

Intellectual Property and European Fundamental Rights

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1. Introduction

This chapter analyses the relationship between intellectual property rights (IPRs) and rights guaranteed by the EU Charter of Fundamental Rights ('the Charter' or EUCFR). The European Court of Justice (CJEU, formerly ECJ) has recently begun to refer to the Charter in IP cases.¹ Whereas the relationship between IP and human rights in general features prominently at the international level, the ECJ had referred only vaguely to 'the balance of IP and fundamental rights' in the few prior cases (the best known one is *Promusicae*²). This chapter focuses on potential changes which might be triggered by the Charter. It is interested in whether the Charter can be instrumental in framing a democratic and deliberative debate on modern European IP conflicts which arise from the societal transformation towards information societies embedded in global markets, similar to the debate prompted by fundamental freedoms in the more traditional areas of both public³ and private⁴ law. The discourse is especially timely with regard to the (non-Union) European patent approved by the European Parliament on 11 December 2012 (projected validity 2014).⁵ For contextual reasons, the article will first map the actual debate on 'constitutionalizing IP' in Europe and identify its structural differences compared to the 'constitutionalization' discourses in other areas of law discussed in this volume (section 2). It will then differentiate the debate on IP and universal human rights in the international fora from the European debate on IP and fundamental rights, and identify what the former debate can contribute to the latter (section 3). The core of the

¹ Case C-70/10, *Scarlet Extended v SABAM*, judgment 24 November 2011, not yet published; Case C-360/10, *SABAM v Netlog*, judgment of 16 February 2012, not yet published.

² Case C-275/06, *Promusicae* [2008] ECR I-271; see also Raue, 'Die Verdrängung deutscher durch europäische Grundrechte im gewerblichen Rechtsschutz und Urheberrecht', 61 *Gewerblicher Rechtsschutz und Urheberrecht-Internationaler Teil (GRURInt)* (2012) 402.

³ The leading case for a fully fledged weighing decision between a fundamental freedom and a constitutional right by the ECJ is Case C-112/00, *Schmidberger* [2003] ECR I-5659.

⁴ For an in-depth analysis of the effects of fundamental freedoms on private law, see G. Brüggemeier, A. Colombi Ciacchi, and G. Comandé (eds), *Fundamental Freedoms and Private Law in the European Union* (2010).

⁵ 'Parliament approves EU unitary patent rules', Press Release, 11 December 2012, available at <<http://www.europarl.europa.eu/news/en/pressroom/content/20121210IPR04506/html/Parliament-approves-EU-unitary-patent-rules>>. Invalidation procedures have been filed by Spain and Italy (C-274/11 and C-295/11) and are pending (opinion by AG Bot submitted on 11 December 2011, see ECJ press release 163/12), for an in-depth analysis see H. Ullrich, 'Select from the System: The European Patent with Unitary Effect' (2012), Max Planck Institute for Intellectual Property and Competition Law Research Paper 12-11, available at <<http://www.ip.mpg.de/files/pdf2/SSRN12-11.pdf>>.

chapter is a discussion of seven factual IP controversies in the light of the potential influence of the Charter rights (section 4).⁶ The final section draws conclusions about the Charter's influence on property rights and private law as a whole (section 5).

2. Constitutionalization of IP

A. Diverging Concepts

Constitutionalization has become a buzzword,⁷ particularly so in contemporary reflections on how to contain the constant flow of newly emerging intellectual property rights and their expanding scope. The debate revolves around legal means of a discursive civilization of conflicts which are in need of articulation and balance. However, underlying concepts differ profoundly. Three broad directions can be distinguished. One holds public institutions accountable,⁸ and reconceptualizes IP rights as 'duty bearing privileges'⁹ in the sense of duties vis-à-vis the public.¹⁰ The second group acknowledges 'opposing rights' as limitations to the IP holders.¹¹ Some of them focus on individual rights, of which the balance is to be secured by parliaments and courts.¹² A third concept refers to a constitutionalization of social orders which re-bind IP rights to the conditions of their emergence. Depending on the conceptual foundations of the author, these

⁶ Compared to the prior 'common traditions of the member states', as the European Court of Justice has put it until now, and neglecting the differences as to how member states have guaranteed the protection of human rights values (in the constitution, as in France and Germany (the latter with a special constitutional court), by direct reference to the European Convention on Human Rights as in the Netherlands, or by reference to universal, non-statutory principles as in England). For more details, see A. Colombi Ciacchi in this volume.

⁷ See, e.g. the term 'constitutionalization' in the context of international law, contributions to C. Joerges and E.-U. Petersmann (eds), *Multilevel Trade Governance and Social Regulation* (2006); C. Joerges, G. I.-J. Sand, and G. Teubner (eds), *Transnational Governance and Constitutionalism* (2004).

⁸ Conceiving them as the central institutions of legitimacy: I. Schneider, *Das europäische Patentsystem* (2010), at 661.

⁹ P. Drahos, *A Philosophy of Intellectual Property* (1996).

¹⁰ Bromley, 'Property Rights: Locke, Kant, Peirce and the Logic of Volitional Pragmatism', in: H. M. Jacobs (ed), *Private Property in the 21st Century: The Future of an American Ideal* (2004) 19, refers to the necessary discourse in public fora (referring to Habermas and Rorty) as 'volitional pragmatism'; C. Godt, *Eigentum an Information* (2007), at 560 as 'Inhaltsbestimmung'.

¹¹ J. Kersten, *Das Klonen von Menschen: Eine verfassungs-, europä-, und völkerrechtliche Kritik* (2004); Geiger, "Constitutionalising" Intellectual Property Law?, *IIC—International Review of Intellectual Property and Competition Law* (2006) 371; Godt, *supra* note 10; L. R. Helfer, 'Towards a Human Rights Framework for Intellectual Property', Vanderbilt University Law School Public Law and Legal Theory, Working Paper No. 06-03 (2007); A. Peukert, *Güterzuordnung als Rechtsprinzip* (2008); Hilty, 'The Role of Patent Quality in Europe', in J. Drexel et al. (eds), *Technology and Competition/Technologie et concurrence—Contributions in Honour of Mélanges en l'honneur de Hanns Ullrich* (2009) 91; Hilty, 'Herausforderung Durchsetzung—Kontrapunkte', in R. M. Hilty, T. Jaeger, and V. Kitz (eds), *Geistiges Eigentum: Herausforderung und Durchsetzung* (2008) V.

¹² Wielsch, 'Differenzierungen des Eigentums. Zur Entwicklung eines rechtlichen Grundbegriffs', in S. Keller and S. Wiprächtiger (eds), *Recht zwischen Dogmatik und Theorie: Marc Amstutz zum 50. Geburtstag* (2012) 329, at 341, argues that a balancing of IP and individual fundamental rights would have 'a better chance of acceptance'. That means that he would not accept collective or diffuse rights (as described by R de Camargo Mancuso, *Interesses difusos: Conceito e legitimação para agir* (1991)) or second generation human rights.

conditions are either rooted in the *volonté* of the individual¹³ or in the functional preconditions of competition.¹⁴

Whereas the first two groups would acknowledge human rights as 'self-standing restrictions', the third group would, as a matter of rule and exception, only accept legislative restrictions. Prime examples of a human rights induced statutory patent exception are, e.g., the exclusion of Article 52(4) European Patent Convention (EPC) (surgery or therapy and diagnostic methods), and the so-called 'Bolar exemption'¹⁵ allowing clinical tests and trials on patented medicaments. All three groups have in common the idea that a property right is sensibly to be restricted. However, they differ about the reasons why they acknowledge property restrictions, and therefore the outcomes of interpretation differ greatly. Yet, their approach in general has not remained unopposed. A strong opponent is Riesenhuber. He argued that, for example, Geiger's approach would violate the principle of private autonomy.¹⁶ Third party rights could not, as a matter of principle, have a self-standing effect on property rights; conflicts are to be decided by parliaments only. These arguments are largely in line with those arguments raised against the horizontal effect of fundamental rights in other areas of civil law. The arguments sound rightfully democratic on the surface. However, they do not take account of modern parliamentary reality, and do not endorse modern deliberate theory. Godt's approach was opposed by Krasser, in the 6th edition of his central textbook on patent law.¹⁷ He argues that Godt underestimates the value of the initial invention, and that the proposed model is too formal. The critique of the first argument goes straight to the point. The concept intends to provide a framework which rationally curtails IP rights, however without underevaluating the pioneer's invention, but it re-establishes the right balance in the light of the expansion of protection.

Following from these conceptual frictions, two discourses struggle for the 'right' balance between IP and other rights in dogmatic terms: the first revolves around the question of whether legislative restrictions to IP are 'exceptions' and therefore have to be interpreted narrowly, or if they protect the subjective rights of others, and therefore demand a broad interpretation.¹⁸ The second discussion concerns the 'contracting away' of regulatory restrictions protecting freedoms (private copies, examination privilege, etc.).¹⁹ The classical approach is to distinguish rules which protect 'subjective rights'

¹³ The conceptual ground is the rejection of the romantic author ideal which would justify restrictions to the right. However, he 'saves' the right to decide of the individual rightholder by 'opt-out rules'. Wielsch, *supra* note 12, at 349.

¹⁴ Ullrich, review of Schneider, *supra* note 8, 61 *GRURInt* (2012) 485.

¹⁵ E.g. Art. 10(6) Directive 2001/83/EC (revision 2009), OJ 2009 L 168/33, on the Community Code relating to medicinal products for human use.

¹⁶ Riesenhuber, 'Technische Schutzmaßnahmen und "Zugangsrechte"', in S. Leible, A. Ohly, and H. Zech (eds), *Wissen-Märkte-Geistiges Eigentum* (2008) 141.

¹⁷ R. Krasser, *Patentrecht* (6th ed.; 2009), at 36.

¹⁸ Taking the example of 'exceptions' in Directive 2009/24/EC, OJ 2009 L 11/16, arguing for a restrictive interpretation: T. Dreier, '§ 69a, para. 1', in T. Dreier and G. Schulze, *Urheberrechtsgesetz, Urheberrechtswahrnehmungsgesetz, Kunsturhebergesetz—Kommentar* (3rd ed.; 2008); for a broad interpretation: Hoeren, 'Der Erschöpfungsgrundsatz bei Software—Körperliche Übertragung und Folgeprobleme', 112 *Gewerblicher Rechtsschutz und Urheberrecht (GRUR)* (2010) 665.

¹⁹ A much debated issue; see only L. Guibault, *Copyright Limitations and Contracts: An Analysis of Contractual Overridability of Limitations on Copyright* (2002); R. M. Hilty, *Lizenzvertragsrecht: Systematisierung und Typisierung aus schutz- und schuldrechtlicher Sicht* (2002); Metzger, 'Vertragliche Ausgestaltung von geistigen Schutzrechten—Erscheinungsformen und Vertragskontrolle nach deutschem und europäischem Recht', in Hilty, Jaeger, and Kitz (eds), *supra* note 11, 85, esp. at 92 et seq.; M. Stieper, *Rechtfertigung, Rechtsnatur und Disponibilität der Schranken des Urheberrechts* (2009); Zech, 'Vertragliche Dispositionen über Schranken des geistigen Eigentums', in S. Leible, A. Ohly, and H. Zech (eds), *Wissen-Märkte-Geistiges*

from 'statutory limits'. Restrictions to 'subjective rights' are submitted to the parties' disposition,²⁰ whereas 'statutory limitations' are conceived of as general 'boundaries' to IP granted (only) in the public interest (which are beyond private disposition). However, the underlying distinction is still contested.²¹

B. ECJ Jurisprudence

The European Court of Justice has actively shaped the content of IP rights since the 1970s. In the first two cases, *Deutsche Grammophon* of 1971 (for copyrights) and *Centrafarm* of 1974²² (for patents), the Court established the European exhaustion principle. It advanced the common market principle to become a central element of the first sale doctrine, which inherently limits IP rights. Even though IP rights exist territorially in member states, the common market effect prevails so that exhaustion ('first marketing rule') occurs for the whole common European market with the first placing in one of the member states. As a consequence, these rulings allow 'parallel trade' throughout the Community. Whereas their momentum is the common market rationale, the economic core is the protection of the competitors' freedom in secondary markets.

The ECJ moved towards an open balancing approach with its *Magill* judgment in 1995.²³ The 'duty to license' reversed of the former subordination doctrine of IP law and competition law, and paved the way towards a European debate about 'legitimate access to IP'. In subsequent cases, the EU and the national courts have further fine-tuned the requirements of the so-called 'competition law's compulsory license'.²⁴

The Court followed this path towards a nuanced and balanced approach to IP adjudication in its trademark cases. It drew, for instance, a sensible line between freeriding (imitating like the *Adidas* case, using two instead of three stripes on sneakers²⁵), and using the trademark as information (car bodyshops²⁶)—thus delimiting professional freedoms.

Eigentum (2008) 187; J. Gräbig, *Abdingbarkeit und vertragliche Beschränkungen urheberrechtlicher Schranken* (2011).

²⁰ Riesenhuber, *supra* note 16; Zech, *supra* note 19, at 191. For a material interpretation of statutory limitation (limiting private autonomy): Geiger, 'Interessenausgleich im Urheberrecht', 53 *GRURInt* (2004) 815, at 818.

²¹ See, e.g. even the structural differences between those who submit boundaries to private disposition, on the one hand, like Riesenhuber, *supra* note 16, explicitly at 143 with further references, also at 151; on the other hand, Zech, *supra* note 19, at 192; and Metzger, *supra* note 19, at 100 (for a case-by-case analysis interpreting and weighting according to the rule's purpose).

²² Case 15/74, *Centrafarm BV and Adriaan De Peijper v Sterling Drug Inc* [1974] ECR 1147.

²³ Case 241/91 P and Case 242/91 P, *Magill TV Guide* [1995] ECR I-74; the case has triggered hundreds of academic articles, see only Ullrich, 'Intellectual Property, Access to Information, and Antitrust', in R. Dreyfuss, D. L. Zimmerman, and H. First (eds), *Expanding the Boundaries of Intellectual Property* (2001) 365; Drexl, 'The Relationship between the Legal Exclusivity and Economic Market Power: Links and Limits', in I. Govaere and H. Ullrich (eds), *Intellectual Property, Market Power and the Public Interest* (2008) 13.

²⁴ Compare e.g. Case 468/06 through 478/06, *Sot. Lélou kai Sia EE et al. v GlaxoSmithKline Farmakeftikon Proionton* [2008] ECR I-7139 (introducing a requirement of 'normal scope of order'), German Federal Supreme Court (BGH), judgment of 6 May 2009, *Orange Book Standard* (printed in *International Review of Intellectual Property and Competition Law (IIC)* (2010) 369), introducing the requirements of an acceptable offer and a deposit, commented on by Ullrich, 'Patents and Standards—A Comment on the German Federal Supreme Court Decision Orange Book Standard', *IIC* (2010) 337, and the Dutch decision Rechtbank 's-Gravenhage, 17 maart 2010, HA ZA 08-2522 en HA ZA 08-2524, *Koninklijke Philips Electronics N.V. tegen SK Kassetten GmbH & Co. KG*, paras 6.19-6.25, which, as a matter of principle, rejects the possibility of a duty to licence.

²⁵ Case 425/98, *Marca Mode v Adidas* [2000] ECR I-4861.

²⁶ Case 63/97, *BMW v Deenik* [1999] ECR I-905.

This argumentation is very similar to that of the German Constitutional Court in the earlier famous *Benetton* cases, in which the Court limited the IP holder's right to injunction where NGOs used trademarks in order to raise public awareness of specific production problems, and acknowledged the right of expression as a counter-right.²⁷

In copyright, many cases touch on constitutional values. A famous national example is the *Germania 3* decision by the German Constitutional Court in 2000.²⁸ It introduced the right to a long citation by a broad interpretation of then section 51(2) of the German Copyright Act, based on Article 5(3) of the German Basic Law.²⁹ The European Court of Justice, in its *Promusicae* ruling in 2008,³⁰ referred to 'the fundamental rights' between which a fair balance has to be struck, and thereby strengthened the constitutional procedural safeguards of users and providers against copyright owners.

However, the Court does not always have recourse to a balancing argument, for various reasons. One reason is judicial self-restraint in Article 230 TFEU procedures. In its ruling on the legality of Biotech Directive 98/44/EC with regard to human dignity,³¹ it seems that the Court was cautious not to substitute the balance struck by the legislative EU institutions by its own one. In other cases, recourse to a constitutional reasoning does not seem necessary since concurring rights can be protected by a strict interpretation of the limits to intellectual property, like in the *Cefetra* case.³² In this case, the ECJ interpreted the Biotech Directive with regard to imports of genetically modified maize to Europe. It argued that once a patent protected product is transformed (here, by the grinding of germinating seeds into flour), the technical teaching cannot be infringed anymore.

In the recent case *UsedSoft v Oracle*,³³ the court missed the chance to refer directly to the Charter when interpreting anew the exhaustion principle with regard to the marketing of 'used' computer software (Article 4 Directive 2009/24). However, it should be noted that Advocate General Yves Bot once more rejected the simplistic argument of property as a rule and limitations as exceptions which are to be interpreted narrowly.³⁴ On the same footing, and in contrast to earlier decisions, the Enlarged Board of the European Patent Agency has become more cautious with regard to the interpretation of rules and exceptions. In the case G1/04, *Diagnostic methods*,³⁵ it rejected the 'narrow interpretation of exception' as of principle and turned to a case-by-case interpretation 'by purpose'.

The balancing approach to IP adjudication in Europe is likely to increase once either a Unitary European Patent³⁶ is introduced, a joint patent court is established which will

²⁷ Geiger, *supra* note 11 (referring to decisions BvG 1762/95 of 12 December 2000, and BvG 426/02 of 11 March 2003).

²⁸ BVerfG, decision of 29 June 2000, *Zeitschrift für Urheber- und Medienrecht* (2000) 867 (Art. 5(3) German Basic Law corresponds to Art. 13 EUCFR: artistic freedom).

²⁹ Dreier, Commentary to Art. 51, para. 22, in: T. Dreier and G. Schulze (eds), *Urheberrechtsgesetz* (3rd ed.; 2008).

³⁰ Case C-275/06, *Promusicae* [2008] ECR I-271, Rec. 68.

³¹ Case C-377/98, *Kingdom of the Netherlands v European Parliament and the Council of the European Union* [2001] ECR I-7079.

³² Case 428/08, *Cefetra* [2010] ECR I-6765.

³³ Case C-128/11, *UsedSoft v Oracle*, judgment of 3 July 2012, not yet published.

³⁴ Opinion of 24 April 2012 in Case C-128/11.

³⁵ G 01/07, Enlarged Board of Appeal of EPO of 15 February 2010, Treatment by surgery—*Mediphysics*, OJ EPO 3/2011, 134, at 169.

³⁶ *Supra* note 5; earlier coined as 'enhanced cooperation', Press Release of the European Commission of 13 April 2011 (IP/11/470)—based on earlier decisions by the European Parliament, 15 February 2011; and the Council of 10 March 2011.

(also) execute jurisdiction about EPC patents,³⁷ or the European Patent Agency bows to the pressure to refer open questions with regard to adopted EU law to the ECJ.³⁸

C. IP and Other Private Law Areas Compared

When comparing this debate on ‘fundamental rights and IP’ with the debate in other areas of private law like contract or labour law, two fundamental differences become evident: (1) In contrast to the founding principles of private law, private autonomy and contractual freedom, IP is in essence regulatory.³⁹ The right only comes into existence when regulatory requirements are met (either automatically, like copyrights, or by state act, like patents and trademarks). Inversely, regulatory limits to IP protect concurring rights. Therefore, the constitutionalization discourse in IP does not aspire to replace existing regulation (like in labour law⁴⁰), but to improve them. (2) The more important difference follows from the utilitarian justification of IP rights. The detrimental effects of exclusionary rights (high prices, and the slowdown of knowledge diffusion) are justified by the public good of progress with regard to wealth, health, and food supply—to the detriment of expeditious knowledge diffusion via competition. Therefore, IP rights serve other human rights. Exceptions and limitations are conceptualized as catering to these goals. Thus, from the perspective of western theory, human rights are drivers of IP, not opposed to them. The balance between public policies, in theory, is struck by the given statutory patentability/copyright requirements, and respectively any written exceptions, and limitations to the scope (e.g. public libraries as exceptions to copyright). It is for this reason that traditional jurisprudence demanded priority of IP law over competition. This claim for priority is in line with the twentieth century development to guarantee IP as (or like) a human right—a concept which Article 17(2) EUCFR took on—although ‘not inviolable and absolute’.⁴¹ Prior to this, countries limited protection to constitutional or utilitarian limits (constitutional limits: Article 14 Basic Law of Germany; utilitarian limits: e.g. Article 5 XXIX Brazilian Constitution, Article I(8) US Constitution). As utilitarian rights they were neither all-encompassing, nor did they assign unlimited discretion of the IP holder.

The absorbance of conflicts by the proposition that IP ultimately serves the public interest rendered intellectual property for long immune against a broad constitutional

³⁷ As is widely known, due to the intergovernmental character of the European Patent Organization (not being a Community agency), EPC patents are not directly submitted to the control of the European court system. However, this situation may soon change if either a European Union’s Patent or a European Patent Review System (‘Unified European Patent Court’) is installed (incorporating those shortcomings which the European Court of Justice has identified in its opinion 1/09 of 8 March 2011, [2011] ECR I-1137); for the historic background on the judicial review discussion see H. Ullrich, ‘Die Entwicklung eines Systems des Gewerblichen Rechtsschutzes in der Europäischen Union: Die Rolle des Gerichtshofs’ (2010), Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series, No. 10-11 (reprinted in P. Behrens, T. Eger, and H.-B. Schäfer, *Ökonomische Analyse des Europarechts* (2012) 147); more recently, with a focus on the history of the unified European patent: Ullrich, ‘Harmonizing Patent Law: The Untameable Union Patent’, in M.-C. Janssens and G. Van Overwalle (eds), *Harmonisation of European IP Law: From European Rules to Belgian Law and Practice* (2012) 243.

³⁸ As rightfully argued by Tillmann, ‘Das Europäische Patentgericht nach dem Gutachten 1/09 des EuGH’, 60 *GRURInt* (2011) 499.

³⁹ Godt, *supra* note 10, at 554 ff.; Grosheide, ‘Introduction’, in F. W. Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010) 21.

⁴⁰ As discussed by Collins in this volume.

⁴¹ Case 360/19, *Scarlet Extended*, *supra* note 1, Rec. 41.

reflection as one of balancing conflicts in industrialized countries for a long time. More so, it makes reflection about conflicts in the area of intellectual property most ambitious: do IP and human rights 'collide' or do they coexist and further each other?⁴²

3. Universal Human Rights versus EU Fundamental Rights

Before concentrating on the European Charter, the difference between the international debate on human rights and IP, which attracted much more publicity, and the European debate on conflicting rights and IP has to be clarified.

Greater affluence and efficient social security systems in the post-WWII era concealed conflicts between IP rights and interests in affordable quality medicines and available food. The 'IP and human rights' debate was perceived as a conflict between industrialized and developing countries which was carried out in international organizations. The debates of the 1970s in WIPO and UNCTAD framed technology transfer as a 'duty' of industrial countries vis-à-vis developing countries, and 'compulsory licensing' as a sovereign right of developing countries.⁴³ The debates around farmers' rights in the International Union for the Protection of New Varieties of Plants (UPOV) revolved around 'rights'—coining the interest of farmers in their access to seeds as a 'right' in contrast to what Western plant breeder's laws conceived as only a farmer's privilege. The two UN Covenants, the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the Covenant on Civil and Political Rights (ICCPR), both of which adopted in 1966 and entered into force in 1976, mark high points in this discussion. They introduced 'second generation' rights like the right to health and the right to food. Both exerted, however, only a limited influence.⁴⁴

The debate on 'IP and human rights' gained momentum with the AIDS debate at the turn of the millennium.⁴⁵ The debate was coined as an issue of 'access to essential medicine', thus reconfiguring the quest for availability of life-saving medicaments from a public good into an individual right.⁴⁶ The debate brought to light that the IP mechanism builds on effective market forces, and that the system will not deliver the projected results where markets fail. At that time, the problem of market failures in the pharmaceutical industry had already entered the public mind due to the debate regarding undersupply of 'orphan drugs' (drugs for diseases which affect a comparatively small number of patients resulting in a lack of research and products). The AIDS debacle added the insight that even where products exist, supply is not guaranteed when manufacturers only supply at world market prices which African patients cannot afford. Eventually the debate about 'IP and public health' led to a revision of the TRIPS Agreement (the amendment to add Article 31bis as agreed in 2005 is still submitted to

⁴² Van Overwalle, 'Human Right Limitations in Patent Law', in Grosheide, *supra* note 35, 236.

⁴³ P.-T. Stoll, *Technologietransfer. Internationalisierungs- und Nationalisierungstendenzen. Die Gestaltung zwischenstaatlicher Wirtschaftsbeziehungen, privater Verfügungsrechte und Transaktionen durch die Vereinten Nationen, die UNCTAD, die WIPO und die Uruguay-Runde des GATT* (1994).

⁴⁴ P. Rott, *Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen* (2002), at 92–98; U. Fastenrath, 'Die Verantwortlichkeiten transnationaler Unternehmen und anderer Wirtschaftsunternehmen im Hinblick auf Menschenrechte', in S. von Schorlemer, 'Die Verantwortlichkeiten transnationaler Unternehmen und anderer Wirtschaftsunternehmen im Hinblick auf die Menschenrechte', in Sabine von Schorlemer (ed), *'Wir, die Völker (...)'—Strukturwandel in der Weltorganisation* (2006) 69.

⁴⁵ Reichman, 'Lessons to be Learnt in Europe from the International Discourse about Patents and Public Health', in C. Godt (ed), *Differential Pricing* (2010) 133.

⁴⁶ Godt, *supra* note 10, at 445.

signature, however⁴⁷). Other rights, which were formerly voiced as collective interests, followed suit and became articulated as individual rights like the ‘right to food’, farmers’ rights, the right to a healthy environment, and the right to development.⁴⁸

There are important differences between the international human rights debate and the European debate on European fundamental rights. The most important one is that universal human rights are binding on states as principles, but are not directly judicializable. Their primary function is to influence governmental policies, and frame a political controversy.⁴⁹ It is only recent that human rights as binding obligations on transnational corporations have become judicialized in court proceedings.⁵⁰ Severe violations of universal rights committed in countries with weak legal institutions are, under certain conditions, actionable (usually in their home countries).⁵¹ In contrast, the central idea of European fundamental rights is that they are directly applicable, and arm citizens with defensive rights against their state. While scholars advocated for years a broadening of individual rights towards interests which have a collective nature,⁵² the Charter finally complemented classical individual rights with collective interests. Whereas the traditional set enjoys direct applicability against actions of the EU and member states in so far as they execute EU law,⁵³ modern collective rights like the right of access to preventive health care and medical treatment (Article 35 EUCFR), the integration principle of environmental policies (Article 37, second half of the sentence, corresponding to Article 11 TFEU), and the goal of a high level of environmental quality and consumer protection (Article 37, first half of the sentence, corresponding to Article 191 TFEU; Article 38, corresponding to Article 169 TFEU) are acknowledged as legal positions resulting from the solidarity of the Community (Title IV), but are not directly enforceable and actionable by individuals. However, in conjunction with enacted secondary law, the Charter rights acquire a higher legal quality.⁵⁴ Beyond the classical catalogue of fundamental rights, e.g. the right to life (Article 2 EUCFR), the Charter acknowledges five constitutional novelties which might have an impact on IP related disputes

⁴⁷ On 30 November 2011, the WTO extended the deadline for acceptance of the TRIPS amendment for the third time until 31 December 2013 (WT/L/829 of 5 December 2011).

⁴⁸ A parallel development is the formal acknowledgement of group rights as the autonomy right of indigenous people in international law (Art. 8j CBD, UNESCO Convention of 2005, WIPO-IGC Draft of 2005); for an overview see Wendland, ‘It’s a Small World (After All)’—Some Reflections on Intellectual Property and Traditional Cultural Expressions’, in C. B. Graber and M. Burri-Nenova (eds), *Intellectual Property and Traditional Expressions in a Digital Environment* (2008) 150.

⁴⁹ For a concise introduction to the political science ‘frame analysis’: Schneider, *supra* note 8, at 75–102.

⁵⁰ Most prominently acknowledged by the US Alien Tort Claims Act. See M. Koebele, *Corporate Responsibility under the Alien Tort Statute* (2009); for cases filed and documented, see the webpage of the European Center for Constitutional and Human Rights (ECCHR): <http://www.ecchr.de/index.php/wirtschaft_und_menschenrechte.html>.

⁵¹ A. Fischer-Lescano and K. Möller, *Der Kampf um soziale globale Rechte* (2012), at 54 ff.; A. Gatto, *Multinational Enterprises and Human Rights: Obligations under EU and International Law* (2011) (reviewed by Topal, ‘Holding your Own to Account: EU Policy Concerning its MNEs Abroad’, 5 *European Journal of Legal Studies* (2012) 201).

⁵² Micklitz, ‘Consumer Rights’, in A. Cassese, A. Clapham, and J. H. H. Weiler (eds), *Human Rights and the European Community: The Substantive Law* (1991) 53; For the ‘right to information’ as a citizen’s right, Reich, ‘Verbraucherpolitik und Verbraucherschutz im Vertrag von Amsterdam’ *Verbraucher und Recht (VuR)* (1999) 1, at 6.

⁵³ J. Kokott and C. Sobotta, *The Charter of Fundamental Rights of the European Union after Lisbon*, EUI Working Papers, AEL 2010/6, at 6, stating that it thus complements the European national constitutions; M. Daus, *The Protection of Fundamental Rights in the Legal Order of the European Union* (2010), at 156.

⁵⁴ For consumer rights already Micklitz, *supra* note 52.

in Europe: the rights of the individual in the biomedical setting (Article 3 EUCFR), individual rights in the information society (Article 11 EUCFR), access to public health (Article 35 EUCFR), access to public services (Article 36 EUCFR), and consumer protection (Article 38 EUCFR). All are geared towards securing the individual's autonomy against modern technological challenges and market changes.

Another central difference is the current limited scope of the European Charter since it is confined to the execution of intellectual property by EU authorities, and to the execution of EU laws by member states. The only Community rights are trademarks issued by the OHIM agency in Alicante,⁵⁵ and plant variety protection issued by the agency in Angers.⁵⁶ Although the introduction of a European patent with unitary effect is imminent (*supra* note 5), it remains to be seen to which extent the European Court of Justice claims jurisdiction over it. However, the Charter will apply to patents and copyrights as far as harmonized by European law (without question for nationally issued patents with regard to the Biotech Directive 98/44/EC⁵⁷ and for copyrights, e.g. with regard to the Info-Soc Directive 2001/29/EC⁵⁸). However, the Charter will not be applicable to the actions of the European Patent Office *as such* since it is a non-EU organization based on the (non-EU) European Patent Convention.

In sum, taking all distinctions into consideration, what can Europe learn from the international debate on IP and human rights? The analysis has clarified that the old status of IP as a human rights enhancing institution per se cannot be sustained. The ambitious international debate on IP and human rights rests on a conception which puts all the rights involved on the same level, and, in particular, denies the precedence of property over other human rights.

4. The European Charter on Fundamental Rights and IP

Structurally, the Charter may influence the legal discourse in three different ways. First, the CJEU may refer to the Charter instead of making reference to the shared constitutional traditions of member states as it did before when interpreting secondary EU law. The recent ruling on provider responsibility is an example and will be described as a first case study (A.1). Secondly, a truly new layer of arguments might be created by the newly established rights, both as individual rights which create (new) directly effective rights against the state (and business partners) (Article 3(2) and Article 42 EUCFR), and as rights which secure due participation (such as Article 35 EUCFR). Four concrete IP cases to which these new rights are relevant will be analysed as to how far the Charter might change the discourse (B.1–4). Thirdly, the Charter might also influence the discourse with regard to rights which are not explicitly stipulated, like the right to decent food, and the right to cultural autonomy. These interests might either be part of other broader fundamental rights, or are stipulated by post-Charter human rights conventions. Since these rights have prompted highly politicized discussions in the EPO and WIPO, and directly affect European patents, a brief evaluation will hypothesize how the European Union might accommodate these universal values in terms of the Charter (C.6–7).

⁵⁵ Office for Harmonization in the Internal Market (OHIM), originally Council Regulation (EC) 40/94 of 20 December 1993; newly published as Council Regulation (EC) 207/2009 of 26 February 2009, OJ 2009 L 78/1.

⁵⁶ Council Regulation (EC) 2100/94, OJ 1994 L 227/1, of 27 July 1994 on Community plant variety rights.

⁵⁷ OJ 1998 L 213/13.

⁵⁸ OJ 2001 L 167/10.

A. Balancing Approach to Secondary EU Law

1. Articles 7, 8, 11, and 16 EUCFR and Enforcement Measures against Providers

Adapting the language (not the grounds) of the opinion of AG Villalón,⁵⁹ the CJEU in its recent decisions *Scarlet Extended* and *Netlog* refers to the necessary trilateral balance which national agencies and courts have to secure between the property right of the copyright holder (Article 17(2) EUCFR), the providers' freedom to operate business (Article 16 EUCFR), data protection (Article 8 EUCFR), and the freedom to receive and impart users' information (Article 11 EUCFR),⁶⁰ when they enforce rights regulated by EU secondary law. The Court vaguely states that the filter measures in question violate five copyright and data protection directives which have to be 'read together and construed in the light of the requirements stemming from the protection of the applicable fundamental rights'. The lack of precision employed by the Court with regard to the violated terms of the directives might stem from the fact that the Advocate General essentially based his argument on the rationale that the national laws on which the filter measures are based are too restrictive and intriguing on the rights secured by the Charter that these measures can be based on general, national civil procedure enforcement rules (Article 52 EUCFR). The legal bases have to precisely direct the content and limits of the enforcement measure in this context. Therefore, the Advocate General considered the national measures void. The Court did not pick up this precise argument. However, it adapted the 'balance rhetoric'.

This new 'balance rhetoric' clearly denotes a turn in ECJ jurisdiction which started in 2008 with the *Promuscaes* judgment. *Scarlet Extended* and *Netlog* gave the ECJ the opportunity to refer directly to a set of Charter rights to be acknowledged on the same level as property, not only as exception or limitation following the legal technique of the directives. Instead, the rights of individual property owners and the rights of numerous users are placed on the same footing.

B. Newly Introduced Charter Rights

1. Articles 1 and 2 EUCFR and Embryonic Stem Cells

Articles 1 and 2 EUCFR might exert an influence on the European debate about human embryonic stem cells (HESC). This has become framed as a conflict between the rights of the patent holder and researchers vis-à-vis the rights of an unborn child (human dignity and the right to life). The CJEU decided the case on referral of the German Federal Supreme Court on 18 October 2011,⁶¹ essentially following Advocate General Bot who had delivered his opinion on 10 March 2011. The decision focuses on an interpretation

⁵⁹ Being the AG in both cases: Case 70/10, *Scarlet Extended*, AG Villalón of 14 April 2011; Case 360/10, *Netlog*, AG Villalón of 7 July 2012.

⁶⁰ Case 70/10, *Scarlet Extended*, judgment of 24 November 2011, not yet published; Case 360/10, judgment of 16 February 2012, not yet published.

⁶¹ Case 34/10, *Brüstle v Greenpeace* [2011] ECR I-821, Opinion of AG Bot submitted 10 March 2011. Comments differ greatly. On the one hand applauding: Schneider, 'Das EuGH-Urteil "Brüstle versus Greenpeace" (Rs. Case 34/10): Bedeutung und Implikationen für Europa', 3 *Zeitschrift für geistiges Eigentum/Intellectual Property Journal* (2011) 475; on the other rejecting: Taupitz, 'Menschenwürde von Embryonen—europäisch-patentrechtlich betrachtet', 114 *GRUR* (2012) 1; Plomer, 'After Brüstle: EU Accession to the ECHR and the Future of European Patent Law', 2 *Queen Mary Journal of IP* (2012) 110. For an earlier, prior to the ECJ judgment, supporting the plaintiffs position: Straus, 'Zur Patentierung humaner embryonaler Stammzellen in Europa. Verwendet die Stammzellenforschung menschliche Embryonen für industrielle oder kommerzielle Zwecke?', 59 *GRURInt* (2010) 911.

of Article 6(2)(c) of the Biotech Directive 98/44/EC, which excludes patents for 'uses of human embryos for industrial or commercial purposes'. The court confirmed that the application for a patent signals the transition from research to 'commercial use'.⁶² Thus, the Court rebutted the claimants' two propositions, that academic patents emerge in an upstream environment and are therefore not 'commercial', and that research regulations and patent regulations must be based on equivalent rationales. In contrast, the ECJ's argument inversely focuses on the human embryo, which cannot be less protected in a research than in a commercial setting. This is not necessarily an argument which stems from the Directive's text (which focuses on 'commercial use' mirroring the non-commercialization principle for humans and body parts). The gravity centre is the Advocate General's value decision in favour of the embryo and the implicit recognition of the German definition of life as beginning with the merging of germ cells,⁶³ and its unconditional protection thereafter (in contrast to other European states like the United Kingdom, which equally acknowledges 'life' from cell fusion on,⁶⁴ but provides unconditional legal protection only from the blastocyte stage on, and allows experimentation on the embryo up to 14 days⁶⁵).

Would the decision have been different had the Court taken reference to the Charter?⁶⁶ Most probably the difference would have been minor, especially since even UK patent agencies did not grant patents on embryonic stem cells.⁶⁷ However, it seems wise for the Court not to make too emphatic an ethical point of when human life starts (compared to the commercialization issue once the human being exists) since member states differ with regard to the definition and regulations of the beginning of human life.⁶⁸

2. Article 3(2) EUCFR and Diagnostics

An interesting intellectual test case for a debate on IP and fundamental rights, if recourse to the Charter were possible, would be the famous *Myriad* case.⁶⁹ This is internationally conceived as a 'paradigmatic case'.⁷⁰ It is about a diagnostic test kit which identifies

⁶² Concurring with Enlarged Board of the EPO in its opinion on G2/06, para. 25.

⁶³ § 8(1) German Embryo Protection Act of 1990.

⁶⁴ Art. 1(2)(b) UK Human Fertilisation and Embryology Act 2008 reads: 'references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo'.

⁶⁵ Art. 4(3)(b) UK Human Fertilisation and Embryology Act 1990 as amended in the HFE (Research Purposes) Regulations of January 2001, and 2008.

⁶⁶ For a discussion on the differences should the case be brought to the ECHR: Plomer, *supra* note 61. Her arguments follow the plaintiffs' and Straus' argument that a unitary balance reasoning with regard to the human rights conflict underlying the research on HESC has to be undertaken for each legal subsystem (patent law, criminal law, research regulation). This assumption is neither shared by the AG and the Court, nor by the author.

⁶⁷ Spranger, 'Aspekte des britischen, amerikanischen, kanadischen und australischen Rechts', in J. Straus, P. Ganea, and Y.-C. Shin (eds), *Patentschutz und Stammzellforschung: Internationale und rechtsvergleichende Aspekte* (2009) 97, at 99.

⁶⁸ The differences are roughly aligned with the accession states of the Oviedo Convention on Human Rights and Biomedicine of 1997. Its Art. 18(2) prohibits the 'the creation of human embryos for research purposes'. This is one of the reasons why many EU member states (including Germany) did not sign it. Art. 21 endorses the non-commercialization principle.

⁶⁹ For a concise summary, see Godt, *supra* note 10, at 197; for a detailed analysis of the US controversy see Minsson, 'Standing on Shaky Ground: USP patent-eligibility of Isolated DNA and Genetic Diagnostics in the Wake of *AMP v USPTO*', 1 *Queen Mary Journal of IP* (2011) 334 and 2 *Queen Mary Journal of IP* (2012) 136.

⁷⁰ Resta, 'The Case Against the Privatization of Knowledge: Some Thoughts on the *Myriad* Genetics Controversy', in R. Bin, S. Lorenzon, and N. Luicchi (eds), *Biotech Innovation and Fundamental Rights* (2011) 11, at 11; Godt, *supra* note 10, at 196 et seq.

specific types of altered gene sequences which indicate a statistical predetermination for breast cancer. Many patents relate to two gene sequences called 'BRCA1' and 'BRCA2'. Patent enforcement on behalf of the owner has inhibited public hospitals from developing their own test kits, which experts believe to be of better quality. Blood probes had to be sent in to the Myriad headquarters in Salt Lake City, Utah, for the price of US\$2,400 to 3,500 per test. In Europe, several patents have been revoked and narrowed down after public opposition procedures against the patent.⁷¹ In the United States, District Judge Sweet Stone revoked 7 out of 16 patents on grounds of a 'matter-of-nature-doctrine' on 29 March 2010. This was reversed by the US Court of Appeals for the Federal Circuit (CAFC) on 29 July 2011. The CAFC decision met with opposition on all sides. The applicants, the American Civil Liberties Union (ACLU), filed a petition for certiorari with the US Supreme Court on 6 December 2011. Academics criticized the CAFC decision as both inconsistent with the rationale of the *numerus clausus*, and politicized.⁷² Few welcomed it for its clarifications.⁷³ On remand by the Supreme Court, the CAFC upheld its preliminary decision on 16 August 2012 in a 2:1 decision.⁷⁴

The debates in the United States and in Europe were fueled by constitutional arguments. Since the European opposition was primarily instigated by public hospitals, the argument in public discourses rested very much on access to health care, i.e. reasonably priced and of a good (superior) quality. In the US, the proceedings were opened on behalf of some of the main professional organizations representing 15,000 geneticists, oncologists, and molecular biologists, various physicians, university researchers, and patients, joined by a long list of *amicus curiae* briefs, with the support of the American Civil Liberties Association. Therefore, arguments were based on the right to health, to scientific research, and on access to information relating to one's genetic make-up.⁷⁵ As many authors have pointed out, the *Myriad* case has been a test case on how the public discourse on constitutional rights gets transformed into a more narrow epistemic IP discourse revolving around patentability requirements which is nurtured by internal systems' need of coherence and unity.⁷⁶ In both cases, the procedures were not pursued in the first place as constitutional reviews. In Europe, an opposition was filed in the internal (quasi-administrative) EPC patent revision procedure open to anybody ('*actio popularis*'). In the US, a court procedure was initiated—whereas standing for plaintiffs remained a disputed issue.

Considering that these procedures have taken place 'inside' the system, i.e. in procedures which legitimately discriminate against constitutional arguments,⁷⁷ it is worthwhile to reconsider the case under the double assumption of an existing constitutional review board (for example the as yet non-existent, in the near future non-European, but

⁷¹ Resta, *supra* note 70, at 24; Murray and Van Zimmeren, 'Dynamic Patent Governance in Europe and the United States: The Myriad Example', 19 *Cardozo Journal of International and Comparative Law* (2011) 287, at 322.

⁷² Resta, 'La privatizzazione della conoscenza e la promessa dei beni comuni: riflessioni sul caso "Myriad Genetics"', *Rivista Critica del Diritto Privato* (2011) 251.

⁷³ Minsson and Nilsson, *supra* note 69.

⁷⁴ Available at <<http://www.ip-watch.org/weblog/wp-content/uploads/2012/08/Myriad-Decision-16-Aug-2012.pdf>>. The court ruled that isolated DNA molecules were patent eligible as were method claims to screening potential cancer therapeutics via changes in cell growth rates of transformed cells. It ruled, however, that method claims which compare or analyse two gene sequences are not patent eligible.

⁷⁵ Resta, *supra* note 70, at 25.

⁷⁶ Resta, *supra* note 70, at 35; Murray and Van Zimmeren, *supra* note 71, at 323; Van Overwalle, *supra* note 42, at 237.

⁷⁷ For this argument Van Overwalle, *supra* note 42.

potentially in the long run European Patent Court⁷⁸) and the European Charter Rights. Three Charter rights could be applied.

The first of these is Article 35 EUCFR as a solidarity right to health which encompasses two guarantees. The right enshrined in the first sentence grants an individual 'right of access to preventive health care'.⁷⁹ The second, enshrined in the second sentence, states that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'. The word 'preventive' is understood as a right to the prevention of health deterioration, not a right to preventive diagnosis. Under this definition, hindrances to access to pharmaceuticals are covered by the provision. Cases fall under its scope in which unaffordable prices or non-marketing (refused marketing) affect the right to preventive health. The second sentence refers to the notion that clinical tests in public hospitals are of a better quality. This sentence endorses the implementation principle—well established for environmental policies in Article 11 TFEU. In its nature, it does not guarantee individual rights but is (only) meant to be a guiding principle in policy making.⁸⁰ It has meaning for policymakers and courts alike: it is the role of policy makers to act on emerging problems which can prompt 'inside' or 'outside the system' responses. Two options 'inside' the IP system are (*de lege lata*) the handing out of compulsory licenses,⁸¹ and (*de lege ferenda*) expanding access rights to public hospitals.⁸² An 'outside' option could be, parallel to public procurement of medicines by social securities, the acquisition of wholesale licences for publicly funded hospitals, either by the Health Ministry or by Public Social Securities.⁸³ Courts reacted to the integration principle for environmental politics in doctrinal concepts. In 2001,⁸⁴ the Court considered environmental policies not (only) as a justification reason (secondary reason submitted to the so called 'Gebhard test' on proportionality⁸⁵), but as a reason limiting the protection of the fundamental freedom on the first level.

Secondly, Article 8(2), second sentence, of the Charter can be invoked. It guarantees the individual's right of access to data which has been collected concerning him or her, and the right to have it rectified. In the *Myriad* case, women could not verify the test results with an independent laboratory due to Myriad's aggressive patent policy. Therefore, patients were impeded to 'access... information relating to one's genetic make up'.

Thirdly, Article 13 EUCFR is affected. This secures respect for academic freedom. In the *Myriad* case, university centres and research laboratories encountered problems due to Myriad's policy. In some cases, they were confronted with direct injunctions. In these cases, the rationale put forward by the German Supreme Court and the German Constitutional

⁷⁸ *Supra* note 3.

⁷⁹ 'Ein echtes Grundrecht' ('a true fundamental right'), H.D. Jarass, *Charta der Grundrechte der EU* (2010), at Art. 25(2), as a right to a benefit in form of participation; however compare for a more restrictive interpretation H. M. Sagemester, *Die Grundsatznormen in der Europäischen Grundrechtecharta* (2010), at 376.

⁸⁰ Jarass, *supra* note 79, para. 3, and functions as a competence rule.

⁸¹ Although the justifying ground would need more sophistication under Western national patent laws.

⁸² Van Overwalle, 'Turning Patent Swords into Shares', 330 *Science* (2010) 1630.

⁸³ Applying Dan Burks' idea of 'governmental buy back' as additional options beyond property and liability rules, following up on Calabresi and Melamed, 'Property Rules, Liability Rules and Inalienability: One View from the Cathedral', 85 *Harvard Law Review* (1972) 1089, presented on 18 May 2012 in Hamburg (Bucerius Law School Conference: The Access Challenge).

⁸⁴ Case 379/98, *PreussenElektra* [2001] ECR I-2099.

⁸⁵ Case C-55/94, *Gebhard* [1995] ECR I-4165.

Court in clinical trials since 1995⁸⁶ informs the constitutional interpretation of patent law. The courts extended the narrow experimental use exception of patent law (here section 11(2) German Patent Act) towards experiments which are directly geared towards the generation of new scientific findings. The courts draw the line at illegitimate patent use (i.e. a property violation) where experiments have no direct link to the technical teaching, or where experiments are undertaken on a non-legitimate large scale, or misused as actual exploitation, or conducted with the intention of interfering with the inventor's distribution. However, this extension of the research exception does not, at least not on paper, exempt 'public clinics'—a proposal sensitively suggested by Geertrui Van Overwalle.⁸⁷ If we transpose this rationale to the *Myriad* case, the extended exception would still have exempted many activities in public research hospitals from the patent's scope.

More complicated in constitutional terms are constellations in which scientific experiments which concern either the protected genes or the diagnostic method are not undertaken. Cases have been reported in which scientists were dissuaded from pursuing their research.⁸⁸ These cases are not judiciable. However, these consequences give colour to the public debate on what 'the research commons' should look like, which rationales and norms should apply, and the generation of which results should be fostered.

All in all, reference to the Charter will certainly transform the discussion on exclusionary effects of patented diagnostics by providing structure to arguments which limit intellectual property on constitutional grounds.

3. Article 3(2) EUCFR and Tissue Banks

Another near-future test case for the delineation of intellectual property and constitutional rights might be the depositing of human tissues and blood samples. The existing European directives⁸⁹ focus on quality control and traceability between donor and recipient. However, the question of whether the donating individual has the power to veto the filing of patents based on his or her material, or to object to commercial research or specific directions of research, is still open. Up to now, public discussions have mainly revolved around issues of consent (written forms, possibility, and consequences of withdrawal) and data protection. With regard to commercialization, the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) of 1997 has revealed more differences among European states than common ground.⁹⁰ It stipulated a strong individual information right (Article 10⁹¹) and a strong non-commercialization principle (Article 21⁹²); its additional Protocol on Biomedical Research laid down a

⁸⁶ BGH, judgment of 11 July 1995, BGHZ 130, 259—*Klinische Versuche I*; confirmed by BGH, judgment of 17 April 1997, BGHZ 135, 217—*Klinische Versuche II*, and by non-acceptance of a constitutional complaint: Federal Constitutional Court, 10 May 2000—1 BvR 1864/95, *GRUR* (2001) 43.

⁸⁷ Van Overwalle, *supra* note 82, at 1631.

⁸⁸ Resta, *supra* note 70, at 30.

⁸⁹ Three directives: the Framework Directive 2004/23/EC, OJ 2004 L 102/48 of 31 March 2004 is complemented by two technical directives: Directives 2006/17/EC, OJ 2006 L 38/40 and 2006/86/EC, OJ 2006 L 294/32.

⁹⁰ Of the 27 EU member states, the Eastern member states ratified during their accession period, while Austria, Belgium, Germany, the UK, and Ireland never even signed. France only ratified in December 2011. Italy and Poland signed early, but never ratified (see <<http://www.coe.int>>).

⁹¹ Oviedo Convention, Art. 10(1): 'Everyone has the right to respect for private life in relation to information about his or her health; (2) Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.' Text available at <<http://www.coe.int>>.

⁹² Oviedo Convention, Art. 21: 'The human body and its parts shall not, as such, give rise to financial gain.'

respective broad consent requirement (Article 14⁹³). Those countries which did not sign or ratify the convention feared its potential stifling effect on research and development. This overall policy consideration is mirrored by the delimitation of fundamental rights. The research project 'Boundaries of Information Property' conducted under the lead of the author under the umbrella of the Common Core of European Private Law (CCEPL) revealed that e.g. in Germany the right of an individual does not encompass the right to determine the direction of future research undertaken with his or her biological material (e.g. the exclusion of commercial purposes). This proposition is perceived as an (illegitimate) restriction of the researchers' freedom. In Italy, in contrast, the culturally embedded conviction prevails that the right to direct future research with one's body material is part of the individual's personality rights,⁹⁴ as stipulated under Article 90 of the Italian Data Protection Code (d.lgs. 196/2003) in conjunction with Article 5 of the d.l. 1-1-2006, n.3,⁹⁵ and interpreted with reference to the Oviedo Convention.⁹⁶

However, it seems that values have shifted. Ten years ago, the patient's right to have a say in future research (to exclude specific fields of research, to exclude commercial research, filing patents on his or her DNA, to claim royalties and financial compensation) was rebutted primarily by referring to the non-commercialization principle,⁹⁷ and only secondly by reference to the personality principle,⁹⁸ and to freedom of research. These claims were conceived as not being covered by the right to personality. Over the years, this argumentation has been reversed and redirected.⁹⁹ An early sign was the German Supreme Court (*Bundesgerichtshof*, BGH) decision in 1993 about a damages claim for infertility due to destroyed sperms. In this decision the Court acknowledges

⁹³ Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Art. 14(1): 'No research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, *specific* and documented consent of the person. Such consent may be freely withdrawn by the person at any phase of the research.' (Emphasis added.)

⁹⁴ Resta, 'Contratto e persona', in E. Roppo (ed), *Trattato del contratto*, vol. VI (2006) 37; Galloux, 'L'utilisation des matériels biologiques humains: vers un droit de destination?', *Recueil Dalloz* (1999) (Chronique) 15; who both refer to the annulment procedure of Italy against the European Biotech Directive (Case C-377/98, [2001] ECR I-7079, application dismissed).

⁹⁵ Resta, 'O acesso ao material biológico humano com fins de pesquisa e de aproveitamento industrial: questões relativas ao consentimento e à responsabilidade na perspectiva do direito comparado', in: J. Martins Costa and L. L. Möller (eds), *Bioética e Responsabilidade* (2009) 145; Germinario, 'L'attuazione della Direttiva n. 98/44/CE in materia di protezione giuridica delle invenzioni biotecnologiche', *Il Diritto Industriale* (2006) 319.

⁹⁶ Italy ratified, but not all decrees provided by the law have been adopted which has raised questions with regard to the binding effect of the Convention, see Resta, case 7 of the Italian Country Report (2009), fn. 41 (on file with the author, and to be published in the BIP project volume under CCEPL-series with Cambridge University Press).

⁹⁷ Godt, *supra* note 10, at 650 et seq. The German Ethics Council in 2004 suggested a generalized prior informed consent (encompassing all research purposes), favoured the exclusion of individual financial claims for benefit sharing in favour of the creation of a fund (Nationaler Ethikrat (ed), Chairman S. Simitis, *Biobanken für die Forschung: Stellungnahme* (2004), at 89); for a critique of this 'blanket consent' see Schneider, "This Is Not a National Biobank . . ."—The Politics of Local Biobanks in Germany', in A. Peterson and H. Gottweis (eds), *Biobanks: Governance in a Comparative Perspective* (2008) 88, at 96.

⁹⁸ The distinction between person and property underlies all case reasonings from the California Supreme Court decision in its famous *Moore Case* in 1990 (which originally prompted the modern debate about commercialization and the human body, Ca. Supreme Ct. [1990] 51 Cal.3d 120) to the English Appeals Court *Yearworth* decision of 4 February 2009, [2009] EWCA Civ 37. The facts of the latter are very similar to the German BGH sperm case of 1993, BGHZ 124, 52:

⁹⁹ C. Halász, *Das Recht auf bio-materielle Selbstbestimmung: Grenzen und Möglichkeiten der Weiterverwendung von Körpersubstanzen* (2004).

that personality and property rights can overlap once material is separated from the body.¹⁰⁰ This flexibility with regard to the old-style dichotomy between body and data seems also to be reflected by the German Ethics Council recommendation of 2010 which now acknowledges the power of the individual to direct the use of body material and data, and recommends that the right to purpose-bound donations should be respected.¹⁰¹ The old concept of prior informed consent which has evolved in the area of medical interventions to the human body has been fine-tuned by purpose limitations developed in data protection for information-bearing human body tissues.

The Charter might contribute a refined constitutional language to this debate. Article 3(2)(a) EUCFR strengthens the right of the individual in the field of medicine and biology in that free and informed consent has to be respected (according to the procedures laid down by law). The interpretation of what the consent covers is influenced by Article 3(2)(c) EUCFR which prohibits the 'making of the human body and its parts as such a source of financial gains'. I argue that Article 3 EUCFR includes the individual's defensive right against commercialization. Since Article 3 EUCFR does not actually concretize what the non-commercialization principle encompasses, it is to be interpreted in that it gives the individual the right to concretization. This right is not limited to the disposition of either commercial or non-commercial research (including the right to oppose the patenting of parts of one's genomic information, be those universal or individual). Article 8 EUCFR adopts the basic principle of specific purpose limitation in data processing. This principle has been adapted in the biobank debate. Applying this principle to genomic material means that the individual may legitimately limit the use of his or her material and data to specific purposes. If the researcher is not interested in such use-restricted material, he or she is free not to include such data in the study (Article 13 EUCFR).

This interpretation is in line with the conceptualization of Giorgio Resta who observes an emerging bipolar regime: intangible aspects of identity are increasingly protected against commercialization through property rules, whereas the corporal elements are protected through liability rules.¹⁰²

Will the Charter add substance to the debate? The unitary reference will certainly highlight the fundamental cultural differences between member states. The issue will most likely not pop up in the patent arena, but is likely to do so in the research arena. In multicentre studies which collect information in as harmonious a manner as possible in order to compare data as well as possible, these significant differences with regard to the prior informed consent sheet, and its consequences for the necessary non-inclusion of patients and volunteers, will certainly raise pressure to introduce a uniform standard form, especially when the study is financed under EU funding schemes. Article 3(2) EUCFR will certainly be an important point of reference which will underline the autonomy of the individual as the subject of biomedical research.

4. *Article 35 EUCFR and Compulsory Licensing?*

Does Article 35 EUCFR provide a patient with the right to claim a compulsory licence for third parties or to a compulsory licence which is limited to importation? It seems that

¹⁰⁰ BGHZ 124, 52.

¹⁰¹ Deutscher Ethikrat, *Human Biobanks for Research—Opinion*, download: <http://www.ethikrat.org/files/der_opinion_human-biobanks.pdf>.

¹⁰² Resta, 'The New Frontiers of Personality Rights and the Problem of Commodification: European and Comparative Perspectives', 26 *Tulane European & Civilian Law Forum* (2011) 33, at 54.

this question has not yet been widely discussed; no precedents are known; an in-depth analysis of academic literature of those countries which have acknowledged an individual's right to public health would be most valuable.¹⁰³ Under the *previsio* that access to medicaments is covered by the solidarity right under Article 35 EUCFR, the question arises if the entitled individual can ask for an action which is directed against a third party (the patent holder) conveying a right to a fourth person (a potential manufacturer). The problematic is inverse to the renowned problem of third party opposition against licences to pollute in environmental law. A third party may only oppose an administrative advantage granted to the addressee under certain conditions (in Germany these are especially restricted in the sense that applied regulations aim at the protection of the third party). The same rules apply if a third party applies for an administrative measure which would grant him or her a privilege but would burden a third party. With regard to compulsory licences, the situation would be similar. A person would request an administrative action on behalf of an undertaking (which may or may not join the procedure) which burdens the respective patent holder.

From a procedural point of view, I propose to derive from the now-acknowledged patient's right that this right covers the right to due and proportionate access to lifesaving medicaments. Since the right is not absolute, but stems from solidarity, the claim is *ab initio* reduced to a reasoned decision based on solidarity, a principle limited by feasibility in practical terms and by available funds. However, I argue that the individual has a right to apply for a measure and is entitled to a reasoned decision.

C. Human Rights beyond the Charter

1. Food Security/Food Quality

The Charter does not pick up the 'right to food', following Article 25(1) Universal Declaration of Human Rights and Article 11(1) International Covenant on Economic, Social and Cultural Rights.¹⁰⁴ However, since one of the most hotly debated current issues in the European Patent Organization is related to food, the case should be revisited with regard to the European Charter.

It is well understood that Europe does not suffer from an undersupply of food, but from overproduction. However, with industrial agricultural production and food manufacture comes along a different style of food. Environmental problems due to fertilizers, monocultures, and deteriorated, undifferentiated field and landscape structures, in conjunction with food security issues due to chemical residues, unsatisfactory living conditions of animals, but also lack of taste, have prompted a discussion of food *quality* incorporating conditions of food production ('organic food' implying a different standard of fertilizers, and animal production). The debate has turned into a human rights debate with the aim that anyone should have the right to choose the kind of food he or she prefers (overhauling the debate about food security as a matter of governmental consumer protection under Article 38 EUCFR). The 'right to choose' proposition is captured by modern national constitutions under the right to individual autonomy

¹⁰³ But it goes beyond the scope of this chapter.

¹⁰⁴ Art. 25(1) UDHR (corresponds to Art. 11(1) International Covenant on Economic, Social and Cultural Rights): 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.'

(Article 6 EUCFR: ‘right to liberty and security of person’). The right to ‘security of person’ implies the right to be protected e.g. against hazardous residues in food (‘food security’). The right to liberty secures the right to free choice. No one can be directed to eat specific food. A reflection of this right in a market economy should also secure the precondition of free choice: the availability of different kinds of food with regard to qualities, origins, and sources. Thus, availability redirects the attention to economic structures in food production. In essence, there is a classical argument against monopolistic structures at stake which legal systems have entrusted to antitrust law. The tension between antitrust and IP law is legendary. An interesting aspect of the food quality discussion in IP law is that the ‘framing’ has been turned into constitutional terms.

As one legal institution among others, intellectual property rights for food (plants and animals: pork, beef, chicken) are acknowledged as an important incentive for food innovations. It is widely acknowledged that the ‘Green Revolution’ of the 1950s and 1960s which brought about a significant increase of yield per acre, was driven by strong plant breeders’ rights. But since plant hybrids can equally be protected under patents (EPO decision *Lubrizol*¹⁰⁵), and since genetic engineering (a term which does not necessarily imply genetic improvement) has become a common and patentable practice (the leading EPO decision is *Novartis*¹⁰⁶), protection policies have shifted to patents.

Due to Article 100 EPC, which allows for opposition by everyone (followed by an *actio popularis* type of procedure), patent related food disputes have become juridified (although not yet in terms of constitutional rights) in the forum of the European Patent Office.

The most current debate revolves around breeding techniques (‘molecular marker selection’, ‘smart breeding’). It does not involve genetically modified plants or animals, but (only) the bioengineering procedure used to select the breeding material—an effective breeding technology, and one which is compatible with the European consumer (with regard to consumers’ resistance against genetically modified food), but one which is still capital intensive. Prominent patent claims range from pigs¹⁰⁷ and cows¹⁰⁸ to broccoli¹⁰⁹ and tomatoes.¹¹⁰ Since the room to manoeuvre for traditional breeders (who are not entangled with the chemical industry) is shrinking, and there is an increased risk for farmers of becoming entangled in patent claims, breeders and farmers have joined forces with environmentalists and consumer alliances.

In a first decision on 9 December 2010, the Enlarged Board of Appeal (EBA) ruled on the patentability of the claims with regard to Rule 23b section 5 EPO Rules (Article 4(1)(b) Directive 98/44/EC), which excludes ‘essentially biological processes for the production of plants and animals’ (*Broccoli*). The EBA ruled that a process is still excluded if it contains

¹⁰⁵ T-320/87, decision of Technical Board of Appeal 3.3.2 of 10 November 1988, *Lubrizol*, OJ EPO 1990, 71.

¹⁰⁶ G-1/98, decision of the Enlarged Board of Appeals of 20 December 1999, *Novartis*, OJ EPO 2000, 111. The case revolved around the content of 6% oil in transgenic maize—claiming all maize plants with an oil content of 6%.

¹⁰⁷ WO 2009097403 (EP 1651777), filed in 2005 by Monsanto, sold 2007 to Newsham Choice Genetics, which renounced the patent on 31 March 2010, resulting in a withdrawal by the EPO on 20 April 2010.

¹⁰⁸ EP 1 330 552.

¹⁰⁹ European patent (EP 1069819), Case G-2/07, decision of the Enlarged Board of Appeals of 9 December 2010, OJ EPO 3/2012, 113.

¹¹⁰ European patent (EP 1211926), Case 1/08, decision of the Enlarged Board of Appeals of 9 December 2010, not published in the OJ but available inter alia at <http://www.ipeg.eu/wp-content/uploads/Plant-Breeding-Method_EPO_G1_08_en.pdf>.

as a further step or as part of any of the steps of crossing and selection a step of a technical nature. Only if 'a process contains within the steps of sexually crossing and selecting an additional step of technical nature, which step *by itself* introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing . . . , the process is not excluded'. Then, it would not be relevant whether a step of a technical nature is a new or known measure. In the aftermath of this decision, many method claims have been withdrawn or narrowed down; many are now formulated as product-by-process claims.

However, the most recent debate (*Tomato II*¹¹¹) tackles the question which has remained unanswered: does the scope of parallel product-by-process claims cover the products or only products which have been manufactured directly using that method? As with the first procedure, the second opposition (against the same patents on broccoli and tomatoes) was filed by competitors (Unilever and Syngenta), not NGOs. The technical question refers to the effect of exclusions (here, Article 53(b) EPC: process claims on 'essentially biological processes') on other claim types. In principle 'product-by-process' claims are hybrids between method and product claims. After years of expansion, the US-CAFC recently narrowed these claims down to the utility actually disclosed.¹¹² In Europe, product-by-process claims are conceived as original product claims,¹¹³ and therefore comprise, as far as they are formulated by 'comprising language',¹¹⁴ all products regardless of their immediate production method and regardless of the utility disclosed ('*absoluter Stoffschutz*'). At the heart of the new opposition procedure is the proposition that the patent exclusion of an 'essentially biological process' would be undermined if the scope of a product-by-process claim granted for the product described by that (unpatentable 'essentially biological') method, encompassed the end product.¹¹⁵ Whereas opponents claim that the exclusion would be undermined,¹¹⁶ patent holders claim a parallel to the Novartis reasoning of G-1/98 which referred to the exclusion of Article 53(b) EPC.¹¹⁷ The core of that latter decision was a narrow, patent-friendly reasoning in favour of patent eligibility as long as 'more than just one' plant breeding right is covered by the patent claim. Methods claims would be valueless since self-propagating material is, most of the time, not a direct product of the claimed process.

Would the Charter add quality to the debate once the judicial patent system were integrated in the European Court system? Despite the necessities of legal technicalities in

¹¹¹ T-1242/06; On 31 May 2012, the EPO Board of Appeal 3.3.04 filed an interlocutory decision and referred the case to the Grand Chamber, available at <<http://www.epo.org/law-practice/case-law-appeals/pdf/t061242ex2.pdf>>.

¹¹² Only recently clarified by the CAFC in *Abbott v Sandoz* on 18 May 2009. Fabry, 'Kein Stoffschutz ohne Verfahrensbenutzung? Zur jüngsten Standortbestimmung des Product-by-Process-Anspruchs in den USA', 58 *GRURInt* (2009) 803; Thor, 'Product-by-Process Ansprüche nach US-Recht', *Mitteilungen der Deutschen Patentanwälte* (2009) 317.

¹¹³ Leading case for product-by-process-claims on plants: BGH, *GRUR* (1993) 651—*Tetraploide Kamille*.

¹¹⁴ With the 'comprising language', the claim covers all products with the described traits (therefore: rationale of absolute protection), whereas with a 'consisting of language', the claim covers only direct products of the described method (therefore: rationale of process claims, Art. 64(2) EPC).

¹¹⁵ Walter, 'Rote Taube-Lila Kuh—Rechtliche Betrachtungen zu Patent- und Sortenschutz', in M. Stephan and K. Bette (eds), *Biodiversität, Geistiges Eigentum und Innovation* (2012) 99, at 105.

¹¹⁶ See, e.g. the arguments of Unilever in G-1/08 (*Tomatoes*); followed by the Court of The Hague in a decision on 31 January 2012 about the validity of radish sprouts in *Taste of Nature v Creso* (case 408315/KG ZA 11-1414).

¹¹⁷ O. Malek et al., 'Plant Patents and Endangered Species?—Surprising New Developments in the Tomato Case' (2012), available at: <<http://www.vossiusandpartner.com/pdf/Plant%20Patents%20An%20Endangered%20Species.pdf>> (also EPI Information 1/2012, 16–22).

the patent discourse, it is still to be expected that constitutional infusion may also change the epistemic discourse, for two reasons. First, in the early case of genetic engineering of plants, the decision was influenced by the (at that time still) European Community's principle of coexistence. While the principle demanded safety measures for agricultural field trials, in patent courts, the principle secured the patentability of genetically engineered plants as technical innovations. The mere technical patent reasoning might change at a moment in time when non-engineered food is non-available, and a causal link can be established to the economic pressures of the IP system. Second, a constitutional reflection about the technical issues might broaden the understanding of the effects of patent protection, which has become narrow due to the technical administration of the patent system by epistemic communities.¹¹⁸ A constitutional conflict perspective brings the colliding interests of farmers and consumers to the forefront, which could enlighten the interpretation of (non-)patentability requirements, and patent principles. This discourse is the more probable the more economic instruments are employed to achieve public policy goals, and heterogeneous actors with procedural rights understand the economic implications of the patent-competition interface on food quality, and frame their arguments as constitutional entitlements. A constitutional reflection about patent exclusions would bring to light the concurring interests protected by them, thus rendering relative the perceived restrictions of the property holder.

2. Cultural Autonomy

It would be too narrow to confine this chapter to rights guaranteed by the Charter and leave aside other human rights related to IP which fundamentally affect the European Union. Cultural autonomy rights of traditional communities, as guaranteed by several UN conventions,¹¹⁹ challenge the western notion of how to define public domain information which can be freely used in order to produce novel patentable information ('technical teachings'). These communities claim a right to 'their' medicinal and plant knowledge, their drawings, their music. The consequence is that 'their' information, though collective and disclosed, might not be considered as 'public domain'.¹²⁰ WIPO¹²¹ and the CBD discuss a veto right to commercialization (similar to the patent's right to veto patenting with one's body materials, *supra* B.4),¹²² and require a mandatory 'disclosure of origin'¹²³ in patent applications. It remains to be seen if a future revision of the EU Biotech Directive 98/44/EC will integrate such a cogent requirement—and react to these recent acknowledgments. Up to now, the respective disclosure has been facultative, and conceived as information relevant only to the novelty requirement (not as a safeguard to protect human rights). It should be evident that a transnational understanding of human rights demands respective safeguards (here, in patent law) which allow rightholders the tracking of used information. That recognition would be the

¹¹⁸ Schneider, *supra* note 8, at 188 et seq.

¹¹⁹ Wendland, *supra* note 48.

¹²⁰ C. B. Graber and M. Burri-Nenova (eds), *Intellectual Property and Cultural Expressions in a Digital Environment* (2008), esp. the conflicts of law approach of G. Teubner and A. Fischer-Lescano therein, 'Cannibalizing Epistemes: Will Modern Law Protect Traditional Cultural Expressions?' 17.

¹²¹ T. Kiene, *The Legal Protection of Traditional Knowledge in the Pharmaceutical Field* (2011).

¹²² Similar to the veto position (at least, a right to be asked) which 'provider countries' claim under the CBD, however, the ground for their claim is sovereignty, not a human right, and is therefore not to be discussed here (see Godt, *supra* note 10, at 264 et seq).

¹²³ Godt, *supra* note 10, at 334.

natural counterpiece to the assumption that human rights, as stipulated by the Charter, and primarily addressed to citizens of the Union, are acknowledged.

5. Conclusion: The Novel Public–Private Interface

The nature of IP disputes has evidently changed. Although the list of the chosen seven examples is not exhaustive, the given limited set of cases—together with the well-known cases not discussed here in depth, like the *Magill* judicature—provides evidence for several characteristic shifts in the IP conflict structure. The growing economic value of IP rights is impressive in itself as reflected by the ratio of the gross national product of information goods¹²⁴ or the infringement value in single IP disputes.¹²⁵ However, more importantly, the legal analysis identifies a shift in structural characteristics which qualify the public–private divide. Whereas formerly the IP right was primarily characterized by its function to exclude competitors and to enable the management of the industrial production chain downstream, today the exclusionary nature of property is restricted both downstream and upstream. Downstream, IP rights have become ‘more public’ resulting in claims for ‘more access’ (A). Upstream, IP rights themselves become linked and limited by preceding rights over material and information (other than e.g. system-conform dominating patents) (B). This new embeddedness of property rights which originally were conceived to secure private sovereignty requires a fresh approach about how to conceive IP rights. Therefore, a final paragraph will position the unveiled normative structures of IP as integral part of the modern European regulatory private law (C).

A. The ‘Access Challenge’

The claim for ‘access’ to IP rights has become a buzzword. In its fuzziness it encompasses assumptions of a variety of natures induced by IP rights ‘becoming more public’. The analysis has identified at least three distinct aspects.

First, beside licences being a tool of industrial property (*vis-à-vis* competitors and contractors), they have become marketing instruments which create *direct* legal relations to *numerous* ordinary consumers. Patents and copyrights have lost their ‘competition only function’, not least due to the quasi-abolition of the private copy. To the extent that the internet has become the general communication tool, and cultural and scientific goods are now marketed in the digital world by licences, the ‘information commons’ debate has given rise to discussions about the right to access as part of universal services¹²⁶ and the ‘culture flat rate’.¹²⁷ The shift towards a more public conception of IP

¹²⁴ Estimations vary, and depend on indicators. For Europe on average, the figure is 3.4% of all R&D-expenditures Eurostat, June–July 2012: <http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/The_EU_in_the_world_-_science_and_technology>; for the US, 34.8% IP value of the gross national value (US Dept. of Commerce, Intellectual Property and the U.S. Economy, published 11 April 2012, available at <http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf>).

¹²⁵ Various procedures between Apple and Samsung worldwide hit the front pages, e.g. San José (USA, CA) the District Court attributed the sum of US\$1.05 billion to Apple on 7 June 2012; a Japanese court, vice versa, attributed the comparably humble sum of €1 million to Samsung on 31 August 2012. German procedures (OLG München, OLG Düsseldorf on 26 July 2012) have focused on patent validity and injunctions.

¹²⁶ In the sense of a ‘duty to provide the service’, H.-W. Micklitz, *Do Consumer and Businesses Need a New Architecture of Consumer Law? A Thought-Provoking Impulse*, *EUI Working Papers Law* 2012/23 (2012), at 41.

¹²⁷ In the sense of a statutory licence with a fixed fee. A. Rossnagel et al, ‘Die Zulässigkeit einer Kulturflatrate nach nationalem und europäischem Recht’ (2009), available at <<http://www>>.

rights has, for example, allowed Spain to transpose the private ordering system of levies for CDs into a purely public tax system.¹²⁸

Secondly, a shift towards ‘being more public’ has been identified in the classical competition arena—which has been mentioned above (*supra*, 2(B)), and discussed in-depth elsewhere.¹²⁹ Among those, one development is paradigmatic: patents have been accepted in the standards which are deemed to be accessible for everyone. Yet, standardization has become central both as industrial policy (slogan: ‘The one who has the standard has the market’), and as a tool to secure interoperability, especially in the IT industry. Despite the tensions between patent exclusivity and standards, the inclusion of patented technology in a standard is now accepted, if the participants declare their willingness to license in a fair, reasonable and indiscriminatory manner (‘FRAND’). Thus, broad access should be secured. The legal implications of the quasi-public declaration are yet to be clarified.¹³⁰

Thirdly, novel public policy considerations come into play. As much as the IP system affects product development and the downstream production chain, the consumer is affected by the market results it generates. Whereas monopoly pricing might become a serious concern in the future, especially in health products (‘access to medicines’), high price levels are currently not of great concern in Western countries (see prices for smartphones, tablet PCs). Instead, consumers worry about reduced choice. For example, the erosion of the genetic pool in various species, resulting in a reduction to a few agriculturally used strains, is not only an environmental concern. It equally affects the consumer’s choice. The autonomous consumer is not only interested in the information *if* a given product contains genetic modifications (classical information paradigm of consumer law). The consumer as market actor is also interested in a product choice which allows him or her to select from different products (beside products he or she rejects). Especially in the food sector, IP systems have induced a reduction of consumer choice, which is the opposite of their intended effect. Here, the public concern is geared towards complementary instruments alleviating the monopolistic tendencies of IP systems (e.g. by a reinforcement of the farmer’s right system).

B. Preceding Entitlements

The description of the shift of the public–private divide would be incomplete without a consideration of the inverse developments. Patent holders are required to acknowledge new rights attributed to materials which function, all in all, as raw material to intellectual property. This transforms what was deemed to be ‘public domain’ (free to take) into a legal sphere.¹³¹ In contrast to subsequent dependent patent holders or manufacturers of interoperative components (*supra*), access to technical teaching is not sought.

gruene-bundestag.de/fileadmin/media/gruenebundestag_de/themen_az/netzpolitik/16_fragen_und_16_antworten/kurzgutachten_zur_kulturflatrate.pdf.

¹²⁸ Royal Decree Act 20/2011, passed on 30 December 2011, abolishes Art. 25 of the Spanish Copyright Act (the levy system).

¹²⁹ Godt, *supra* note 10, at 584 ff.; D. Wielsch, *Zugangsregeln: die Rechtsverfassung der Wissensenteilung* (2007).

¹³⁰ Ullrich, ‘Patent, Wettbewerb und technische Normen’, *GRUR* 109 (2007) 817; Ullrich, ‘Patent and Standards—A Comment on the German Federal Supreme Court Decision “Orange Book Standard”’, 41 *IIC* (2010) 337; Straus, ‘Das Regime des European telecommunications Standards Institute—ETSI’, 60 *GRURInt* (2011) 469; A. Balitzki, ‘Patente und technische Normen’ (PhD thesis on file at the University of Oldenburg, January 2013) (publication forthcoming).

¹³¹ Explored in more detail by Godt, *supra* note 10, at 261, 303, 437.

These rightholders demand injunction, influence on exploitation, and only sometimes a share in profits. In other words, they claim an influence on exploitation. For instance, homeowners hold a right to their home's façade and pictures thereof which are to be respected by Google Street View.¹³² Donors of human tissue material have rights to their own body material. This entitlement raises the question of whether 'prior informed consent' also includes the right to have a say in the use, be it scientific or commercial, of the material. These questions go beyond the popular debate about data protection, and consumer protection (labour rights, insurance contracts), and direct attention to the set of rights of the modern individual, formulated as fundamental rights conflicting with IP. In very similar terms, the collective rights of farmers, indigenous communities, and the countries of origin of genetic resources ('CBD rights') demand a right to have a say in if and how commercialization might occur (sometimes also referred to as 'access'). These rights reformulate the public-private divide, and create an additional layer of prior rights which are to be respected by later IP holders.

C. Property as Integral Part of European Regulatory Private Law

These two developments have rendered IP more of a 'normal' property right which forms the basis for contractual relationships with regard to information and which is shaped by regulations *and* constitutional considerations.¹³³ The seven cases give evidence that the Charter has already embarked on a reformulation of the public-private debate, and will determine the evolution of information property into the modern transformation of what has been coined as 'European Regulatory Private Law'. This term refers to a transformation of norms, remedies, acknowledged actors, procedures, and institutions as a general phenomenon of European private law.¹³⁴ It shifts the attention from systematic private autonomy to a body of law embedded in regulatory policies. Since the focus of this article is on the relationship of IP and the European Charter, a classification of the observed changes in IP with regard to these five analytic categories of European Regulatory Private Law has to be brief.¹³⁵ However, in order to embark on a joint discussion across the various subdisciplines of private law,¹³⁶ a rough attribution to these categories shall be provided, before turning to general conclusions.

With regard to *norms*, four cases out of the set of seven (case 2 on human embryonic stem cells: the right to life; case 3 on diagnostics: the right to preventive public health care; case 4 on tissue banks: the right to one's own body information; and case 7 on cultural autonomy: the collective property right in information) show that IP *norms* do change under the influence of constitutional values (other than single individual rights of

¹³² A good overview is provided by G. Spindler, *Persönlichkeitsschutz im Internet—Anforderungen und Grenzen einer Regulierung* (2012), Expert Opinion for the 69th Conference of the German Lawyers Union (69. Deutscher Juristentag).

¹³³ For the structure of the 'constitutionalization of IP', see Godt, *supra* note 10, at 573–654.

¹³⁴ Micklitz, 'A Self-Sufficient European Private Law—A Viable Concept?', in: H.-W. Micklitz and Y. Svetiev (eds), *A Self-Sufficient European Private Law—A Viable Concept?* EUJ Working Papers Law 2012/31 (2012), at 5.

¹³⁵ The author, however, will contribute to the 'European Regulatory Private Law' debate by the project 'Boundaries to Information Property' which she co-manages since 2003 with G. v. Overwalle, L. Guibault, and D. Beylveid under the umbrella of the Common Core of European Private Law Project (<<http://www.common-core.org>>). Documentation and results are to be published by Cambridge University Press in 2014/15.

¹³⁶ I am indebted to H.-W. Micklitz for his insistence and his hints with regard to the following paragraph.

others in the Kantian sense). The Charter enhances the status of the acknowledged values by either acknowledging individual interests as 'rights' (the right to one's own body information) or by providing language to a novel interpretation of existing norms (embryonic stem cells, public health, cultural autonomy). With regard to *remedies*, case 1 (*Scarlet Extended v Netlog*) is indicative of how the classic remedy of injunction can be fine-tuned by acknowledging competing interests. *Procedural* implications become evident once the many high profile cases in patent law are considered which have been initialized by way of the everyone's right under Article 100 EPC (case 2 on human embryonic stem cells: the non-governmental organization Greenpeace; case 3 on diagnostics: public hospitals, professional organizations of physicians, and patient organizations; and case 5 on the patient's right to compulsory licensing; case 6 food quality: consumer organizations). New actors are granted access to judicial procedures ('access to justice'). Thus, they enrich the set of arguments exchanged in patent administrations and court rooms, and render the decision more complex. This enshrines the possibility of making the decision 'more just', but equally bears the risks of all balancing decisions.¹³⁷ Last but not least, *institutions* are incrementally changing by responding to international pressures. The acknowledgment of forms of collective property (case 7 on cultural autonomy) is due to international treaties signed by the member states and the European Union. Since collective rights contradict the idea of private property,¹³⁸ their recognition subtly changes the notion of intellectual property as a (sovereign) private right. Another institutional change is the acknowledgement of an individual right to one's own body information (thus reducing the public domain). It was pushed by southern European states to become the Council of Europe's Oviedo Convention on Human Rights and Biomedicine (1997, in force 1999, *supra* 4(B)4.), which is not signed by all EU member states. But its value implications have found their way into Article 3 EUCFR.¹³⁹

The essence is that legal relations in private law have absorbed regulatory policies. Regulation today is not limited to property restrictions controlled by public law only. In private law, regulatory policies frame legitimate expectations of individuals protected by the constitution beyond classical 'rights'.¹⁴⁰ This is what Micklitz coins the 'constitutionalization challenge to private law'.¹⁴¹ The conceptual shift follows the societal transformation from a society organized by status towards one organized by markets.¹⁴² Private law adapted by turning the focus from exclusion towards the inclusion of market actors, roughly speaking, 'other than property owners'. Joerges recently spoke of respect towards others as a 'legal imperative',¹⁴³ referring openly to Habermas' paradigm of 'the right of the other'.¹⁴⁴ It is the double orientation of the twentieth century towards

¹³⁷ Reich, 'Thoughts on Hybridisation', in Micklitz, *supra* note 134, 199, at 200.

¹³⁸ Godt and Clarke, 'Comparative Property Law: Collective Rights within Common Law and Civil Law Systems', in C. Godt (ed), *Cross Border Research and Transnational Teaching under the Treaty of Lisbon* (2013) 61.

¹³⁹ Which corresponds to Micklitz's observation of national/international hybrids. Micklitz, *supra* note 134 at 25.

¹⁴⁰ Godt, *supra* note 10, at 426, 436, 444, and in theoretical terms at 572.

¹⁴¹ Micklitz, *supra* note 134, at 25.

¹⁴² Frerichs, 'The Law of the Market Society: A Polanaian Account of Its Conflicts and Dynamics', in Micklitz and Svetlev, *supra* note 134, 45; also C. Joerges and J. Falke (eds), *Karl Polanyi, Globalisation and the Potential of Law in Transnational Markets* (2011).

¹⁴³ C. Joerges (interview 22 February 2013 by Maximilian Steinbeis), 'Ernstnehmen des Anderen. Und zwar als Rechtsgebot! Darum geht es in Europa', available at <http://www.verfassungsblog.de/de/europe-2023-christian-joerges/#:UWAoXze_xxY>.

¹⁴⁴ J. Habermas, *Die Einbeziehung des Anderen* (1999); building on his earlier seminal book *Faktizität und Geltung* (1992), in which Habermas developed the reciprocal relationship ('Wechselbezüglichkeit') of individual rights, and more public rights (rights of others).

democratic relations *and* markets which demands private law to turn from a status securing 'law of freedom' towards the law of 'regulatory markets' which conceives consumers, patients, workers, information providers, and information users as functional subjects of the market dressed with rights, not as objects of state protection.

A central characteristic of modern European regulatory private law are 'legal hybrids' which dilute the classic public-private divide,¹⁴⁵ and create 'disorder'.¹⁴⁶ Competition law serves as a prime example.¹⁴⁷ Since intellectual property has always been part of competition law,¹⁴⁸ the same characteristics are to be expected. IP grants a property right bound to the regulatory expectation of creating a behavioural incentive. Therefore, it was for long conceived as an institution of economic law only adjacent to private law (but not quite 'real private property'). In essence, IP rights have always been 'public-private hybrids'. Therefore, it is not surprising that the modern discursive transformations are especially translucent in IP law. All seven cases are indicative of how much embedded the exclusionary function of property has become. It is quite reassuring that the EU Charter of Fundamental Rights is supportive, and has been civilizing this process of transformation.

However, in contrast to many other areas of European regulatory private law, European IP law is not (yet) 'self-sufficient'.¹⁴⁹ Too strong is the non-European regulatory setup with only singular regulatory impact by a few EU directives and regulations. This is due *inter alia* to the historic harmonizing influence of international conventions on existing national laws,¹⁵⁰ and in patent law, the strong intergovernmental institutionalization of the European Patent Office by the EPC. As the (failed) negotiations about the European Patent Litigation Agreement, and the two agreed Regulations on the Unified Patent Court and the European patent with unitary effect have shown, the interests of the various European institutions and of the member states still differ greatly in the field of technology policies.¹⁵¹ Consequently, the European Union's influence has remained marginal. In how far this will change by the 'European unitary effect patent' and the (non-Union) Unified Patent Court remains to be seen. However, once the European Court of Justice adjudicates IP matters under the Charter, a new body of EU constitutional IP law might evolve.

As the analysis of the seven cases shows, the Charter proves to be remarkably articulate and nuanced in its framing of rights with regard to IP. Whereas in some cases reference to the Charter will not fundamentally change the discourse as it is, since the relevant values have already been enshrined in national constitutions (copyright conflicts, the right to life with regard to human embryonic stem cells), its influence (and thus that of the CJEU) might be substantial in modern areas like biomedicine and information technology. The Charter rights provide a language for growing conflicts between, on the one hand, the newly emerging sentiments of information commons (like the research commons, the genome commons, public health as a commons, etc.) which give rise to

¹⁴⁵ The very reason for the creation of sectorial laws in the first place, like consumer law, workers laws, etc.

¹⁴⁶ K. Tuori, 'On Legal Hybrids', in Micklitz and Svetiev, *supra* note 134, 67, at 73.

¹⁴⁷ *Ibid.*, at 69.

¹⁴⁸ For the historic debate on the public nature of IP law see Godt, *supra* note 10, at 505 ff.

¹⁴⁹ On this characteristic, Micklitz, *supra* note 134, at 6.

¹⁵⁰ Paris Convention of 1883 on patent laws, Bern Convention of 1886 on copyright laws, Madrid Convention of 1891 on trademark laws.

¹⁵¹ Ullrich, *supra* note 3.

the individual's right of participation¹⁵² (an aim which goes beyond the political quest for 'access'),¹⁵³ and on the other hand, the increasing vulnerability of the individual with regard to technological progress in the field of information technology and biomedicine. Reference to the Charter will expose the epistemic IP community to pressure to justify the exclusionary effects of information property under constitutional values.¹⁵⁴

Thus, the Charter will presumably become the central reference for IP conflicts. References to fundamental rights in general have been shown to become more significant and frequent, the higher the level of convergence of legal systems becomes. This was the surprising result of a research project conducted by Brüggemeier, Colombi Ciacchi, and Comandé.¹⁵⁵ The very same discursive connection is predictable for the European Charter of Fundamental Rights in IP conflicts.¹⁵⁶ It will thus be instrumental to a constitutional reflection of property conflicts in the modern information society, and will decisively influence consecutive debates in other areas of private law like insurance and labour law. It is cogent that the definition of rights, as framed by the novel public–private debate which acknowledges collective interests and enhances the status of the private individual with regard to information, will be transposed to contracts and torts. Thus, the modern EU Charter on Fundamental Rights is likely to become the central tool for the framing of conflicts in the modern information society.

¹⁵² Mattei, 'Eine kurze Phänomenologie der Commons', in S. Helfrich and Heinrich Böll Stiftung (eds), *Commons: Für eine neue Politik jenseits von Markt und Staat* (2012) 70, at 70; English translation in print: 'Thoughts for a Phenomenology of Commons', in D. Bollier and S. Helfrich (eds), *The Life of the Commons* (2012) (digital pre-publication: 'The State, the Market, and Some Preliminary Question about the Commons' (2011), available at <http://works.bepress.com/cgi/viewcontent.cgi?article=1040&context=ugo_mattei>).

¹⁵³ Resta, *supra* note 70, at 19.

¹⁵⁴ Recently: Ullrich, 'Intellectual Property: Exclusive Rights for a Purpose—The Case of Technology Protection by Patents and Copyright', in K. Klafkowska-Waśniowska, M. Mataczyński, and R. Sikorski (eds), *Problemy polskiego i europejskiego prawa prywatnego. Księga pamiątkowa Profesora Mariana Kepińskiego* (2012) 425.

¹⁵⁵ *Supra* note 4, Volume 2, 436.

¹⁵⁶ The reference to universal human rights in the international debates can be seen as a precedent as common ground for IP disputes.

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