The Appropriate Scope of IP Rights in the Area of Genome Editing

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The contribution focusses on the scope of granted patents in the area of genome editing. Presuming that all patentability requirements are met (including the exclusion provisos of 'essentially biological'/'matter of nature'), it discusses the extent of the patent scope for three reasons: Future patent claims have to be compatible with principles of civil procedure, competition law and EU fundamental freedoms. This contribution comes to the conclusion that, eventually, only process claims can be enforced.

A. The Issue

The "hype" around patents and genome editing has "just begun". This is the conclusion, Heinz Müller, Patent Expert at the Swiss Federal Institute of Intellectual Property, drew from his inquiry into genome editing patents.[1] He identified 2219 active patent families of genome editing patents. Among them are the two clusters around CRISP-Cas9 and CRISP-Cas5, and the

* Carl von Ossietzky University Oldenburg, Professor of International and European Economic Law, https://www.uni-oldenburg.de/eurowr/. This contribution is based on an earlier paper "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" published in IIC (International Review of Intellectual Property and Competition Law) 2018 (Vol. 49), 2018, pp. 512–535. The reader will notice the changes in argumentation.

1 Heinz Müller, "Das Umfeld der Patentschlacht um CRISP/Cas9", Oral Presentation at the Conference "Genome Editing/CRISP als Herausforderung für das Life Science Recht", organised by B. Fateh-Moghadam/C. Seitz/H. Zech, 11./12. Oct. 2018 in Basel (CH).

two patents which gave rise to the now "canonical"[2] dispute between the BROAD Institute and UC Berkeley. While the public debate has focussed on the prospects (and the risks[3]) for the medical sector, many plant related patents have been issued.[4] Laboratories in the plant sciences already employ the technology as a standard tool.[5] Heinz Müller cautions against the effects of the canonical patents. While he expects that basic research will not be impaired due to the broad licensing scheme pursued vis-à-vis academic

2 J. S. Sherkow, The CRISPR Patent Landscape: Past, Present, and Future, CRISPR Journal 2018, Vol.1, issue 1 (published online: 1 Feb 2018; https://doi.org/10.1089/crispr.2017.0013 = https://www.liebertpub.com/doi/full/10.1089/crispr.2017.0013). While the central patents have all a priority date in 2012, U.S. Patent No. 7,919,277 of 2004 already mentions "CRISP". This '277 patent, assigned to the Danish food chemistry company Danisco A/S claimed a method of sequencing certain CRISPR regions in a sample to detect variants of Lactobacillus acidophilus, a 'bacterial workhorse' of industrial yogurt production (ibid). It seems, that the query around the two first initial patents came to an end with the CAFC decision of 10.9.2018 (Regents of the Univ. of Cal. v. Broad Institute, Inc., Case. No. 2017-1907 – Fed. Cir. Sept.10, 2018) and that both patents are held valid, both in the UA and Europe, J. S. Sherkow, The CRISPR-Cas9 Patent Appeal: Where Do We Go From Here? CRISPR Journal 2018, Vol.1, issue 5, published online:17 Oct 2018, https://doi.org/10.1089/crispr.2018.0044.

3 Central to the future debate will be the public discussion around genome editing of humans, propelled by the proclamation on Nov. 26, 2018 of the birth of CCR-5 genome-edited twins by Chinese scientist He Jiankui, Southern University of Science and Technology Shenzhen, on this debate C. Nüsslein-Volhard, Grenzen der Menschheit, FAZ, 8.12.2018, p. 13., J. Cohen, After last week's shock, scientists scramble to prevent more gene-edited babies, 4.12.2018, Sciene online, doi:10.1126/science.aaw2752; for an earlier discussion see All European Academies (ALLEA), Statement on Patent-Related Aspects of CRISPR-Cas Technology of June 2016, download: http://www.allea.org/wp-content/uploads/2016/08/Statement_CRISPR_web_final-1.pdf.

4 Instructive for the plant-breeding sector: C. Parisi, New Plant Breeding Techniques: State of the Art, Potential and Challenges (Doctoral Thesis, University of Cordoba), 2013 (http://helvia.uco.es/xmlui/handle/10396/9492); C. Parisi/E. Rodríguez-Cerezo/H. Thangaraj, Analysing patent landscapes in plant biotechnology and new plant breeding techniques, 22 Transgenic Res (2013), 15–29. For a legal analysis of modern breeding techniques under European GMO-regulation: S.O. Callebaut, New developments in modern biotechnology – A survey and analysis of the regulatory status of plants produced through New Breeding Techniques, (Master Thesis, Faculty of Law Ghent University), (2015), http://lib.ugent.be/fulltxt/RUG01/002/213/647/RUG01-002213647_2015_0001_AC.pdf.

5 Cp. contributions to S. Plaschil (ed.), Zweites Symposium Zierpflanzenzüchtung in Quedlinburg, 13.–14. März 2017 – Proceedings, Julius-Kühn-Archiv 457, Quedlinburg.

institutions, and therefore, a "bottle neck situation" will most likely not stifle academic research. His concern are the broadly formulated claims. These may render many recently filed patents "obvious". In addition, it is open to which extent any improvements or further developments will be qualified as 'dependent'.

Research is evolving at a high speed. The dispute between the BROAD Institute and UC Berkeley only covered CRISPR Type II systems using Cas9. The "Doudna Group", affiliated with UC Berkeley, continues to work with smaller proteins compared to Cas9 (CasY, CasX and Cas13a), and the Broad Institute filed a patent on CRISPR-Cpf1, substituting Cas9. Important for the current state of the art (November 2018) is the assessment that it is unlikely that all currently famous patents will be upheld once infringements disputes clear the field.[6] Consequently, also the license architecture (despite of the value of the firms involved[7]) may not survive.[8] A prominent example for the current fragility is the European Patent Office's repeal of the BROAD Institute's patent EP 2 771 468 based on obviousness.[9] In addition, patent attorneys start to oppose granted genome editing patents based on their claim formulation. Especially contested are claims on "methods of manufacturing" which allow for an extension to products under Art. 64 sec. 2 EPC/35 US § 271 (g). For seeds, e.g., it is questioned if genome edited products are "materially changed". This argument neither

6 D. Ku, The Patentability of the CRISP-Cas9 Genome Editing Tool, 16 Chi.-Kent J. Intell. Prop. (2016), 408–439; The European Patent Office Board of Appeals confirmed the opposition division's decision that revoked the BROAD Instiute patent EP 2771468, case T-844/16, decision of 16.1.2020, based on lack of novelty. Yet, other BROAD-patents related to CRISPR remain untouched.

7 Which is sensitive to any development in the patent and licensing, cp. A. Mannwieler, Wusste die Börse schon früher von den Gen-Babies, FAZ, 1.12.2018, (Finanzmarkt).

8 On the licensing structure: J. L. Contreras/J. S. Sherkow, CRIPS, surrogate licensing, and scientific discovery, 355 Science (17.2.2017), 698–700; J. L. Contreras/J. S. Sherkow, Patent Pools for CRISPR Technology – Response, 355 Science (28.6.2017), pp. 1274–1275.

9 M. Klos, Milliardentechnologie: EPA kippt erstes Genscheren-Patent des Broad Institute, Juve, 18.1.2018, < https://www.juve.de/nachrichten/verfahren/2018/01/milliardentechnologie-epo-kippt-erstes-genscheren-patent-des-broad-institute>.

questions the "technicity" per se, which is hotly debated in public.[10] Nor is it related to the peculiar problem of product protection based on non-patentable processes (cp. Tomatoes/Broccoli II, the Commission's Notice of Nov. 2016 and the 2017 reformulated Rule 28 EPC Implementing Regulation).[11] The point here is that product protection for method claims is arguably only available if the outcome of a claimed method is a "modified cell".[12] The argument is that product protection requires "absolute novelty" for the product itself. This reading is based on the context that the extent of method claims, in most countries, is limited to *direct* products only. This debate revitalizes the debate on "native traits", and reminds the community that genome editing, while the technology is innovative, does not necessarily make an existing trait "inventive". Further requirements give reasons for caution. While the basic genome editing techniques have become part of the tool kit in the art, the requirements for inventiveness and novelty are steadily growing. It is therefore that 'inventiveness' demands a surprising effect of the product or unexpected obstacles in the making. That means that claims on knock-out traits may not be eligible. Furthermore, claims are to be supported by disclosure.

The focus of this contribution, however, are neither patentability requirements nor specific applications of genome editing ranging from genomic therapy to the transplantation of pig livers. As far as human cells are concerned, the simple reference to the exclusions of Art. 53 a EPC in conjunction with Rules 28 and 29 EPC-IR does suffice. For national applications, even more restrictions such as § 2 Abs. 2 German Patent Code

10 For a discussion on the distinction between (mostly unpatentable) random and intended mutagenesis (mostly patentable) see C. Godt, 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 IIC 2018 (Vol. 49), 512–535; for the parallel US-discussion on CRISP-Cas9 and the challenge of not being "patentable subject matter", see D. Ku (supra n. 6).

11 The European Patent Office's Enlarged Board of Appeal (EPO-EBA) followed the EU Commission's interpretation and overruled its own piror decisions G2/12 and G2/13 of 2016 with its decision in case G 3/19 of 14 May 2020.

12 M. Kock, 'Genome Editing: Implications for IP in the Agricultural Sector', Oral presentation at the Conference "Genome Editing/CRISP als Herausforderung für das Life Science Recht", 11./12. Oct. 2018 in Basle (CH), supra fn. 1.

might apply.[13] This contribution is strictly limited to the technical question related to the patent's scope only. At the center of this piece is the following assessment: Regardless of the way in which the DNA has been changed, whether by introducing foreign or the species' own DNA, the existing DNA is changed in such a way that the resulting product can – in most cases – not 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, the isolated result might not be identifiable as the outcome of a genome editing process.[14] This observation is not only the origin of the debate if such modified plants and organisms are "non-transgene" (related to the question if these products fall into the scope of respective biotechnology regulation[15]). The indistinctiveness begs the question if a patent holder can start an infringement procedure against everyone who uses the "same" plant or cell. Already the mere threat of a violation and the process risk would severely restrict the freedom to operate for all who produce and use existing plants, cells, organisms. The problem is largely identical with the discussion on (patented) characteristics and DNA sequences which naturally occur in plants and fruits ("native traits"),[16] and to the famous neighbor cases where field crops got contaminated by the neighbor's GMO

13 I. Schneider, Patent Governance, Ethics, and Democracy: How Transparency and Accountability Norms are challenged by Patents on Stem Cells, Gametes, and Genome Editing (CRISPR) in Europe, in: S. Ravenscroft/T. C. Berg/ R. Cholij (eds): Patents on Life, Cambridge: Cambridge University Press (2019, forthcoming).

14 A publicly discussed example is the suppression of three genes in wheat resulting in a resistance to blight, Sentker, Unser bedrohtes Gold, Die Zeit, 20.7.2017, p. 31.

15 C-528/16, CJEU of 25.7.2018, ECLI:EU:C:2018:583 discussed by C. Seitz, Modifiziert oder nicht? Regulatorische Rechtsfragen zur Genoptimierung durch neue biotechnologische Verfahren, EuZW 2018, 757.

16 It must be acknowledged that the term can have a number of meanings. Cp. Metzger (2017) p. 214 "new properties resulting from classical breeding methods of crossing and selecting"; cp. Lawson (2015), p. 99: "Limited nature of genetic traits and their limited substitutability"; and cp. M. Kock, Patenting Non-Transgenic Plants in the EU, in D. Matthews/H. Zech (eds), Research Handbook on Intellectual Property and the Life Sciences, Cheltenham: Elgar, 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'".

plants (known as 'Schmeiser constellation'[17]). If the burden of proof is not regulated specifically (like for damage claims under § 34 administrative German Biotech Law, and for propagating material on farm similar to § 9a sec. 3 German Patent Code), the normal privilege of property protection applies: If violating material is found, the burden of proof reverts to the defendant.[18] 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 laid in the hands of the claimant.

The problem was already contemplated by the EPO member states during the consultation process in 2017 with regard to "essentially biological processes" which are excluded from patentability; they discussed whether the problem could be resolved by reference to the resulting genetic composition (instead of reference to the process).[19] 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.

This argument goes beyond the debate if biotech patents are too broad and therefore overly reward the patent-holder (primary market). The central concern is that the patent holder's control reaches too far through the production chain.[20] Patent law does not only structure the relationship between

17 The facts of the case are highly contested, see: S. Hubicki, 'The Story of a Love Spurned': Monsanto in the United Republic of Soy", in: C. Lawson/B. Charnley (eds), Intellectual Property and Genetically Modified Organisms – Convergence in Laws, Ashgate: Surrey/Burlington, 2015, pp. 70–71. In Germany, the contamination constellation is exempt from patent protection under § 9c sec. 3 of the German Patent Act.

18 A problem of overprotection of the patent holder was already detected by Lichtman/ Lemley in 2007. They therefore proposed as two-tier system of patent validity, with patents that are subject to intensive scrutiny accorded a strong presumption of validity, while untested patents are left to be evaluated more fully in court, Stanford Law Review, Vol. 60, p. 45, 2007=UCLA School of Law, Law-Econ Research Paper No. 07–12.

19 EPO Doc. CA/PL 4/17 of 23.3.2017, p. 36.

20 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.

competitors, but also between primary and secondary markets.[21] It structures technology markets both via patentability requirements and scope principles. Originally, two principles governed the secondary markets. The concept of dependency balances the interests of improvers and pioneers with regard to subsequent innovation markets, the principle of exhaustion secures the freedom of the secondary trade market.[22] While the European legislator extended the patent holders' reach by way of Art. 8 and 9 Biotech Directive, their content and limits were not discussed until the case *Monsanto* v. *Cefetra* was deliberated by the European Court of Justice in 2010.[23] Afterwards, further questions emerged especially with regard to Art. 8.2 Biotech Directive. While some argue that method claims always extend to products as long as they cause any characteristic,[24] others require a causal link between the claimed method and the essential characteristic of the product based on the wording of Art. 8.2 Biotech Directive ("result of the invention shall extend to biological material directly obtained through that process").[25] This problem is yet unresolved.

21 Godt 2018a (supra fn. 11); earlier T. Dreier, Primär- und Folgemärkte, in: G. Schricker/T. Dreier/A.Kur (eds), Geistiges Eigentum im Dienst der Innovation, Baden-Baden: Nomos, 2001, pp. 51–81.

22 For biotechnological inventions, the exhaustion principle is concretized by Art. 10 Dir. 98/44/EC – and its respective national transpositions, e.g. § 9b and § 9c of the German Patent Code.

23 C-428/08, *Monsanto Technology LLC v Cefetra BV* [2010] ECR I-6761. Technically, the case revolves around determining the meaning of Art. 9 Dir. 98/44/EC ("contained and performs its function") vis-à-vis the principle of absolute product protection. Hubicki (2015, supra n. 17), pp. 27–80 documents the discussion how far biopatents extend to secondary markets. At p. 69, fn. 176, he reports the discussion about food (e.g. polenta made from GMO maize, an 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). At p. 78 he discusses textiles made of Bt-cotton.

24 England and Wales High Court, 5.7.2011, *MedImmune v. Novartis Pharmaceuticals UK Ltd.*, (2011) EWHC 1669 (Case No. HC09 C04770).

25 M. Kock (2017, supra n. 16).

The following article contribution modifies an earlier contribution[26] and aims to identify the conditions under which a patent holder may start an infringement procedure by examining the principles of civil procedure, competition law, and European Union's Fundamental Freedoms (2). The conclusions are formulated under (3).

B. Legal Analysis

I. Principles of Civil Procedure

One of the central judicial principles is due process. For the plaintiff, the due process principle secures the right to be heard. For the defendant, it secures the right to be kept safe from illegitimate procedures. In civil procedure, the balance of the competing interests is enshrined in the plaintiff's duty to substantiate the facts for all elements of the legal cause of action.[27] Does the defendant contradict, it is up to the claimant to produce evidence for the legal requirements in his favor. For those, he "bears the burden of proof". As to the degree of evidence, the civil law standard is 'the balance of probabilities', often referred to in judgments as "more likely than not". These principles are buffered by the constitutional guarantees of judicial relief and due process.

26 C. Godt, Patentschutz in der (Zier-)Pflanzenzucht, in: Plaschil (ed.) 2017, supra n. 5, p. 28.

27 In German: „Anspruch auf rechtliches Gehör", guaranteed by Art. 19 sec. 4 German Constitution. For Civil procedure, the German Supreme Court (BGH) clarified on 10. Juli 2012 (II ZR 212/10): "(...) the claiment sufficiently substantiates his presentation, when he/she produces facts related to the legal cause of action suitable to deem the requirements for the claim to be met. (translation CG, original: „Tatsachen anführt, die in Verbindung mit einem Rechtssatz geeignet sind, das geltend gemachte Recht als in ihrer Person entstanden erscheinen zu lassen"). The duty to substantiate is only then not met when the Court cannot assess if the legal requirements are given. (BVerfG, WM 2012, 492 Rn. 16; BGH, Beschluss vom 9. Februar 2009 – II ZR 77/08, WM 2009, 1154 Rn. 4; Beschluss vom 21. Mai 2007 – II ZR 266/04, ZIP 2007, 1524 Rn. 8; Urteil vom 25. Juli 2005- II ZR 199/03, WM 2005, 1847, 1848 m.w.N.). If the Court overstresses the requirements of substantiation, and therefore does not hear the evidence proposed by the party, the Court violates the "Anspruch auf rechtliches Gehör" (BVerfG, WM 2012, 492 Rn. 20 f.; BGH, Beschluss vom 9. Februar 2009 – II ZR 77/08, WM 2009, 1154 Rn. 4).

These principles ensure that the plaintiff "gets her right", and that fellow citizens are shielded against legal harassment. No-one should be bossed around, neither by other citizen fellows, nor by courts. This is a basic guarantee of a liberal society.

In patent infringement procedures, the claimant's duty to substantiate is already met when the violating material is covered by the claim. While disputed in academic literature,[28] and in one singular decision of the German Supreme Court (Bundesgerichtshof, BGH) in 2005,[29] the courts' practice does not require to substantiate further facts.[30] If the delinquent material shows the characteristics of the patent claim, the violation of the patent is assumed and the burden of rebuttal shifts to the defendant. This is the *problématique* at hand: In most cases, genome edited material is identical to naturally occurring material. If we accepted product claims (including pbp-claims[31]), a category of infringements were created where the burden of proof rests with the defendants from the outset. This reverses *de facto* the given set of fundamental principles of civil procedure. It will be the defendant to produce the facts about where he/she got the material from. The plaintiff only has to present the paper claim and the defendant's material, and ask the court for the comparison. No further substantiation is required.

Michael Kock advocates a statutory exception to render this shift legitimate.[32] While this proposal would formally remedy the legal conflict, it would perpetuate the degradation of the due process principle. It is for the

28 T. Büttner, Vom Patentprozess lernen? Zum unterschiedlichen Gewicht der Schwierigkeiten mit dem Streitgegenstand im Wettbewerbs- und Patentverletzungsprozess, in: W. Büscher et al. (eds.), Festschrift Ahrens, Heymanns: Köln, 2016, 341.

29 BGH GRUR 2005, 569 – *Blasfolienherstellung*.

30 A practice defended e.g. by T. Kühnen, Eine neue Ära bei der Antragsformulierung? Kritische Gedanken zur BGH-Entscheidung „Blasfolienherstellung", GRUR 2006, 180 (183); C. Lenz, Sachantragsformulierung im Patentverletzungsprozess, GRUR 2008, 565 (568).

31 These are, by legal nature, product claims. This type of claim is granted by the EPA, but their recognition is left to the contract parties… (D. Walter, Klassische und markergestützte Zuchtverfahren – Noch kein Patentrezept für Tomaten und Brokkoli, GRUR Prax (2010) 329–332). In Germany, absolute product protection is also granted to pbp-claims: German Federal Supreme Court (BGH), decision of 30.3.1993, GRUR 1993, 651 – *Tetraploide Chamomille*.

32 Oral Presentation, Conference "Genome Editing/CRISP" in Basel, Oct. 12, 2018.

protection of the defendant that the claimant is burdened with producing first evidence. Patent law goes too far if it deviates from the standard rule that the claimant not only has the formulate what he/she wants ("Antrag"), but also the facts as far as relevant for the legal base (in German "the Klagegegenstand", den "Lebenssachverhalt"). The law has to react to the intricacies of life, and has therefore to deny the enforcement of product claims which are only based on phenotype material identical to naturally occurring material. A pure procedural decision based on the burden of proof upon the failure to produce first evidence for *non*-infringement of a pbp-claim or a product claim by the defendant violates the due process principle.

II. Principles of Competition

Today, it is well understood that patents only function properly under conditions of competition.[33] Only when the market generates a demand which sustains prize flexibility (higher prizes), can the privilege deploy its function as a return of initial investment (thus creating an incentive to invent and invest). For this reason, patents today are not any more conceived as exceptions to competition, but as essential elements of innovation markets embedded in competition.[34] This understanding has been broadly adapted, both by competition lawyers and the patent community, since the European Court of Justice's handed down its landmark decision *Magill* in 1995 in which the court began to define the conditions under which a patent holder has a duty to license. Patents are understood as incentives, not as absolute right to exclude in the sense of a natural right. It is for the sake of innovation that patent holders might be obliged to grant a remunerated license when she or he has been engaged in a standardisation process.[35]

Historically, the eminent role of competition law was seen to control the patent holder not to reach beyond the patent. The scope was defined by the

33 M. Lamping, Patentschutz und Marktmacht, Heymanns: Köln, 2010.

34 H. Ullrich, TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy", 4 Pacific Rim Law & Policy Journal 1995, 153–210.

35 C-170/13, CJEU of 16.7.2015, *Huawei*, ECLI:EU:C:2015:477; for preceding analysis in academia see A. Balitzki, Patente und technische Normen – Zugangsmöglichkeiten für Normnutzer, Tectum: Marburg, 2013.

wording of the claims (Art. 69 sec. 1 EPC)[36] and the scope of protection (absolute product protection),[37] supplemented by the uncompetitive misuse of overly restrictive licenses.[38] Until the mid-90s, the distinction was made between "existence and use", implying that competition law can only be applied "beyond" the scope of the right. Modern case law[39] on the interface of patents and competition focusses on a balanced reasoning of criteria for "misuse" of a legally protected exclusionary position.[40]

Embedded in this novel conceptualisation of property and competition, the nexus became well understood that expanding patent protection narrows down the other parties' freedom to operate. Yet, in contrast to patent protection, the legal conceptualisation of the freedom to operate has attracted little constitutional recognition[41] and academic attention.[42] While Art. 8 and 9 Biotech Directive installed "reach though claims", and extended the scope

36 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 sec. 2 EPC); first judicial decision of 14.3.1888 by the Supreme Court of the German Empire (Reichsgericht) of 14.3.1888, RGZ 22, 8 – *Methylenblau*.

37 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 sec. 3 and 4 German Patent Code – for human genomic inventions); (2) Any other mode of production beyond the disclosed production process is also protected.

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

39 The most recent decision of the CJEU, C-170/13, *Huawei*, ECLI:EU:C:2015:477 of 16.07.2015, digital publication only.

40 A. Strowel/H.-E. Kim, The Balancing Impact of General EU Law on European Intellectual Property Jurisprudence, in: A. Ohly/J. Pila (Hrsg.), The Europeanisation of Intellectual Property Law, OUP 2013, 121–142 (p. 128).

41 Also acknowledged by Dreier (2001, supra fn. 21), p. 60, p. 70.

42 A noteworthy exception is Hubicki (2015, supra n. 17). An emblematic example is the narrowing of the competition law-rooted exhaustion principle by the CJEU decision in *Greenstar v. Kanzi* (C-140/10, dec. of 20.10.2010). 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.

of patent control, it was not until the CJEU's *Monsanto* case that their language was discussed in courts. Until then, the majority of patent lawyers understood the Directive's articles as confirmation of the "absolute" product protection, and neglected the provisos.[43] A notion of *absolute dominium* prevailed: Once a patent claim is granted (for a technical step), any subsequent products resulting from crossing and selection are in any form protected and patentable in themselves.[44] As petrified in Art. 27 sec. 2 last clause TRIPS,[45] the right to exclude and the right to use were conceived as two different areas of law (patent law versus public law). The "use" could be regulated, either by public regulation or by competition rules, but not by patent law.[46]

While the linkage of broadening patent claims with stiffling effects on the freedom to operate was already discussed in WIPO[47] as early as 1983, the CJEU explored the limitations of Artt. 4, 8, and 9[48] Dir. 98/44/EC[49] as late as 2010 with the *Monsanto* decision.[50] Until then, limitations evolved mainly as law on patentability requirements through the internal review procedures of the European Patent Office (EPO). These focused on patentability

43 European Commission (2016a), p. 197 commented on by Godt (2016b).

44 A presumption strengthened by the wording of Art. 8 Dir. 98/44/EC.

45 Art. 27 sec. 2 TRIPS says: "Members may exclude from patentability inventions [...] necessary to protect ordre public [...], provided that such exclusion is not made merely because the exploitation is prohibited by their law."

46 K.-J. Melullis, Zu Sinn und Notwendigkeit der Versagung von Patenten aus ethischen Gründen, in: W. Büscher/W. Erdmann/A. Fuchs/V. Jänich/M. Loschelder/M.-R. McGuire (eds), Rechtsdurchsetzung: Rechtsverwirklichung durch materielles Recht und Verfahrensrecht (FS Ahrens), Köln: C. Heymanns, 2016, 287–404.

47 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, supra n. 17), at p. 44.

48 Complementing "contained" by "and performs its function".

49 Which became only incompletely transferred to the EPC regime, Godt 2007, pp. 112–114, pp. 619 et seq (on function limitation). On the complex relationship between the EU and the EPO system after the transposition of the EC Biotech Dir. 98/44/EC into the EPC system in 1999, see I. Schneider, Das Europäische Patentsystem, Campus: Frankfurt/M, 2010, p. 394.

50 Especially in the area of plant breeding and production, for various restrictions to the "freedom to operate" in modern plant breeding see Parisi (2013, supra n. 4).

exclusions,[51] relied on a narrow interpretation of those,[52] and allowed a broad patent-claims language.[53] Legislative safeguards in the Directive, like compulsory licenses, turned out to be too strict to be operable.[54] Against this backdrop, it did not come as surprise that the CJEU used *Monsanto* to clarify the limitations to the patent's scope which the Directive sought to implement. The spirit of the decision is to safeguard the freedom to operate. The Court identified the disclosed function as the central *raison d'être* of the Biotech Directive and interpreted Art. 8 and 9 Biotech Directive in this light. It ruled that *meal* from genetically modified soy does not infringe the patented Bt resistance since it does not fulfill the claimed modified EPSPS[55] 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.[56] As far as the decision was read as abolition, it met with strong opposition from the professional community.[57] Yet, the lively

51 E.g. "plant varieties" in Art. 53 b EPC, G 1/98, EPO Enlarged Board of Appeal (EPO-EBA), 20.12.1999, Off.J. EPA 2000, 545 – *Novartis.*

52 Applied, e.g., in EPO-EBA G1/08 (*Tomatoes I*) and G2/07 (*Broccoli I*), 9.12.2010 (OJ EPO 2012, 130). Even more articulated in G2/13 (*Broccoli II*) and G2/12 (*Tomatoes II*), both 25.3.2015 (OJ EPO 2016, 17); for a critical discussion see F. Dolder, Die Anwendung von Patentansprüchen nach dem *whole content approach*, Mitteilungen der deutschen Patentanwälte, 2017, 1–15.

53 Parisi (2013, supra n. 4) p. 130, p. 134.

54 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 favor, see: Allred 2017; also Melullis, in: G. Benkard (2015) § 2a, para. 9.

55 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.

56 V. Overwalle, The CJEU Monsanto Soybean Decision and Patent Scope: As Clear as Mud, IIC, 2001, 1–3; M. Lamping, Monsanto Case Note – Purpose-Bound Patent Protection for Genes, European Journal of Risk Regulation, 2010, 445–450.

57 Adding to the persistent resistance to judicial patent oversight on the part of the CJEU, see C. Godt, Überforderung des EuGHs im Recht des Geistigen Eigentums? Autonome Unionsrechtsauslegung versus immaterialgüterrechtsimmanente Prinzipien", in: A. Metzger (ed.), Methodenfragen des Patentrechts, Tübingen: Mohr Siebeck, 111–135. 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".

initial debate quickly died away when the meaning of the justices' words become more and more unclear in the course of the unfolding discussion.

The *Monsanto* discussion provides the juridical background for discussing the challenges of a *de facto* reversal of evidence to competition as an institution deemed to secure the freedom to operate. The *de facto* reversal confronts competitors with the constant threat of being dragged into a lawsuit. Already the potential costs of producing evidence stifle creative strategies to compete. Thus, a *de facto* reversal impairs the forces of competition in a similar way as an extension of protection beyond the patent claims, the issue of the CJEU's *Monsanto* ruling. Neither do Art. 8 and 9 Biotech Directive stipulate the principle of absolute product protection, nor do they provide for an assumption of infringement based on the presentation of material. If we allowed *de facto* the basic rules of evidence to be reversed, we would fall behind the compromise of the Biotech Directive and back onto the old property paradigm which the Biotech Directive curtailed. The institution of competition is there to protect the freedom to operate, as a prerequisite for economic growth. As both, an economic and societal legal order, competition is essential to liberal societies. A *de facto* reversal of evidence would impair competition as an essential institutional guarantee.

III. Fundamental Freedoms under European Union's law

The freedom to operate is constitutionally guaranteed as part of the professional fundamental freedoms, both under EU law (Artt. 5 and 6 ECHR, Artt. 6 and 47 CharterHR, Art. 28 and Art. 56 TFEU) and the national constitutions. From the perspective of EU law, civil procedure and competition law are *lex specialis* to these general constitutional guarantees. These liberties, today, do not recede to property protection under e.g. Art. 17 EU Charter on Human Rights. In today's constitutional reading, liberties and rights together constitute the legal framework of free market economies.

Especially in intellectual property law, property does not simply take priority over other freedoms. Intellectual property is functionally embedded to enhance growth. In this broader picture, intellectual property is justified under its performance condition, and therefore no stronger than other professional freedoms. It differs from property in land or movables in three important aspects which require a constitutional confinement. First, IP rights have to get along without physical control (possession). There-

fore, extent and limits of control have to be defined by the law. Second, the scope of the IP-right is determined by the property holder him-/herself (through the piece of work, through the claims formulated by the applicant). Since an IP-right is not "bound" a priori, the proprietor's discretion reaches "as far as" the law allows. Therefore, legal scrutiny is required. Third, the scope of the IP-right is wider. While physical property protection is focused on injunction and restitution of the single item, the patent claim is geared towards control of the production chain. Central limits are the elapse of time and exhaustion. Yet, the immaterial nature of the IP-right allows for a contractual control way beyond singular items. By its very nature, the power assigned to IP property collides with the freedoms to operate of others. Therefore, the legal delineation of the various freedoms is key.

The freedom to operate is at risk where the threat of a lawsuit is not contained by the duty of the claimant to substantiate the facts of the infringing action. Strategic market behavior is invited, favoring economic potent players over less potent players. A bossy strategy can severely restrict the liberty to operate. A reversal of the risks of a law suit endangers the rule of law installed to protect civil liberties. Procedural law sensitively enshrines the equilibrium of both parties in order to protect their freedoms. It is therefore an eminent task of the state to secure the basic principles of procedural rules for the sake of the protection of fundamental freedoms. A *de facto* shift of process burdens would therefore violate constitutionally guaranteed fundamental freedoms.

C. Conclusion

As far as genome editing patents result into a reversal of proof in infringement procedures with the encapsulated risk of a procedural decision based on "burden of proof" for lack of evidence to the detriment of the defendant based on indistinguishable material, the patent claim is untenable. In such situations, the enforcement of pbp and product claims violates the principles of civil procedure, competition law, and Fundamental freedoms under EU law and the constitutions of the member states.

In this case, a central reasoning of Hanns Ullrich with regard to competition law, can be transposed to civil procedure and fundamental freedoms. He insisted for years that it is the preeminent task of patent law itself to limit the scope of patents for the sake of novel innovations. Competition law

cannot make up for failures of patent law:[58] it comes too late, and investigates only singular cases. The misuse standard, both under national law and Art. 102 TFEU, is too far up to properly regulate markets.[59] As much as competition law provides a framework in which patent holders have to operate, the same holds true for civil procedure and fundamental freedoms. It is up to patent law to respect these limits.

Three conclusions result from the preceding analysis.

First, the current practice in patent infringement procedures has to adapt to the standard principles of civil procedure: It is up to the claimant to substantiate the facts of the claim violation. Where the submission of the patent claim and of infringing material is countered by the defendant by presenting naturally occurring material, it is again up to the claimant to produce evidence for the violation of the patent by the defendant. In these cases, the burden of proof reverts back to the claimant. No further substantiation is required by the defendant at this moment.

Second, resulting difficulties to produce evidence might *de facto* result in product claims to be curtailed to process claims. This consequence is justified for the reasons as analyzed. In addition, this consequence is backed up by the consideration that the scope of the principle of product protection is not part of the core of property protection. This extension of protection

58 H. Ullrich, Intellectual Property, Access to Information, and Antitrust: Harmony, Disharmony, and International Harmonization, in: R. Dreyfuss/D.I. Zimmerman/H. First (eds), Expanding Boundaries of Intellectual Property, Oxford: OUP, 2001, 365–402; equally: C. Wolf, Vertikale Kontrolle durch Immaterialgüterrechte, Nomos, Baden-Baden, 2009, p. 263: „Die genaue Justierung der vertikalen Kontrolle kann nicht nur schutzrechtsextern durch Kartellrecht erfolgen".

59 A. Léonard, 'Abuse of Rights' in French and Belgian Patent Law – A Case Law Analysis, 7 JIPITEC 2016, 30; Ullrich, Strategic patenting by pharmaceutical industry – towards a concept of abusive practices of protection, in: Drexl J, Lee N (eds), Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective, Cheltenham, UK/ Northampton, MA: Elgar, 2013, 241–272.

for chemical and biotechnological inventions was installed by judge made law.[60] Where these extensions violate superior principles, it is again for the judges to re-curtail the extensions.

Third, for the sake of the individual patent applicant and the credibility of the patent system as a whole, it is up to the European Patent Office and the Council of the European Patent Convention to clarify the constitutional reading of genome editing patent claims. The European Patent Office should avoid to grant product and pbp claims which foreseeably extend to indistinguishable material. As often in the multi-level patent system,[61] we face the problem that the constitutional reading cannot be adjudicated by a superior, authoritative court decision for all 38 EPO states, plus 4 validation and 2 extension states. Since violation procedures are a matter of contracting states, the problem will pop up in national courts or (for the participating states) inside the future Unitary Patent Court (unless the UPC project will be cancelled). Therefore, it is ultimately up to the Administrative Council of the European Patent Convention to clarify the constitutional reading of genome editing patent claims and amend the EPC Guidelines.

60 The principle of absolute protect protection is one of five principles which form the intellectual backbone of chemical and biotechnological patents. They emerged as follows: (1) derived product protection of process claims was accepted by the Supreme Court of the German Empire (Reichsgericht) of 14.3.1888 – *Methylenblau*; for more detail R. Uhrich, Die Geschichte des Stoffschutzverbots im deutschen Patentrecht, in: M. Otto/D. Kippel (eds), Geschichte des deutschen Patentrechts, Tübingen: Mohr Siebeck, 2015, p. 174 et seq.; (2) Recognition of the "surprising effect" in order to constitute inventive step and novelty, became common practice of the German Patent Office since 1934; see H. Schippel, Zur Patentierung landwirtschaftlicher Kulturverfahren, GRUR Ausl. 1958, p. 336 (fn. 21), (3) pbp-claims got acknowledged in Germany since 1971, BGHZ 57, 1 – *Trioxan*, confirmed by BGH, GRUR 1993, 651 – *Tetraploid Chamomile;* (4) the isolation theorem was installed by two decisions of the German Supreme Court: BGH of 28.7.1977, *GRUR* 1978, 238 – Naturstoffe; BGH of 14.3.1972, BGHZ 58, 280 = *GRUR* 1972, 541 – Imidazoline. (5) Absolute product protection got recognized by the Federal Patent Court (BPatG) on 28.7.1977, *GRUR* 1978, 238 – *Antanamid* (discussed by Godt 2018a [supra fn. 11] and 2018b [supra fn. 56], and Schneider 2010 [supra n. 48]), p. 225.

61 I. Schneider (2010, supra n. 48).

New Genetic Engineering in Public Discourse: Requirements and Perspectives

*Beate Jessel**

The rapid developments in the field of biotechnology present new challenges and require a broad scientific and social discourse on the conditions of their application. The European Court of Justice has ruled in 2018 on organisms obtained by directed mutagenesis. But genome editing encompasses much more, extending from single point mutations to gene drives. Their application holds opportunities and risks that need to be balanced fairly in a social debate. The objective of our conference has been to establish and strengthen a scientific dialogue to share different viewpoints and opinions on this topic.

The Federal Agency for Nature Conservation (BfN) belongs to the German competent authorities responsible for the experimental release and placing on the market of genetically modified organisms (GMOs) and products derived from GMOs. As such the BfN contributes to the assessment of GMO applications and to a national position that is passed on to the European Food Safety Authority (EFSA). In its assessment BfN focusses on effects of GMOs on the environment and on biodiversity and monitoring of such effects.

In order to further improve the methodology and concepts of risk assessment and monitoring, BfN funds departmental research and closely collaborates with other authorities, research institutes and universities. BfN provides scientific advice on all matters of biosafety and related legal issues to the German Ministry for the Environment and Nuclear Safety (BMU).

* The author is the President of the German Federal Agency for Nature Conservation.

Tade Matthias Spranger (Ed.)

Genome Editing under Gene Technology Law: Legal Aspects and Latest Developments

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Introduction

Gene technology law is recognised as one of those legal fields in which legal, ethical, economic, political and social concerns are particularly closely intertwined. It is not only for this reason that the debate on green gene technology, which has been conducted with a certain intensity for decades, has left its mark on various actors. A side effect of this is the formation of 'camps', which all too often tend towards clear 'black-and-white thinking'. European genetic engineering law, which essentially consists of Directive 2001/18/EC (for releases and placement on the market) and Directive 2009/41/EC (for work in closed systems), is, depending on the country of storage, either regarded as a functioning control regime for a potentially risky technology or, conversely, as a partly unjustified vote of no confidence regarding the established technical processes.

Against this background, it is not surprising that the CRISPR/Cas method, which was published by a working group led by Emmanuelle Charpentier and Jennifer Doudna in 2012 and declared as a breakthrough by the Science Journal in 2015, was regarded not only as a scientific milestone, but also as a legal policy milestone. Although the Zinc Finger Nucleas Technology (ZFN), the Oligonucleotide Directed Mutagenesis (ODM), and the Transcription Activator-Like Effector Nucleases (TALENs) were already known as other methods of genome editing, the CRISPR/Cas method opened up the prospect of a technology that could find widespread adoption in practice. The simplicity of the method and the breadth of possible applications in both plant and human environments go a long way to explaining enthusiastic response from the scientific community.

Various circles of experts decided unusually quickly on the line of argument that so-called 'New Techniques' for genome editing, almost without exception, do not fall within the scope of European gene technology law. What is remarkable about this process is not only the pace with which this was accepted, but above all the fact that legal expertise was almost completely missing in the relevant committees. This was a big surprise to those who are familiar with the high degree of complexity of European gene technology law. One should have expected that expert committees discussing the (non-) applicability of highly complex laws should, at least, have gained an overview of the multi-faceted legal issues. Finally, it also seems unusual that the

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