violation of property principles or a viable delineation of markets. The answer will be derived from a discussion of three patent law principles: (4.1) the disconnection of the claim defined by patentability requirements and claim types (product, pbp, process) from scope; (4.2) adequate property protection (Art. 27 TRIPS, Art. 17(2) EU Charter of Fundamental Rights); and (4.3) principles of chemicals patent law.

4.1 The Linkage of Patentability Requirements, Claim Types and Scope

It is submitted that the approach of a dogmatic disconnection of patentability requirements and scope is overruled by the novel Rule 28 EPC-IR.[108] Patent protection rules (viz. property) have no priority over exclusions. Exclusions may not be overridden by general rules granting extensions. Product protection is not automatically bound to process claims. Derived product protection was originally created by jurisprudence,[109] became later stipulated in Art. 64(2) EPC, and cannot be deduced from doctrine. In essence, this argument was already accepted by the EPO-EBA in the decision G01/98 *Transgenic Plants/Novartis II* of 20 December 1999.[110] The disconnection argument, however, is legally correct as far as the procedural competences are concerned: the EPO applies the criteria of patentability and issues patents; member states adjudicate violations disputes – and thus determine the protective scope of patents, as far as the EPC leaves room for discretion (e.g. Art. 64(2) EPC and pbp-claims). However, complementary competences should not be mistaken for a dogmatic structure. As far as scope restrictions have an impact on claim language, patent-granting agencies are required to apply the law.

4.2 Adequate Property Protection

It is often purported that the active filing for biotechnological patents in the plant sector is fueled by protection *lacunae* in the breeders' rights system. Essentially three *lacunae* are deplored: first, the breeders' privilege is criticized for allowing the breeder not only to *produce* but also to *market* plants; second, there is opposition to the lack of protection against imports of (contractually illegally produced) "harvested material" (e.g. cut roses) from UPOV countries[111]; and third, lack of protection is criticized for not providing protection for processes, which is central to recombinant-DNA-technology, in particular to Agrobacterium mediated gene

[108] If, indeed, it ever existed. However, in patent adjudication it was often invoked, *see* EPO-EBA statement in G2/12 under VIII. 2. (6) b) (OJEPA 2015-A27, p. 55): "Whether a product claim or a product-by-process claim is patentable is to be examined irrespective of the extent of protection that is conferred by it after grant".

[109] Supreme Court of the German Empire (Reichsgericht) of 14 March 1888 – *Methylenblau* (*supra* note 24).

[110] Ziff. 5.3 of the EPO-EBA decision G 1/98 of 22 December 1999.

[111] Parties to the International Treaty of the International Union for the Protection of New Varieties of Plants, (French: "*Union internationale pour la protection des obtentions végétales*", UPOV).

transfer.[112] The argument goes as follows: Because of inappropriate protectior under the breeders' rights system, plant science and breeders seek patent protectior and push the limits of patentability of plants.

Leaving aside legitimacy and rationales of the complementary systems of plan varieties and patents, the shift towards the patent system is explained by ongoing profound socio-economic transformations. Plant production on a global scale has shifted towards explicit (scientific) knowledge[113] and adopted the chemical industry's governance schemes,[114] including institutional ideologies.[115] Modern IP-based management strategies, taxation privileges for licensing, and defensive reactions of (traditional) plant breeders[116] have supported the push for patent protection.[117] However, the protection *lacunae* deplored by some are parallel deliberate freedoms of others. This conflict is mirrored by the opposing stance of patent lawyers versus economists and competition lawyers. The latter deplore that patent law does not properly respect freedoms to operate in subsequent market stages. Against this background, the *protection lacunae* is to be discussed as *theory lacuna*. The long history of patent priority over competition law prevented respective theory-building and differentiation. Article 27 TRIPS re-enforced this line of reasoning.[118] It is the lack of *theory* which make restrictions on genome-editing product claims appear illegitimate (infra 3.3). The narrative of product protection, however, lacks historic consciousness.[119] Legal researchers have for too long limited themselves to patentability questions and principles which broadened patent protection such as the principle of absolute product protection. Whereas under European law, the restriction of property for the sake of market freedoms has become common sense,[120] restrictions of patent protection are opposed as illegal

[112] I owe this third *lacuna* to a note of an anonymous peer-review.

[113] Brandl (2017).

[114] A scientific-technological bias based on the idea of authoritative knowledge, as Habermas coined it, *see* Girard (2015).

[115] Schneider (2010), describing an institutional enclosure of the patent system based on an epistemic community.

[116] The breeders' privileges in the biopatents' schemes are usually very limited and do not function. While § 11 No. 2 German Patent Act allows research *on* and research *with* patented material (allowing the breeder to actually integrate patented material into new lines); however, the breeding material is only freely marketable after expiration of the patent term; *see* § 9a(3) German Patent Act. Cross-licensing schemes are too rigid to be operable.

[117] Yet, national policies remain possible. This is documented by the case of Argentina which is at the bottom of the CJEU *Monsanto* case: Argentina had denied patent protection to Monsanto's glyphosate resistant soy. Therefore, the production of soy from seeds patent protected in the US/EU was legal in Argentina. Attorney General Mengozzi based his opinion on the argument that it is not the patent law's function to remedy protection *lacunae* in other countries (Opinion of 9 March 2010, para. 35, ECLI:EU:C:2010:128), discussed by Hubicki (2015), pp. 78–79.

[118] Schneider (2010), p. 226, p. 236.

[119] Schneider (2010), p. 225, *e.g.*, describes the former rules for process protection and how these developed.

[120] The long list of cases starts with C-15/74, CJEU of 31 October 1974, ECR 1974, 1147 – *Centrafram* establishing the principle of Community exhaustion. Yet, the principles applys equally to immobile property, *see* C-69/88, CJEU of 7 March 1990, ECR 1990, I-583 – *Krantz*, C-515/99, C-519/99 to C-524/99, C-526/99 to C-540/99, CJEU of 5 March 2002, ECR 2002, I-2157 – *Reisch*.

and as violating TRIPS. It is this intellectual narrowing which rendered the patent discipline incapable of translating the functional restrictions of the Biotech Directive,[121] and of understanding that the Directive requires a delineation of markets by patent law. It is high time for change.

4.3 Principles of Chemicals' Patent Law

Principles predetermine the interpretation of law. Regarding chemicals, influential intellectual strongholds have evolved since the birth of the industry in the 19th century. Against the contemporary restrictive patent stance of economists, legislators and governments (chemical substances were at the time excluded from patent protection in Germany[122]), the standard for chemicals patent protection was fought through with the help of the judiciary between 1877 and 1968. The legal discipline created two doctrines which made up for the lack of product protection: the principle of derived product protection of process claims[123] (now Art. 64 II EPC), and the "surprising effect" to overcome the lack of coverage for the inventive step and novelty.[124] After the prohibition was abolished, these standard doctrines were not put in question, but reinforced by three additional doctrines: the acceptance of pbp-claims,[125] the isolation theorem,[126] and the principle of absolute product protection.[127] These five principles have come to form *the* intellectual backbone of chemical patents.[128]

Despite the material differences,[129] this standard was transposed to biotechnological inventions. Biotechnology was conceived as a sub-discipline between chemistry and biology. It is in this context that DNA became conceptualized as a chemical substance,[130] and encoding genes became objects of the "isolation" of acid sequences. Any information characteristics were denied,[131] and such

[121] Notwithstanding how equivocal the concepts are, *see* Godt (2007), p. 112 et seq.

[122] Uhrich (2015), p. 204); also Krasser and Ann (2016), § 11 No. 28. For an overview of the legislation on exclusion of chemical substances in Europe, *see* Schneider (2010), p. 226.

[123] Supreme Court of the German Empire (Reichsgericht) of 14 March 1888 – *Methylenblau*; for more detail Uhrich (2015), p. 174 et seq.

[124] German Patent Office practice since 1934; *see* Schippel (1958), p. 336 (fn. 21).

[125] In Germany since 1971, BGHZ 57, 1 – *Trioxan*, confirmed by the German Federal Supreme Court, 1993 GRUR p. 651 – *Tetraploid Chamomile.*

[126] Two decisions account for it: German Federal Supreme Court of 28 July 1977, 1978 GRUR p. 238 – *Naturstoffe*; German Federal Supreme Court of 14 March 1972, BGHZ 58, 280 = 1972 GRUR p. 541 – *Imidazoline.*

[127] German Patent Act of 28 July 1977, 1978 GRUR p. 238 – *Antanamid.*

[128] Schneider (2010), focuses on three principles, pp. 232, 233, 237.

[129] The most evident one is self-reproduction. This issue was first discussed with regard to microorganisms (*cf.* Budapest Convention 1981). Later, this reasoning was transposed to genetic engineering (discussed by EPO-EBA in G 1/98, para. 5.2, at p. 34).

[130] EPO Board of Appeals, T 0272/95 – 3.3.4, 23 October 2002 (ECLI:EP:BA:2002:T027295.20021023) – *Relaxine.* Critical: Melullis, in: Benkard (2015), § 2a, para. 10; also Krauss and Takenaka (2013), pp. 255–270.

[131] Schatz, Art. 53, in: Singer and Stauder (2003), para. 28.1.

complexities as the multiple coding of sequences and the phenomenon of epigenesis, at least in academic legal writing, sidestepped. Thus, the standard for chemical patents became the stronghold for the defense of the "patentability" of biotechnological inventions. Until today, the five doctrines appear to many as "given, natural, and logical".[132] The legislators of the EC Biotech Directive in 1998 struggled to adapt the standard[133] and to find common ground for a compromise.[134] In the end, the various parties "could live with the text", since formulations of each "camp" were knitted into the fabric of the Directive's text.

By now, it has become evident that doctrinal ideas can be stronger than legislative intent. Concepts enjoy persistent strength since any discourse necessarily resorts to preceding thoughts and language. Legislators encounter enormous problems when they attempt to alter standing doctrine. Neither the legislative history of the Biotech Directive, nor the evolution inside the EPO can be reiterated here in further depth. The argument is that the five principles were altered in the parliamentary process; they did not "survive" unchanged.[135]

5 Conclusion

Reiterating the triangle of technology, law and markets, it is the patent law's task to function as a hinge joint between technology and markets. On the legal–technical level, I submit that Art. 4 Directive 98/44/EC is to be interpreted in the light of the three preceding considerations explored under Sect. 4. An EU autonomous interpretation gives credit to the aim of the legislator to secure an equilibrium of patent protection and economic freedoms. Article 4 Directive 98/44/EC shapes the patents' scope and thus delineates subsequent market stages. It aims to provide structure, both for primary and secondary markets. This reading is imperative for patents issued under Art. 53 lit. b EPC. For genomic information of human origin, Art. 5 Directive 98/44/EC limited the primary market by way of requiring a clear description of the industrial applicability. For plants, the primary market control is narrowed down by way of exclusion under Art. 4 Directive 98/44/EC. Respective secondary markets are structured by Arts. 8 and 9 Directive 98/44/EC: Protection is granted against material in which the invention is "contained and performs its function". The consequence is that subsequent markets are assigned to the patent owner but strictly limited by the function performed. According to the CJEU in

[132] Schneider (2010), p. 238.

[133] For an in-depth discussion *see* Schneider (2010); Hubicki (2015).

[134] On the discussion of how the Directive 98/44/EC implemented/changed the doctrine of product protection *see* Uhrich (2010). He describes the attempts to restrict the doctrine of product protection as having "miscarried" (German "*missglückt*", p. 299) because it was dogmatically implemented as part of "commercial usefulness" – which he qualifies as "carelessness" (German "*Nachlässigkeit*", p. 300); also Godt (2007), p. 114 ("contradicts the spirit of the Directive"). Both see the concrete transposition of the restriction delegated to Member States [Uhrich (2010), p. 300; Godt (2007), p. 114]. For a recent dispute on the meaning of patent protection under the Directive, *see* the Expert Report on Biopatents of May 2016 (commented on by Godt 2016b).

[135] Godt (2007), p. 3; Krauss and Takenaka (2013).

Monsanto, the "function" is to be defined narrowly along the patent claim. This is the central function of linking patentability and scope.

On the conceptual level, patent law has to live up to its task is to translate technological developments into legal doctrine with regard to market ordering. With genome editing, society has come to a crossroads. While globalization demands control over internationally dispersed and independent contractors along the production chain and patents evolved into key institutions for control and contractual communication, we risk that capitalism "swallows its own children" – freedoms.[136] That is to say that the patent system risks to inhibit independent undertakings and to overly restrict the freedom to operate.

It is time to re-conceptualize both sides of patent power (the "haves" and the "have-nots"). On the legal–technical level, the limitation of genome editing patent claims to the process scope in cases where violating and non-violating material cannot be distinguished is imposed by the rationale of patent law if otherwise the patent scope would cover naturally occurring phenomena. On the conceptual level, respect has to be given to the freedom to operate on subsequent market stages – for the sake of future innovations. Patent law has to live up to its tasks in the triangle of technology, law and markets. The subtle delineation between enough protection and sufficient freedom to operate is not only a task for competition law. And while competition law has, for a while now, taken on the responsibility to also control power in vertical market relations, patent law has neglected its own responsibility for securing freedom on subsequent markets until today. It is an eminent task for patent law itself to reflect the very foundations of economic freedoms and to provide for the respective operative decision-making structures.

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[136] Adapted from the quote attributed to Georg Büchner, *Dantons Tod*, orig. 1853, Insel Verlag; Frankfurt, 1963.

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