ARTICLES

Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It

By Christoph Ann[*]

A. Introduction

Whether patents should be granted on human genes or gene sequences is highly controversial, both ethically and politically; not only in Germany but throughout Europe and in most parts of the world.[1] Proof of this has been the attention created by US biotechnology company Myriad Genetics, which, in 2001, obtained European patents for human gene sequences indicating an increased risk of certain types of cancer.[2] In Germany the *Bundestag* has recently addressed the issue: the core of a

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[1] *See* Jeanne Clark et al., *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents*?, United States Patent and Tradmark Office, Dec. 5, 2000, http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf; David J. Faye, *Bioprospecting, Genetic Patenting and Indigenous Populations – Challenges under a Restructured Information Commons*, 7 J. WORLD INT'L. PROP. 401 (2004); Atina Krajewska, *Fundamental Rights Concerning Biomedicine in the Constitutional Treaty and Their Effect on the Diverse Legal Systems of Member States*, 6 GERMAN L. J. 1693 (2005), http://www.germanlawjournal.com/article.php?id=666; Franklin Strier, *Stemming the Gold Rush: Public Policy Alternatives to Gene Patenting*, 110 BUS. & SOC. REV. 47 (2005); Emma Toumi, *In Defence of Gene Patents*, 9 J. COMM. BIOTECH. 135 (2003); Human Genome Organisation (HUGO), *Statement on Patenting of DNA Sequences*, April 2000, http://www.gene.ucl.ac.uk/hugo/patent2000.html; German National Ethics Council, *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin*, Opinion of Oct. 6, 2004, http://www.nationalerethikrat.de/_english/publications/opinions.html.

[2] *Myriad Genetics* owns these patents in Canada, the United States and various other countries. It also owns several gene-based screening tests for cancer. In 2001 the European Patent Office (EPO) granted *Myriad Genetics* two European patents on a gene BRCA1. European opponents have been fighting these patents since 2001 on grounds that its claims were to broad in scope. Another cause of controversy is the company's exclusive licensing policy in Europe. This policy and the risk of being sued for infringement allegedly prevented other researchers in Europe from carrying out their own tests. In May 2004 the first BRCA1 patent (EP 699754) was revoked completely for lack of novelty under European patent law. Following two public hearings in January 2005, the of the EPO' Opposition Division rejected some elements of the claims of the second BRCA1 patent (EP 705903). The patent could, however, be

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newly introduced provision of the German Patent Statute (PatG) is Paragraph 1a Sec. 4 PatG, which limits the scope of patent protection available for human gene sequences or parts thereof. If the subject of an invention is a human gene sequence, Paragraph 1a Sec. 4 PatG requires disclosure of not only the sequence but also at least one application. Without such disclosure a human gene sequence is not patentable under German Patent Law. This is remarkable, because under the Directive of the European Parliament and the Council on the Legal Protection of Biotechnological Inventions, the so-called Biotechnology Directive of 1998[3], a piece of European Union legislation, the situation is different.

The Biotechnology Directive was enacted because the European Council as well as the European Parliament deemed biotechnology and genetic engineering to be technologies of the future. It obligated all EU member states[4] to provide patent protection for biotechnological inventions within a harmonized framework of the member states' respective national patent laws by July 30, 2000.

In Germany the Directive's transposition triggered a lengthy and extremely controversial discussion in the *Bundestag*[5] as well as among legal scholars.[6] Key

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maintained, had its claims been amended. *See* Stéphanie Bodoni, *EPO Revokes Cancer Test Patent*, 140 MANAGING INTELL. PROP. 6 (2004); Press release, European Patent Office, "Myriad/Breast" Cancer Patent Revoked After Public Hearing, (May 18, 2004) *available at* http://www.european-patent-office.org/news/pressrel/2004_05_18_e.htm; Press release, European Patent Office, (Jan. 25, 2005) *available at* http://www.european-patent-office.org/news/pressrel/2005_01_25_e.htm.

[3] Council Directive 1998/44, 1998 O.J. (L 213) 13 (EC), *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf (hereinafter Biotechnology Directive).

[4] At present EU member states are: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finnland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Sweden, Slovakia, Slovenia, Spain, United Kingdom, but *not* Switzerland.

[5] *See* Motion of Fractions of Social Democratic Party (SPD) and Green Party (Bündnis 90 / Die Grünen) *Für ein modernes Biopatentrecht (For a Modern Biopatent Law)* of March 10, 2004, BTDrucks 15/2657, *available at* http://dip.bundestag.de/btd/15/026/1502657.pdf; Recommendation and Report of the Bundestags Judicial Committee of Dec. 01, 2004, BTDrucks 15/4417, *available at* http://dip.bundestag.de/btd/15/044/1504417.pdf; BT-PLENARY PROTOCOL 13678 D, BTDrucks 15/146, *available at* http://dip.bundestag.de/btp/15/15146.pdf.

[6] *See* Peter Egerer, *Patentschutz für Erfindungen auf dem Gebiet der Biotechnologie – Stoffschutz für Gene*?, *in* FESTSCHRIFT FÜR REIMAR KÖNIG ZUM 70 GEBURTSTAG 109 (Christoph Ann et. al. 2003); Uta Köster, *Absoluter oder auf die Funktion eingeschränkter Stoffschutz im Rahmen von „Biotech"-Erfindungen, insbesondere bei Gen-Patente?*, ZEITSCHRIFT FÜR GEWERBLICHEN RECHTSSCHUTZ UND URHEBERRECHT (GRUR) 833 (2002); Hans-Georg Landfermann, *Umsetzungsspielräume bei der Biopatent-Richtlinie*, *in* FESTSCHRIFT FÜR WINFRIED TILMANN ZUM 65 GEBURTSTAG 527 (Ehrard Keller et al. eds., 2003); Karl-Nikolaus Peifer, *Patente auf Leben – Ist das Patentrecht blind für ethische Zusammenhänge?*, *in* FESTSCHRIFT FÜR REIMAR KÖNIG

issues in this debate were the technology's great opportunities and high hopes for medical breakthroughs as well as its economic significance and a plethora of ethical issues.[7] Many who viewed the human genome as the common heritage of mankind were concerned that the Directive might breed "patents on life" and, thus, overcompensate inventors. In 2000/01 the seemingly endless debate led to the failure of first efforts to transpose the Directive.[8] Only after Germany had been found in violation of its European obligations by the European Court of Justice (ECJ) in 2004 for its failure to transpose the Biotechnology Directive[9] did it enact the necessary national legislation. When Germany's national legislation went into effect on March 1, 2005, the *Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen*[10] brought about changes of the German Patent Statute (*Patentgesetz – PatG*), namely the introduction of Paragraph 1a PatG governing the granting of German national patents on human gene sequences or parts thereof.[11]

When discussing patents on human gene sequences in Europe, attention must, however, be paid not only to the EU's Biotechnology Directive and the member states' national laws, but also to legislative acts of the European Patent Organisation. The European Patent Organisation is not part of the European Union. It is an independent Organisation based upon the European Patent Convention (EPC),[12] a multilateral convention under international law.[13] Provisions on

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ZUM 70. GEBURTSTAG 435 (Christoph Ann et. al. eds., 2003); Nikolaus Kunczik, *The German Way of Dealing with "The Tragedy of the Anticommons" - Purpose-Bound Protection for Product Patents on Genetic Information in Germany,* 2 J. OF INT'L BIOTECH. L. 194, 197 (2005), abstract *available at* http://www.extenza-eps.com/WDG/doi/abs/10.1515/jibl.2005.2.5.194.

[7] *See* National German Ethics Council, *The Patenting of Biotechnological Inventions Involving the Use of Biological Material of Human Origin,* Opinion 2005, *available at* http://www.ethikrat.org/_english/publications/Opinion_patenting-of-biotechnological-inventions.pdf.

[8] *See* BTDrucks 14/5642, *available at* http://dip.bundestag.de/btd/14/056/1405642.pdf.

[9] Case C-126/03, Comm'n of the European Communities v. F.R.G. 2004 E.C.R. I-11197, *available at* http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=OJ:C:2005:6:0018:0018:EN:PDF.

[10] Statute Implementing the European Council's Biotechnology Directive, Jan. 21, 2005, BGBl. I at 146, *available at* http://www.bgblportal.de/BGBL/bgbl1f/bgbl105s0146.pdf.

[11] German Patent Statute, Dec. 16, 1980, BGBl. I at 1 (F.R.G.) (for an English translation of modest quality www.ip-firm.de/patentact.pdf).

[12] Convention on the Grant of European Patents, Oct. 5, 1973, *available at* http://www.european-patent-office.org/legal/epc/e/ma1.html (last amended on December 10, 1998) (hereinafter EPC).

[13] Contracting states of the EPC are at present: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finnland, France, Germany, Greece, Hungary, Ireland, Iceland, Italy, Liechtenstein, Latvia, Lithuania, Luxemburg, Monaco, Netherlands, Poland, Portugal, Rumania, Sweden, Switzerland,

biotechnological inventions in general and on the patentability of human gene sequences under the EPC in particular are contained in Rules 23b *et seq.* of the Implementing Regulations to the Convention on the Grant of European Patents (EPC-IR).[14]

As different as the EU and the European Patent Organisation are, with respect to their organisation and their respective memberships, their legal sources are also equally distinctive. This leads to questions for countries like Germany that belong to both the EU and the European Patent Organisation. Can these countries enact only laws that are in accordance with the EU Biotechnology Directive as well as with the EPC? Or does it suffice that their patent laws satisfy EU law requirements, even if they do not meet those of the EPC? In Germany, these questions arose when the German *Bundestag*, in December of 2004, debated and voted on the aforementioned *Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen*.[15] This German law satisfied all requirements of the EU Biotechnology Directive. It did, however, permit the patenting of human gene sequences or parts thereof only under conditions stricter than those laid down in the EPC and the EPC-IR for European patents, even though European patents can be valid in Germany, if the applicant so chooses.

For applicants this gives rise to an interesting question: should patent applications for identical biotechnologial inventions regarding human gene sequences with effect for Germany only be submitted to the *European Patent Office (EPO)* in order to avoid negative decisions by its neighbour, the German Patent Office (*Deutsches Patent- und Markenamt*), which applies the stricter Paragraph 1a German Patent Statute and and not the more liberal EPC and EPC-IR?

B. EU Biotechnology Directive, EPC respectively EPC-IR, German Patent Law

Two steps shall be taken in order to clarify the relationship between EU law, German patent law, and EPC and EPC-IR (which can also be called European Patent Organisation law). First, the substance of the EU-Biotechnology Directive and its transposition into German patent law need to be scrutinized and compared

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Slovakia, Slovenia, Spain, Turkey, United Kingdom; Extension states, i.e. states to which EPO-patents can be extended, are Albania, Bosnia and Herzegovina, Croatia, former Yugoslav Republic of Macedonia, Serbia and Montenegro.

[14] Implementing Regulations to the Convention on the Grant of European Patents Oct. 1973, *available at* http://www.european-patent-office.org/legal/epc/e/ma2.html#REG (last amended by Decision of the Administrative Council of the European Patent Organisation Dec. 9, 2004) (hereinafter EPC-IR).

[15] *See* German Patent Statute, *supra* note 11.

to that of the EPC and EPC-IR. In a second step, the relationship between the EPC, on the one hand, and the national patent law that Germany has enacted in order to meet its obligations under EU law, on the other hand, needs to be reviewed.

I. EU Biotechnology Directive

All EU member states' patent laws have long struggled with granting patent protection for inventions covering biological materials. The objective of the EU Biotechnology Directive therefore had been primarily to *harmonize* existing rules for patents on biotechnological inventions in EU member states,[16] and not to *create* patent law in the field.[17] All EU member states, in other words, had to implement the provisions of the EU Biotechnology Directive into their national patent laws. This included the provisions on human genes and gene sequences in Art. 5.

In this respect Art. 5 Sec. 1 clarified, "For the purposes of this Directive, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." This rule, however, is limited in Art. 5 Sec. 2, which provides: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." This, however, requires full disclosure in the patent application, or, as Art. 5 Sec. 3 states: "The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

Nevertheless, the directive's enactment had been preceded by almost a decade of European consultations. In 1995 a first draft[18] had been rejected by the European Parliament because of ethical concerns regarding the patentability of manipulations of human genes and a resulting monopolization of rights to the human genome. In response to these concerns the EU Commission had presented a second draft of the Directive in December of 1995.[19] This draft, containing changes that the EU

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[16] *See* Biotechnology Directive, *supra* note 3, at considerations 5, 6, 7.

[17] *See* Biotechnology Directive, *supra* note 3, at consideration 8.

[18] Proposal for a Council Directive on the Legal Protection of Bioltechnological Inventions, COM(1988) 486 final (Oct. 17, 1988), 1989 O.J. (C 10) 3.

[19] Proposal for a Council Directive on the Legal Protection of Bioltechnological Inventions, COM (1995) 661 final (Oct. 8, 1996), 1996 O.J. (C 296) 4.

Parliament had suggested, was enacted in 1998 as the Biotechnology Directive.[20] As late as October 9, 2001, the European Court of Justice (ECJ) rejected an action brought by the Netherlands, with the support of Italy, to declare the Directive void under Art. 230 EC Treaty.[21]

II. EPC and EPC-IR

The European Patent Organisation is independent from the EU. Consequently, the EPC is *not* EU Law. Nevertheless, it is highly relevant for patent law practice worldwide. As a convention under international law the EPC creates a unitary procedure before the EPO that leads to a patent which is valid in as many of the 30 contracting states[22] as the applicant designates. Pursuant to Art. 2 Sec. 2 EPC, the European Patent affords the same rights within each designated state as a national patent that has been granted by the respective state's national patent authorities. Every European patent application undergoes substantive examination regardless of whether the states that the applicant designates operate on an examination system or merely a registration system. The examination conducted by the EPO may be based only upon the requirements laid down in the EPC, namely Art. 52 – 57 EPC. National patent law does not bind the EPO in any way. It can become relevant only in the "post-grant-phase," *i.e.*, after the European patent has been granted. Art. 2 Sec. 2, 64 EPC establishes that, in this national phase, the patent needs to be translated and fees have to be paid in each designated state in order for the European patent to have the same effects as a national patent.

After the EU Biotechnology Directive had been issued in 1998, the European Patent Organisation was faced with the question of whether to integrate its provisions into

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[20] Council Directive 98/44, 1998 O.J. (L 213) 13, *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.

[21] *See* Case C-377/98: The Kingdom of the Netherlands v European Parliament and Council of the European Union, 2001 E.C.R. I-7079, *available at* http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Rechercher&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=C-377/98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100; *see also* C-377/98R Order of the President of the Court in The Kingdom of the Netherlands v. European Parliament and Council of the European union, 2000 E.C.R. I-06229, *available at* http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61998O0377#MO (on plaintiff's application for interim measures to suspend the operation of Directive 98/44/EC); *see also* Malcom MacLaren, *Patently Unsatisfactory?: Community Legislative Competence and the ECJ Biotech Decision*, 2 GERMAN .L.J. 18 (2001), http://www.germanlawjournal.com/article.php?id=114; *see also* Tade Matthias Spranger, *Indigene Völker, "Biopiraterie" und internationales Patentrecht*, 103 ZEITSCHRIFT FÜR GEWERBLICHEN RECHTSSCHUTZ UND URHEBERRECHT (GRUR) 89 (2001).

[22] *See* EPC-IR, *supra* note 14.

the EPC. Because the EU and European Patent Organisation are completely independent organisations, there was no legal obligation to do so, and the 30 contracting states of the EPC did not attempt such an integration. The required majority at the necessary diplomatic conference[23] would have been too difficult to achieve, and dissenting states might have tried to put a price on their consent. Therefore, until today, the EU Biotechnology Directive has not been integrated into the EPC. The EPC also does not contain any other specific provisions for patents on biotechnological inventions.

The European Patent Organisation did, however, address the issue of biotechnological patents in a manner consistent with the law that the EU had enacted and that, therefore, most of the European Patent Organisation's member states had been obligated to implement: effective September 1, 1999, the EU Biotechnology Directive's provisions on the patenting of human gene sequences became part of the *Implementing Regulations to the Convention on the Grant of European Patents (EPC-IR)* as Rules 23b *et seq*. From a practical viewpoint this made sense because the EPC-IR can be changed more easily than the EPC.[24] Rule 23e EPC-IR contains a literal implementation of Art. 5 Sec. 1 - 3 EU Biotechnology Directive.

The practical relevance of this implementation is that European patents, i.e. patents according to the European Patent Convention, are granted for human gene sequences or parts thereof upon successful examination of Art. 52 - 57 EPC and Rules 23b – 23e EPC-IR for as many of the 30 contracting states as the applicant chooses to designate.[25] In the "post–grant phase" these patents have the same effects as patents granted by the EPC-signatory states' respective national patent offices.

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[23] *See* EPC, *supra* note 12, at Art. 172.

[24] EPC, *supra* note 12, at Art. 33 Sec. 1, Art. 35 Sec. 2. Note that some criticize this as an approach to circumvent regulations on EPC-revisions; *see* RUDOLF KRAßER, PATENTRECHT 90 (5th ed. 2004).

[25] S*ee* Steven Hildebrand, *Patenting of Human Genes in Europe; Prerequisites and Consequences*, http://www.bepress.com/cgi/viewcontent.cgi?article=1014&context=ndsip (for the EPO's grant policy).

III. German Patent Law, particularly Paragraph 1a PatG

On March 1, 2005, the transposition of Art. 5 Sec. 1 - 3 of the EU Biotechnology Directive into German (national) patent law went into effect as the new Paragraph 1a PatG. The provision immediately follows Paragraph 1 PatG, which provides for the substantive requirements that inventions must meet in order to be patentable under German patent law.

Sections 1 - 3 of the new Paragraph 1a PatG do not pose any problems. They do not contain more than (almost) literary adoptions of the Directive's Art. 5 Sec. 1 – 3. With respect to Paragraph 1a Sec. 4 PatG, however, the situation is different. Paragraph 1a Sec. 4 PatG limits the scope of patent protection available for human gene sequences or parts thereof from the German Patent Office. In contrast to the Directive, German patent law does not provide for absolute substance protection. In other words: if the subject of an invention is a human gene sequence, Paragraph 1a Sec. 4 PatG requires not only the sequence, but also at least one application to be disclosed. Patent protection for human gene sequences is thus limited *to that application*. Inventions of new applications do not lead to dependent patents[26] and, thus, cannot only be patented but also used without the first patent holder's consent. As long as this disclosure is missing, the German Patent Office will reject the national (German) patent application on the grounds that, in Germany, absolute substance protection is not available for human gene sequences.

The legislative history of this provision is somewhat peculiar. The German Federal Government's initial draft[27] had not provided for any such limitation but would have allowed for absolute substance protection. The more limited scope of Paragraph 1a Sec. 4 PatG was suggested in the first session of the Bundestag's judicial committee on December 1, 2004.[28] This suggestion, unexpected at the time, was justified with respect to the particular nature of the human genome in contrast to that of animals or plants.[29] By means of its "critical implementation" of the Biotechnology Directive some German MPs wanted to send "a signal to Europe"

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[26] Dependent patents are patents that cannot be used without simultaneously using one or more older patents and that thus can be used only with the respective older patent holder's consent.

[27] *See* Comm'n of European Communities v. F.R.G., *supra* note 9.

[28] *See* Recommendation and Report by the Bundestag's Judicial Committee, *supra* note 5.

[29] *See supra* note 5.

that would trigger a new discussion on desirable limitations for the scope of patents on parts of the human genome.[30]

C. The Relationship between EPC respectively EPC-IR and Paragraph 1a Sec. 4 PatG

So, German law on the patenting of human gene sequences, on the one hand, and the respective European Patent Organisation law, on the other hand, are not identical. Instead they now differ substantially. Whereas the EU Biotechnolgy Directive has been integrated into the EPC-IR with the result that European Patent Organisation law provides absolute substance protection for human gene sequences, Germany has chosen to limit substance protection for the same subject matters in Paragraph 1a Sec. 4 PatG.

This gives rise to an important question: does European patent law, now nearly fully assimilated into EPC and EPC-IR law, on the one hand, and German patent law, on the other hand, stand isolated from one another without any influence on the other? Or, can German patent law, which prohibits absolute substance protection in Paragraph 1a Sec. 4 PatG, affect European Patent Organisation law and, thus, essentially limit the scope of inventions patentable before the EPO? The answer yields considerable consequences. If European and German patent law are wholly autonomous, there is no conceptual problem, even if the German Patent Office were to grant only limited patent protection, because further reaching protection would be available from the EPO. An application for a European Patent Organisation patent could simply be chosen in order to negotiate around the limits of German national patent protection. If, however, Paragraph 1a Sec. 4 PatG is relevant not only to German patents but also to European patents granted by the EPO and designated as applicable for the Federal Republic of Germany, this elevated form of detour does not promise success. Limits on substance protection, according to Paragraph 1 a Abs. 4 PatG, then affects European patents assigned for Germany as well as (national) German patents.

The answer is that, as a rule, German and European Patent Organisation patent laws are two strictly independent bodies of rules. This includes the new Paragraph 1a Sec. 4 (German) PatG. It affects neither the EPC and the EPC-IR, nor European Patent Organisation patents granted under their rule. This independence is the

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[30] The Commission sees no reason to change the Directive in this regard; *see Report from the Commission to the Council and the European Parliament – Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering,* at 5, COM (2005) 312 final (July 14, 2005), *available at* http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0312en01.pdf.

reason why the elevated form of detour does indeed work: in order to circumvent the German patent law's limitations for patents on human gene sequences, an inventor can indeed apply for a European patent and designate Germany as one of the countries in which the patent is to take effect. Given that this constitutes a circumvention of German patent law the result may seem strange. Nevertheless, European patents are subject to European Patent Organisation law with regard to requirements as well as to the granting procedure, and to national laws with regard to these patents' effects. This is shown by the systematics of patent law, by its history, and by a comparison with the patent laws of other European Patent Organisation countries, namely Swiss patent law.

In systematic terms Paragraph 1a Sec. 4 (German) PatG is part of Paragraph 1a PatG that governs the substantive patentability requirements for German patents on human gene sequences. As part of the same paragraph, Sec. 4 is obviously connected to the foregoing Paragraph 1a Sec. 1 and 2 PatG, which define when human gene sequences or parts thereof can be patentable inventions. Paragraph 1a Sec. 4 PatG merely specifies these provisions by laying down the limits for substance protection as applicable for human gene sequences. Paragraph 1a Sec. 4 PatG therefore contains a patentability requirement, not a provision on the effects of a patent, which would fall into the jurisdiction of Germany as a EPC member state.[31] This is confirmed by the grounds upon which German patent law allows for the revocation of a patent. Under Paragraphs 21, 22 PatG a patent may be revoked or declared void if it should not have been granted in the first place, *i.e.*, mainly if its subject matter lacked patentability under §Paragraph 1 – 5 PatG. This includes Paragraph 1a Sec. 4 PatG, which also indicates that the provision contains a substantive patentability requirement, not a ruling on a patent's effects.

As regards legislative history, the German *Bundestag*, in the course of the parliamentary proceedings, assumed and accepted that the new Paragraph 1a Sec. 4 PatG would have no effect on European patents. When it enacted Paragraph 1a Sec. 4 PatG, the *Bundestag* knew that this provision could not do more than create a national standard for the patentability of human gene sequences and that this standard would be different from the European Patent Organisation-standard that already existed.[32] In an effort to avoid this a few German MPs had suggested to make the limitation for the substance protection of human gene sequences part of

[31] *See* Franz Josef Zimmer & Svenja Sethmann, *Act Implementing the Directive on the Legal Protection of Biotechnological Inventions in Germany* (BioPatG), 24 BIOTECH. L. REP. 561, 561-566 (2005), *available at* http://www.grunecker.de/download/publications/biorili.pdf, p. 7.

[32] *See* BT-Plenary Protocol, *supra* note 5.

Paragraph 9 PatG rather than of Paragraph 1a Sec. 4 PatG.[33] Paragraph 9 PatG governs the effects of (German) patents. Such provisions in the 30 EPO member states' patent laws, according to Art. 64 Sec. 1 EPC, are not part of European Patent Organisation law but continue to fall into these member states' jurisdictions. The *Bundestag*, however, chose not to adopt this proposal.

Consequently, Paragraph 1a Sec. 4 PatG cannot be viewed as governing the effects of German patents but merely as one of several substantive patentability requirements. It therefore binds only the German Patent Office but not the EPO: on the EPO-level a European patent application therefore will be examined by the EPO exclusively according to Art. 52 – 57 EPC as well as Rules 23b – 23e EPC-IR. The German Patent Office in contrast will examine the same application according to the narrower §Paragraph 1 – 5 PatG, including Paragraph 1a Sec. 4 PatG. This means that for inventions involving human gene sequences or parts thereof European patents will be more accessible than German patents.

As the granting processes before the EPO and the German Patent Office are completely independent from one another, Paragraph 1a Sec. 4 PatG cannot effect the EPO's decision whether a European patent should be granted in any respect whatsoever. German law comes to bear only once the grant-phase before the EPO has been completed and the European bundle patent has reached the national phase. In this national phase the patent needs to be translated and fees have to be paid in each designated state in order for the European patent to gain the same effects as a national patent would, had it been granted by the respective state's national patent office, Art. 2 Sec. 2, 64 EPC. In other words: the European patent is subject only to national, here subject to German provisions governing the *effects* of a patent, *e.g.* with regard to scope of protection, infringements *etc*. These provisions, however, do not contain a rule that could potentially effect substance protection for European patents granted by the EPO. Paragraph 1 sec. 4 PatG, as a rule governing the requirements of a patent, is not among them.

Finally it may be added, that Switzerland – a country that is not an EU-member but still an EPO-signatory - plans to voluntarily implement the EU Biotechnology Directive. Driven by similar concerns as Germany, Switzerland also plans to limit substance protection for all(!) gene sequences. While aiming for the same goal as Germany, Switzerland nevertheless approaches the issue from a different, possibly more effective angle: other than Germany, Switzerland wants to integrate its limitation of substance protection into those of the Swiss patent statute's provisions that govern not the granting, but the effects of a Swiss patent, *i.e.*, that govern the

[33] *See* BT-Plenary Protocol, *supra* note 5, at enclosures 6, 8.

post–grant phase.[34] As mentioned before, these provisions do not fall into the jurisdiction of the European Patent Organisation but continue to remain under the signatory states' exclusive national jurisdiction.

The reason is obvious: Switzerland explicitly wants to avoid a competing existence of differing European and Swiss rules on patents for human gene sequences. Or, put somewhat more directly: Switzerland wants to avoid the loss of knowledge about patent law and/or of legislative skill that have been brought about by German patents.[35] The Swiss example, thus, shows how the relevant German lawmakers' policy goal could have been achieved simply by carefully choosing the right part of the patent law for implementing the intended limitation for substance protection.

D. Conclusion

Paragraph 1a Sec. 4 (German) PatG is an exemplary provision in a number of ways: it is a good example of the legal and political problems that can grow out of dual track solutions, *i.e.*, parallelism of transnational and national regulations. Even states cannot have the same cake, *i.e.*, enjoying the benefits of transnational law, and eat it, *i.e.*, exercise national sovereignty by independent lawmaking. If states hope for better results by means of pooling resources, here by jointly creating and running a European Patent Organisation that can issue patents for all designated signatory and a number of extension states, then they must reduce national sovereignty and control. Everything else invites symbolic lawmaking as has occurred here.

If patents for one territory can be obtained before two different patent offices, the European Patent Office and the European Patent Organisation member states' national patent offices, competition between these offices will be the result and all or at least most of the applications will go to the patent office that promises applicants the most success. Here, with Germany refusing absolute substance protection before its German Patent Office, the winner will be the (European) EPO. Or, in more general terms, competition between government agencies easily sparks a race to the bottom. The resulting expense is borne either by the taxpayer or – as is the case with patents – by the consumer. It is the consumer who will have to pick

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[34] *See* Swiss Federal Institute of Intellectual Property, http://www.ip4all.ch/E/jurinfo/j100.shtm#a03 (last visited Feb. 26, 2006) (with links to documentation on the Swiss Patent Law Revision in all three Swiss official languages: German, French, and Italian).

[35] *See* Draft for a Revision of the Swiss Patent Statute, Art. 8c, *available at* http://www.ip4all.ch/E/jurinfo/j100.shtm#a03.

up the cost of monopolies that should and would not have been granted in the first place, had one of the competing office's higher patentability standards been applied. In order to prevent this, uniform patenting standards need to be established – in Europe, but preferably also worldwide. Otherwise applicants seeking the broadest protection possible will chose to file their patent applications with the office that applies the more lenient standards.

By filing before the EPO, applicants for patents on human gene sequences or parts thereof will ensure absolute substance protection for their inventions in all EPO member states that they designate. This will include Germany, in spite of the fact that, according to Paragraph 1a Sec. 4 PatG, such protection would otherwise not be available before the German Patent Office.

Paragraph 1a Sec. 4 PatG therefore presently does not do more than send a message. The feebleness of this message in light of the existing European Patent Organisation patent law on human gene sequences reduces Paragraph 1a Sec. 4 PatG to a piece of symbolic law. Symbolic law, however, never is good law. So even if it can be dealt with, Paragraph 1a Sec. 4 PatG is an example of bad lawmaking.