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I. INTRODUCTION

The lure of biotechnology investment has finally transformed Europe from passive recipient to active provider of biotechnology.[1] For three decades, the United States appeared as the harbinger of the biotechnology industry's development, a position now gradually challenged by emerging European players.[2] Great Britain appeared as the first such player in the 1980s.[3] Germany then followed in 1995 with its *BioRegio Wettbewerb*, a contest for government funding to develop research centers or "biotech clusters."[4] Germany continued with the creation in 1997 of its own high technology market, *Der Neuer Markt*, which offers German venture capital funds a market to trade shares of biotechnology start-up companies.[5] As a result, the German biotechnology industry increased by 150 percent from 1996 to 1999.[6] In the same period, France, Italy and other European countries established Nasdaq-like financial markets which, as their U.S. counterpart, attract venture capital and promote biotechnology start-ups.[7] Further, the French government increased its investment in

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1 Darrell G. Dotson, Comment, *The European Controversy Over Genetic-Engineering Patents*, 19 HOUS. J. INT'L L. 919, 919 (1997).

2 Oliver Morgan, *Hi-Tech Britain Hijacked*, THE OBSERVER, Nov. 26, 2000, at 5.

3 *Id.*

4 Morgan, *supra* note 2. The German government awarded 50 million marks each to the areas of Munich, Cologne and Heidelberg for the construction of research centers. Karen Lowry Miller, *The Biotech Boom*, NEWSWEEK, Oct. 30, 2000, at 56.

5 Morgan, *supra* note 2.

6 *Id.*

7 Miller, *supra* note 4.

biotechnology research from $26 million to $260 million in the last ten years.[8] Despite such efforts to create an attractive market, total biotechnology investment in Europe reached only $579 million in 1999, less than half of the corresponding investment in the United States, but reflecting an increase of 53 percent over 1998.[9]

Such an overview helps underscore the tensions over the ethical and economic issues that accompany the growing importance of the biotechnology industry to Europe. This Comment relies on the University of Edinburgh's controversial European Patent (EP) 0695351 "Isolation, Selection and Propagation of Animal Transgenic Stem Cells," granted on December 8, 1999, to examine some of these tensions.[10] Part II presents Europe's current position on the patenting of genetically modified organisms by studying the material articles of the European Patent Convention (EPC) and the line of decisions issued by the European Patent Office (EPO) concerning plant and animal patents up to the grant of EP 0695351. Part III analyzes the source of the scandal, namely Claim 48 of EP 0695351, in terms of its significance and of the motivation of the applicant and the EPO in respectively drafting and granting such a claim: "A method of preparing a transgenic animal, said animal comprising a selectable marker capable of differential expression in (a) desired stem cells and (b) cells other than desired stem cells . . . ." Finally, the conclusion examines the future of EP 0695351 and the most recent developments in Europe for the protection of biotechnological inventions.

II. PROTECTION FOR GENETICALLY MODIFIED PLANTS AND ANIMALS UNDER THE EPC

A. Material Articles of the EPC

Prior to 1973, a natural or legal person seeking patent rights in Europe for an invention needed to apply to each national patent office. The procedure was long, costly, and often led to an inconsistent scope of protection between the countries.[11] The EPC emerged as the solution when the then contracting states ratified its

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8 *Id.*

9 *Id.*

10 *See* European Patent No. 0695351 (issued Dec. 8, 1999).

11 Dotson, *supra* note 1, at 922.

articles on October 5, 1973,[12] and it came into effect in late 1977.[13] With the preamble, the EPC states its goal: "[T]o strengthen co-operation between the States of Europe in respect of the protection of inventions, . . . that such protection may be obtained in those States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted."[14] The EPC thus enables a natural or legal person to submit one patent application to its granting body,[15] the EPO, which if allowed gives that person a "bundle" of national patents[16]—one patent for each of the member countries designated in the application. However, the equivalence between the European patent and the multiple national patents is illusory, because, although granted under the EPC, the patent's validity, infringement and enforceability are defined by the national courts.[17] Thus, the scope of protection of the patent will vary with the interpretation given to it by the various national courts and laws.[18]

In November 2000, Turkey (TR) most recently joined the group of EPC contracting states, which includes Austria (AT), Belgium (BE), Switzerland (CH), Cyprus (CY), Germany (DE), Denmark (DK), Spain (ES), Finland (FI), France (FR), the Hellenic Republic (GR), Ireland (IE), Italy (IT), Liechtenstein (LI), Luxembourg (LU), Monaco (MC), the Netherlands (NL), Portugal (PT), Sweden (SE) and the United Kingdom (GB).[19] Together with the Extension States of Albania (AL), Lithuania (LT), Latvia (LV), the former Yugoslav Republic of Macedonia (MK), Romania (RO) and Slovenia (SI), an inventor can submit a European patent application for a total of 26 countries and enter a European patent market open to over 450 million people.[20] Although the Extension States are not contracting members of the EPC, they "have entered into an agreement . . . to

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[12] Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, *available at* http://www.european-patent-office.org/legal/epc (last visited Dec. 1, 2001) [hereinafter EPC].

[13] Press Release, European Patent Office, Turkey now a member state of the European Patent Organization (Nov. 1, 2000) *available at* http://www.european-patent-office.org/news/pressrel.

[14] EPC, *supra* note 12.

[15] *Id.* art. 4.

[16] *Id.* art. 64.

[17] *Id.*

[18] Dotson, *supra* note 1, at 924.

[19] EUROPEAN PATENT OFFICE, EPO MEMBER STATES, *at* http://www.european-patent-office.org/epo/members.htm (last updated Nov. 2, 2001).

[20] EPO press release dated Nov. 1, 2000, *supra* note 13.

extend the protection conferred by European patent applications and patents to their territory."[21]

Before issuing as a patent, an application submitted to the EPO must first satisfy the standards for patentability under Article 52(1): "inventions which are susceptible of industrial application, which are new and which involve an inventive step."[22] More specifically, the "inventive step" requirement demands the application present a technical problem then solved by the invention to illustrate that invention's industrial applicability.[23] U.S. statutory patent law imposes parallel standards, simply under a different nomenclature. Under the U.S. system, an invention must demonstrate usefulness,[24] non-obviousness,[25] and novelty[26] (respectively industrial application, inventive step, and novelty under the EPC). However, under U.S. patent law, an invention must also show enablement[27] and the best mode.[28]

The EPC standards for patentability may strike the unwary applicant as straightforward, but their deceptive nature lies in broadly stated requirements then restricted through the use of exceptions in subsequent articles. Article 52(2) lists specific categories of inventions excluded from patent protection, such as discoveries, scientific theories, mathematical methods, aesthetic creations, methods of doing business, and computer programs.[29] However, Article 53 represents the EPC's true limiting provision concerning patentable subject matter:

> European patents shall not be granted in respect of:
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> (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

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21 *Id.*

22 EPC, *supra* note 12, art. 52.

23 Akim F. Czmus, M.D., Comment, *Biotechnology Protection in Japan, the European Community, and the United States*, 8 TEMP. INT'L & COMP. L.J. 435, 438 (1994).

24 35 U.S.C. § 101 (1994).

25 *Id.* § 103.

26 *Id.* § 101–02.

27 *Id.* § 112.

28 The "best mode" requirement signifies the best mode contemplated by the inventor for making and using his invention at the time of filing the patent application. *Id.*

29 EPC, *supra* note 12, art. 52.

> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.[30]

This article restricts the scope of patentable subject matter under sections (a) and (b) only to broaden it anew as an exception to the exception in the second phrase of section (b).[31] As a result of such convoluted wording, plant or animal varieties seem unpatentable under the EPC, except as the products of microbiological processes.[32] However, Part II.B. of this Comment will show the analysis of Article 53(b) is not so straightforward. Further, Article 53 offers perhaps the best illustration of how the EPC falls short of its proposed goal of "[establishing] . . . certain standard rules governing patents so granted"[33] by failing to explain the key concepts of the exceptions to patentability.[34] Indeed, the absence of binding definitions of "contrary to 'ordre public' and morality," "essentially biological," and "microbiological" leaves the national courts of the EPC contracting states free to interpret and apply these terms to patents, and in doing so contradict one another.[35]

Once the Examining Division of the EPO reviews a patent application for compliance with the requirements of patentability and the exceptions to acceptable subject matter, it can either grant or refuse the application.[36] In the case of a denial, the applicant may then appeal to the Board of Appeal.[37] The Board of Appeal in turn can affirm the decision of the Examining Division or remit the application to the Examining Division for further prosecution.[38] Irrespective of how harmonious the examination procedure, the EPO loses the ability to amend or revoke a patent once granted, except in accordance with an opposition procedure.[39] There lies one of the significant differences with the U.S. patent system, which allows the Commissioner of Patents to order, on his own initiative, the reexamination of a patent, following a substantial new question of

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30 *Id.* art. 53.

31 KLARA GOLDBACH ET AL., PROTECTION OF BIOTECHNOLOGICAL MATTER UNDER EUROPEAN AND GERMAN LAW 46 (Walter Franzke ed., 1997).

32 *Id.*

33 EPC, *supra* note 12, at Preamble.

34 Czmus, *supra* note 23, at 441–42.

35 *Id.*

36 EPC, *supra* note 12, art. 97.

37 *Id.* art. 106.

38 *Id.* art. 111.

39 *See id.* art. 102.

patentability affecting a claim,[40] and to issue a certificate canceling such claim if the patentee fails to defeat the question.[41] The EPC compensates for the seemingly great limit on amendment and revocation by allowing any person to file with the EPO a notice of opposition to a European patent within nine months of the grant date.[42] The notice must only cite one of the grounds for opposition listed in Article 100:

> Opposition may only be filed on the grounds that:
>
> (a) the subject-matter of the European patent is not patentable within the terms of Articles 52 to 57;
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> (b) the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;
>
> (c) the subject-matter of the European patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed in accordance with Article 61, beyond the content of the earlier application as filed.[43]

The Opposing Division will hear the patentee and then take one of three possible actions: revocation of the patent, if the ground for opposition is prejudicial to its maintenance; rejection of the opposition, if the ground for opposition is not prejudicial to the maintenance of the patent in its unamended form; or amendment of the patent, if pursuant to the patentee's suggested modifications the patent and invention now comply with the EPC requirements.[44]

B. Analysis of the relevant EPO Decisions

In addition to the text of the EPC provisions, an analysis of a recent line of opinions by the EPO Technical Board of Appeal and Enlarged Board of Appeal helps elucidate the scope of the protection available in Europe for genetically modified organisms. Like the key terms of Article 53 that they seek to clarify, these opinions often do not dispose of all issues raised and at times even approach inconsistency. Nonetheless, such a study is crucial for understanding

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40 35 U.S.C. § 304 (1994).

41 *Id.* §§ 305–06.

42 EPC, *supra* note 12, art. 99.

43 *Id.* art. 100.

44 *Id.* art. 102.

why the legal representative for the University of Edinburgh so drafted Claim 48 of EP 0695351.

1. Decision T19/90

In 1985, Harvard University filed an application with the EPO for a transgenic[45] non-human mammalian animal (preferably a rodent such as a mouse) produced by introducing an activated oncogene into the animal's chromosomal deoxyribonucleic acid (DNA); upon incorporation into the genome, such oncogene increased the probability of the animal developing cancerous tumors.[46] In part for the present discussion, the Examining Division (the "Division") rejected the application by interpreting the term "animal varieties" in Article 53(b) as excluding animals per se from patentability.[47] Thus, Claims 1, 17, and 18 included unacceptable subject matter in the form of a method of producing a transgenic animal, the genetically modified animal itself, but also its descendents through sexual reproduction:

> 1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage.
>
> 17. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of Claims 3 to 10.
>
> 18. An animal as claimed in Claim 17 which is a rodent.[48]

Harvard University appealed the decision of the Division to the Technical Board of Appeal (the "Board"). On October 3, 1990, the Board issued its landmark decision T 19/90 setting aside the

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[45] "The term 'transgenic animals' shall mean animals which contain a foreign DNA sequence that is normally not observed in said animals." Goldbach, *supra* note 31, at 281. "Such animals are produced from fertilized eggs injected with foreign DNA that is subsequently incorporated into the genetic composition of the developing embryo." WILLIAM S. KLUG & MICHAEL R. CUMMINGS, CONCEPTS OF GENETICS 237 (Sheri L. Snavely ed., Prentice Hall, Inc. 6th ed. 2000) (1983).

[46] *See* European Patent No. 0169672 (issued May 13, 1992).

[47] *See* HARVARD/Onco-mouse: Application 85 304 490.7, 5 EUR. PAT. OFF. REP. 4, 7 (1990).

[48] *Id.* at 6.

Division's decision and remitting the application for further prosecution.[49] T 19/90 can be understood best as a three-part explanation of the exceptions to patentability under Article 53(b): 1. animal varieties, 2. essentially biological processes, and 3. microbiological processes.

First, the Board rested its interpretation of "animal varieties" on its decision T 320/87 LUBRIZOL/Hybrid plants, which held that exceptions to patentability should be strictly construed,[50] and on Article 177(1), stating that the English, French, and German texts of the EPC are equally authentic.[51] The Board identified a discrepancy in the terminology used between the three texts of Article 53(b):

> European patents shall not be granted in respect of:
>
> (a) . . .
>
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; . . . .
>
> Les brevets européens ne sont pas délivrés pour:
>
> (a) . . .
>
> (b) les variétés végétales ou les races animales ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux; . . . .
>
> Europäische Patente werden nicht erteilt für:
>
> (a) . . .
>
> (b) Pflanzensorten oder Tierarten sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren; . . . .[52]

Indeed, the French term *races animales* and the German term *Tierarten* translate in English as animal breeds[53] and animal species[54] respectively, and as such the German term covers a higher taxonomic order than both the English and French counterparts.[55] The Board's

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[49] HARVARD/Onco-mouse: T 19/90, 5 EUR. PAT. OFF. REP. 501, 513 (1990).

[50] *Id.* at 502.

[51] EPC, *supra* note 12, art. 177(1).

[52] *Id.* art. 53(b).

[53] COLLINS ROBERT FRENCH-ENGLISH ENGLISH-FRENCH DICTIONARY 740 (5th ed. 1998).

[54] THE OXFORD-DUDEN GERMAN DICTIONARY 709 (rev. ed. 1997).

[55] HARVARD/Onco-mouse: T 19/90, *supra* note 49, § 4.2, at 510.

conceptualization of "higher taxonomic order" signifies the German term *Tierarten* includes more complex organisms, which imparts this term with a greater scope of exclusion and leads to narrower protection for the invention. Thus, an applicant seeking protection for a genetically modified animal must at most satisfy the limits on patentability imposed by the German term *Tierarten*. In addition to the language discrepancy, the Board noted the legislators could not have intended to exclude animal varieties and animals as such from patentable subject matter, and thus rejected this interpretation of Article 53(b) by the Division.[56] The legislators used the word "animals" in a general sense and as a qualifier in "animal varieties," in the same section (b) of Article 53, which suggests that the terms "animal varieties" (*races animales*, *Tierarten*) and "animals" (*animaux*, *Tiere*) are not synonymous.[57] The Board remitted the application to the Division with the order to examine whether the application's subject matter qualified as an "animal variety" within the elucidated meaning of Article 53(b).[58]

Second, the Board confirmed the Division's interpretation of "essentially biological processes" as meaning the opposite of man-made transformations.[59] Claim 1 recites the method for producing a transgenic non-human mammalian animal by injecting the oncogene into a vector plasmid and transfecting a cell at an early embryonic stage, or a fertilized oocyte no later than the 8-cell stage.[60] Hence, if the subject matter of the application survived the "animal variety" exception on remand, the Division should hold the process claim[61]—Claim 1—as patentable. The product claims,[62] Claims 17 and 18, presented a greater challenge, especially Claim 17, which covered the transgenic animal produced according to the method of Claim 1 and the descendents of such an animal. The transgenic animal resulted from a man-made transformation, but its descendents could be the outcome of the biological process of sexual reproduction and thus fall under the "essentially biological processes" exclusion from patentability.[63] The Board concluded the Division's analysis of Claim

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56 *Id.* § 4.4, at 510.

57 *Id.* § 4.6, at 510.

58 *Id.* § 4.8, at 511.

59 *See id.* § 4.9.1, at 511.

60 EP 0169672, *supra* note 46.

61 *See generally* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 753 (David L. Shapiro ed., 1998) (for a definition of "process claim").

62 *See generally id.* (for a definition of "product claim").

63 *See* HARVARD/Onco-mouse: T 19/90, *supra* note 49, § 4.9.2, at 511–12.

17 being an attempt to bypass the limitation under Article 53(b) by combining a non-biological and a breeding process was incorrect.[64] Perhaps T 19/90's greatest flaw lies in the Board remitting this issue to the Division without further guidance. The Board simply wrote: "[T]his question may be left open for the time being since the basic assertion in the contested Decision – that Claim 19[65] circumvents Article 53(b) EPC, and thus precludes the grant of a patent – is wrong in any case."[66] The question referred to contemplates whether the original transgenic animal and its descendents represent different products.

Third, the Board rejected the Division's disposition of the "microbiological processes" exclusion to patentability. The Division justified avoiding an examination of whether the invention included a microbiological process by stating that the second phrase of Article 53(b) failed to apply if the product—here a transgenic animal—was excluded from patentability under the first phrase of the same article.[67] The Board concluded that the second phrase of Article 53(b) must be read as an exception to the exception, thus reinstating the general standards of patentability of Article 52(1) to microbiological processes and the products thereof.[68]

On remand, the Division finally granted the claims in dispute on May 13, 1992.[69] In part, the Division held on the issue of whether the transgenic non-human mammalian animal qualified as an "animal variety":

> The only claims in the present patent application that are directed to animals are generically drafted claims to non-human "mammals" and to "rodents." Accordingly, the question to be answered is whether or not the subject-matter of these claims is covered by the term "animal variety" or its counterparts in the other two official languages as referred above. Although the term

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[64] *Id.* § 4.9.2, at 512.

[65] Applicant redrafted Claim 17 as Claim 19 in his first auxiliary request as part of his appeal to the Technical Board of Appeal. Claim 19 is, for the most part, identical to Claim 17 of the original patent application:

> 19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at an embryonic stage, said oncogene optionally being further defined according to one of Claims 3 to 10.

Id. § IV, at 505.

[66] *Id.* § 4.9.2, at 512.

[67] *Id.* § 4.10, at 512.

[68] *Id.*

[69] EP 0169672, *supra* note 46.

> "animal variety" is not entirely clear, in particular in view of the differing wording in the three equally binding languages of the EPC, it nevertheless can be stated with certainty that rodents or even mammals constitute a taxonomic classification unit much higher than species ("Tierart"). An "animal variety" or "race animal" [sic] is a sub-unit of a species and therefore of even lower ranking that a species. Accordingly, the subject-matter of the claims to animals *per se* is considered not to be covered by the above three terms of Article 53(b) EPC.[70]

The grant of the application as EP 0169672 did not mark the end of the dispute. Pursuant to EPC Article 99, seventeen different parties, including religious groups, animal rights organizations, legal and political entities, environmental protection agencies, and private individuals filed notices of opposition with the EPO to the Harvard onco-mouse patent.[71] The EPO Opposition Division held oral proceedings related to these oppositions on November 21, 1995.[72] Nonetheless, these proceedings yielded no definite resolution; the hearings ended in confusion on November 24, 1995 with four EPO officials leaving the room.[73] The Opposition Division declined to return an immediate decision and plainly stated that further notices of opposition must be submitted in writing to a tribunal.[74]

For almost five years, the Opposition Division remained silent while the patentee, Harvard University, impelled for a favorable decision in light of the Enlarged Board of Appeal G 01/98 opinion concerning transgenic plants.[75] Finally, on September 20, 2000, the

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[70] HARVARD/Onco-mouse: Application 85 304 490.7, 6 EUR. PAT. OFF. REP. 525, 526 (1991).

[71] List of entities that filed notices of opposition: Compassion in World Farming Supporters et al.; Bundesverband der Tierversuchsgegner et al.; Ökologisch Demokratische Partei; Büchner Reinhard; Meinel A. et al., Fraktion Bündnis 90; Fuchs U. et al.; Fraktion Bündnis 90 Die Grünen im Bayer. Landtag; Evangelischer Stadtkirchenverband Köln; Bundesland Hessen vertr. durch das Hessische Ministerium für Jugend, Familie und Gesundheit; Koechlin F., Schenkelaars P. et al. "No Patents on Life"; Voggenhuber J. et al. Grüner Klub im Parlament; Keine Patente auf Leben; Sylvia Hamberger et al. "Kein Patent auf Leben"; Bundeszentrale der Tierversuchsgegner Österreichs; Wiener Tierschutzverein und Zentralverband der Tierschutzvereine Österreichs; Helletsberger H.; Deutsches Tierhilfswerk. European Patent Register, *at* http://www.epoline.org/register.html (last updated Dec. 12, 2001) (search for publication number EP0169672).

[72] *Id.*

[73] Tom Wilkie, *"Onco-mouse" Spreads Confusion in Patent Office*, THE INDEPENDENT, Nov. 25, 1995, at 8, LEXIS, Nexis World Library, Allwld File.

[74] *Id.*

[75] E-mail from Philip L. McGarrigle Jr., Chief Intellectual Property Counsel, Affymetrix, Inc. (Jan. 8, 2001, 08:51:43 PST) (on file with author). See below Part II.B.3. for a discussion of G 01/98.

EPO invited Harvard University, and sixteen different parties advocating for the revocation of the onco-mouse patent, to request that the opposition procedure be resumed.[76] On May 9, 2001, the EPO dispatched to all parties summons to three days of oral proceedings, starting on November 6, 2001.[77] At the close of the second day of hearings, the Opposition Division ruled that Harvard University's onco-mouse patent was maintained in amended form and "the patent must be limited to transgenic rodents containing an additional cancer gene."[78] In its press release, the EPO added that either Harvard University or any of the opponents may appeal the Opposition Division's ruling.[79]

2. Decision T 356/93

Decision T 356/93[80] contributes the next piece to what seems a puzzle for the elucidation of the key terms of Article 53(b). On October 10, 1990, the Examining Division granted European patent No. 0242236 to its applicant Plant Genetic Systems.[81] The invention claimed the production of plants and seeds resistant to the class of herbicides known as glutamine synthetase inhibitors (GSIs), and thus selectively protected against weeds and fungal diseases.[82] The organization Greenpeace then filed a notice of opposition declaring the subject matter of the invention unpatentable under EPC Article 53(b)'s "plant varieties" exclusion.[83] The Opposition Division rejected the notice and T 356/93 was issued as the Technical Board's decision following Greenpeace's appeal.

The Technical Board wrote its "conclusions [were] not at variance with Decision T 19/90,"[84] but in fact, T 356/93 directly

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[76] Press Release, European Patent Office, "Oncomouse" opposition proceedings resume at EPO (Nov. 5, 2001), *available at* http://www.european-patent-office.org/news/pressrel.

[77] *Id.*

[78] Press Release, European Patent Office, European Patent Office limits Harvard's "oncomouse" patent (Nov. 7, 2001), *available at* http://www.european-patent-office.org/news/pressrel.

[79] *Id.*

[80] *See generally* Hans-Rainer Jaenichen, Dr., *Is It Possible to Patent Transgenic Animals and Transgenic Plants in the European Patent Office After the Technical Board's Decision T 356/93, "Plant Cells/PLANT GENETIC SYSTEMS"?*, 14 BIOTECH. L. REP. 545 (1995) (for an introduction to the main points of T 356/93 before reading the original text of the decision).

[81] PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, 5 EUR. PAT. OFF. REP. 357, 360 (1995).

[82] *Id.* at 357.

[83] *Id.*

[84] *Id.* § 40.12, at 382.

contradicts the holding of the Examining Division on remand that a claim to a genetically modified animal survives Article 53(b)'s limits on patentability. The full text of disputed Claims 1, 7, 14 and 21, along with a very simplified summary of the substance of those claims, is necessary for understanding the contradictory holding of T 356/93:

> 1. Process for controlling the action in plant cells and plants comprising such cells of a glutamine synthetase inhibitor when the former are contracted with the latter, which comprises causing the stable integration in the genomic DNA of said plant cells of a heterologous DNA including a promoter recognized by polymerases of said plant cells and a foreign nucleotide sequence capable of being expressed in the form of a protein in said plant cells and plants, under the control of said promoter, and wherein said protein has an enzymatic activity capable of causing inactivation or neutralization of said glutamine synthetase inhibitor.
>
> 7. Process for producing a plant or reproduction material of said plant including a heterologous genetic material stably integrated therein and capable of being expressed in the said plants or reproduction material in the form of a protein capable of inactivating or neutralizing the activity of a glutamine synthetase inhibitor, which process comprises transforming cells or tissue of said plants with a DNA recombinant containing a heterologous DNA including a foreign nucleotide sequence encoding said protein as well as the regulatory elements selected among those which are capable of causing the stable integration of said heterologous DNA in said plant cells or tissue and of enabling the expression of said foreign nucleotide sequence in said plant cells or plant tissue, regenerating plants or reproduction material of said plants or both from the plant cells or tissue transformed with said heterologous DNA and, optionally, biologically replicating said last mentioned plants or reproduction material or both.
>
> 14. Plant cells, non-biologically transformed, which possess a heterologous DNA stably integrated in their genome, said heterologous DNA containing a foreign nucleotide sequence encoding a protein having a non-variety specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognized by the polymerases of said plant cells.
>
> 21. Plant, non-biologically transformed, which possesses, stably integrated in the genome of its cells, a foreign DNA nucleotide

> sequence encoding a protein having a non-variety-specific enzymatic activity capable of neutralizing or inactivating a glutamine synthetase inhibitor under the control of a promoter recognised by the polymerases of said cells.[85]

In brief, Claim 1, a process claim, covered a process for controlling a GSI in plant cells and in plants containing such cells, by stably integrating a controller enzyme encoded by foreign DNA into the genomic DNA of the plant cells.[86] Claim 7, also a process claim, covered the method of producing a plant containing the stably integrated foreign DNA.[87] Claim 14, a product claim, covered the plant cells containing the foreign DNA and thus expressing the controller enzyme.[88] Claim 21, also a product claim, covered the plants grown from the cells of Claim 14.[89]

The Technical Board focused on interpreting the terms "essentially biological process" and "microbiological process" to determine whether the subject matter of the invention encompassed "plant varieties." The Board first formulated an indirect definition of an "essentially biological process" by describing which type of process survives the exceptions to patentability under the "essentially biological" concept, namely "a process . . . comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result."[90] Thus, plants generated following at least one essential technical step or, better still, according to a microbiological process, do not fall under the "essentially biological process" restriction and are patentable.

The Board then explained "microbiological process" following what it called an objective teleological approach—or "the principal of equal treatment of what is of the same kind or similar"[91]—to justify regulating subject matter that legislators could not have anticipated. First, the Board appreciated that modern microbiology extended beyond such traditional processes as fermentation and biotransformation to include also genetic engineering techniques.[92]

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85 *Id.* § I, at 360–61.

86 Dotson, *supra* note 1, at 935.

87 *Id.*

88 *Id.*

89 *Id.*

90 PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, *supra* note 81, § 28, at 376.

91 *Id.* § 32, at 377.

92 *Id.* § 35, at 378.

Second, the Board noted that the term "microorganisms" covered not only bacterial and yeast cells, but also all cells maintained and grown in culture in a way similar to algae, fungi, protozoa and human, animal and plant cells.[93] Third, the Board combined these observations to conclude that "microbiological processes" comprise "technical activities in which direct use is made of microorganisms"[94] and "'the products thereof' . . . encompasses products which are made or modified by microorganisms as well as new microorganisms as such."[95] However, the Board then restricted this definition severely by stating that multi-step technical processes cannot be seen as equivalents of microbiological processes simply because the former include a microbiological step; nor can the products of such multi-step technical processes qualify as "products thereof" within the meaning of Article 53(b) second phrase.[96]

Armed with this definition, the Board held the process claims (Claims 1 and 7) patentable because the process for introducing recombinant DNA into the plant cells or tissue represented "an essential technical step which has a decisive impact on the desired final result" (i.e., not an essentially biological process, under the Board's indirect definition of this term) despite such transformations being dependent on chance.[97] Similarly, the Board allowed product Claim 14 because the definition of "plant varieties" does not extend to plant cells.[98] However, the Board's rejection of Claim 21 single-handedly overruled the Examining Division's decision on remand in the Harvard onco-mouse case and created an extremely negative precedent for the biotechnology industry.

The Board noted the language of Claim 21 carefully avoided references to varieties, specific plant genes or species,[99] but the working examples cited "genetically transformed" plant varieties as embodiments of the invention.[100] The Board concluded Claim 21 covered modified plant varieties showing the distinctive feature and thus was unpatentable.[101] Further, the plant of Claim 21 was obtained

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93 *Id.* § 34, at 377.

94 *Id.* § 35, at 378.

95 *Id.* § 36, at 378.

96 PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, *supra* note 81, § 39, at 379.

97 *Id.* § 40.1, at 379–80.

98 *Id.* § 40.2, at 380.

99 *Id.* § 40.3, at 380.

100 *Id.* § 40.5, at 380.

101 *Id.* § 40.11, at 382.

from the initial microbiological recombinant DNA transformation of plant cells followed by the multiplication and propagation of the transformed plant cells.[102] Hence, only the first step of the multi-step process was microbiological, while the subsequent steps were essentially biological. The following statement best illustrates the repercussion of this reasoning:

> No transgenic plant or animal could ever possibly be patentable under the Board's holding because the production of a differentiated life-form always includes essentially biological processes. Moreover, multicelled transgenic life-forms would also be unpatentable because patent disclosures invariably give specific examples comprising a particular species, and production of these inventions always requires performance on a particular species, resulting in an unpatentable "derived variety."[103]

3. Decision G 01/98

The Enlarged Board of Appeal (the highest decision-making body of the EPO) issued Decision G 01/98 in response to a question referred by the Technical Board of Appeal:

> Does a claim which relates to plants but wherein specific plant varieties are not individually claimed *ipso facto* avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?[104]

This question in turn arose from the Technical Board's review of an opposition filed by Greenpeace[105] to European patent No. 0436257 granted on September 14, 1994 to Novartis for an invention controlling plant pathogens in agricultural crops.[106] The patent claimed transgenic plants whose genomes were transformed with specific foreign genes, the expression of which caused the production of antipathogenetically active substances, and the methods of producing such plants.[107]

The Enlarged Board first noted that the product claims described the transgenic plants simply by their characteristics for

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[102] PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, *supra* note 81, § 40.9, at 381.

[103] Dotson, *supra* note 1, at 941.

[104] NOVARTIS/Transgenic plant: G 01/98, 5 EUR. PAT. OFF. REP. 303 (2000).

[105] *Id.* § 3.9, at 318.

[106] *See* European Patent No. 0436257 (issued Sep. 14, 1994).

[107] NOVARTIS/Transgenic plant: G 01/98, *supra* note 104, § II, at 305.

inhibiting the growth of plant pathogens.[108] The invention defined neither a single variety nor a multiplicity of varieties, so that its subject matter did not aim to cover a specific variety or varieties of plants.[109] Further, the Enlarged Board explained the patentee's contribution as a series of steps. The first step consisted of developing a technique for the introduction of a gene into the plant's genome and the second step of carrying out this procedure.[110] The patentee's choice of one suitable plant for the embodiment of his invention did not represent a step of his contribution.[111] To find otherwise would grant the inventor inappropriate protection because the aim of genetic engineering is not the production of specific plant varieties.[112] Further, the inventor disclosed a technique for introducing the gene in all plants and not simply in a few varieties.[113] The Enlarged Board concluded the exclusion under Article 53(b) failed to apply when the subject matter related to plants but did not claim specific plant varieties.[114]

III. ANALYSIS OF EP 0695351

EP 0695351 represents the most recent patent whose interpretation by the national state courts stands to affect the protection given to biotechnological inventions in Europe. The EPO awarded this patent to the University of Edinburgh on December 8, 1999 for an invention relating to the method for isolation, selection, and propagation of genetically modified animal stem cells,[115] and for transgenic animals used in such method.[116] The patent includes forty-eight claims, of which only Claims 37[117] and 38[118] are product claims

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108 *Id.* § 3.1, at 313.

109 *Id.*

110 *Id.* § 3.8, at 318.

111 *Id.*

112 *Id.*

113 NOVARTIS/Transgenic plant: G 01/98, *supra* note 104, § 3.8, at 318.

114 *Id.* § 3.10, at 319.

115 Stem cells are defined as such cells isolated from tissue samples which are capable of differentiating to form certain cell types found in the adult animal. Embryonic stem cells display the greatest ability for differentiation. EP 0695351, *supra* note 10.

116 *Id.*

117 37. An animal cell capable of being cultured to form a mixture of cells including desired stem cells and cells other than the desired stem cells, characterised in that all cells in the said mixture of cells contain a selectable marker and in that in the said mixture of cells, under appropriate selective culture conditions, differential expression of the selectable marker in (a) the desired stem cells and (b) cells other than the desired stem cells enables

directed to the animal cells, which pursuant to Decision T 356/93 fall outside Article 53(b) "animal varieties" restriction to patentability.[119] All other claims cover methods of preparation. Unlike the Harvard onco-mouse, the Plant Genetic Systems, and the Novartis patents, EP 0695351 includes no direct claim to a genetically modified organism; yet its Claim 48, a process claim, ignited a flurry of controversy:

> 48. A method of preparing a transgenic animal, said animal comprising a selectable marker capable of differential expression in (a) desired stem cells and (b) cells other than desired stem cells, the method comprising:
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> providing a blastocyst;
>
> providing animal cells according to any of Claims 37 – 38;
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> introducing the animal cells into the blastocyst;
>
> transferring the blastocyst to a recipient; and
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> allowing an embryo to develop to a chimaeric animal to enable germline transmission of the selectable marker.[120]

The interest of Claim 48 lies in the difficulty of ascertaining whether it resulted from crafty drafting or an opportune mistake. The patentee's representative chose not to draft Claim 48 as: 48. A transgenic animal whose stem cells contain a selectable marker introduced into said animal . . . or 48. A transgenic animal, which possesses, stably integrated in the genome of its cells, a selectable marker . . . . Thus, as written, Claim 48 avoids a line of prosecution similar to that of the Harvard onco-mouse patent, where a claim to a transgenic animal must be broad enough to encompass a taxonomic order higher than the German term *Tierarten* (animal species) to defeat the "animal varieties" bar to patentability. The patentee also averted the EPO's objection that Article 53(b)'s second phrase "products thereof," as an exception to the exception restoring patentability under Article 53(a), fails to protect the products of multi-

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> selective survival or growth of the desired stem cells to occur, so as to enable isolation and/or enrichment and/or propagation of desired stem cells.

Id.

[118] 38. An animal cell as claimed in Claim 37 wherein the selectable marker is an antibiotic resistance gene. *Id.*

[119] *See* PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, *supra* note 81.

[120] EP 0695351, *supra* note 10.

step processes including microbiological and essentially biological steps.[121]

The University of Edinburgh elected to protect its method of preparing the transgenic animal, which seems wise in light of T 19/90's failure to resolve whether the descendents of a patented transgenic animal fall under the scope of protection. Indeed, an individual would avoid the risk of infringement, brought by replicating the method of preparing the transgenic animal, by simply using that animal's descendents. With a protected method, the University of Edinburgh can draft material transfer agreements and license agreements to exercise strict control over its invention and transgenic animal.[122] The U.S. patent granted for the same invention offers an interesting parallel. It, too, contains no language directly claiming the genetically modified animal; only its Claim 15 covers "an isolated mammalian stem cell."[123]

In its allowed form, Claim 48 reads as a process claim for the method of preparing the transgenic animal. However, process claims must satisfy the "essentially biological processes" and "microbiological processes" limits imposed under Article 53(b). Following the Technical Board's Decision T 356/93, the success of such claims appeared unpredictable. When assessing the process claim (Claim 7), the Technical Board declared:

> [A]lthough the subsequent steps of regenerating and replicating the plants or seeds make use of the "natural" machinery, the decisive step, namely the insertion of the relevant DNA sequence into the genome of the plant, could not occur without human intervention. . . . Therefore, the process of Claim 7 as a whole is not "essentially biological" and, thus, not excluded from patentability under Article 53(b) EPC, first half-sentence.[124]

However, further in the opinion, the Technical Board concluded that a multi-step process could not be equated with "microbiological processes" simply because its initial step involved a microbiological manipulation.[125] Nonetheless, the allowance of EP 0695351 Claim 48 seems justified under the Enlarged Board's statement in Decision G 01/98: "To escape the prohibition of Article 53(b) EPC, the

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[121] *See* holding of T 356/93 analyzed under Part II.B.2.

[122] Telephone Interview with Dr. Carol A. Stratford, Ph.D., J.D., Vice President, Intellectual Property, Galileo Laboratories, Inc. (Jan. 7, 2001).

[123] U.S. Patent No. 6,146,888 (issued Nov. 14, 2000).

[124] PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, *supra* note 81, § 40.1, at 379-80.

[125] *Id.* § 40.9, at 381–82.

approach adopted in Article 2 no. 2 of the draft E.C. Biotechnology Directive would require at least one clearly identified non-biological process step but would allow any number of additional essentially biological steps."[126] It is interesting to note that the patentee described every step of the method, thus suggesting at least four manipulations requiring "human intervention," when more simply, the invention consists of transfecting embryonic animal cells with the selectable marker and using the animal's biological reproductive system to develop a chimeric animal showing that characteristic.

An analysis of EPC Article 64(2) outlines the deftness of the patentee's representative for claim drafting. As explained above, Claim 48 relates to the method of preparation and not to the transgenic animal itself. However, Article 64(2) reads: "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process."[127] Thus, the patentee circumvents the EPO's possible objection that the genetically modified animal does not qualify as the product of a "microbiological process," and indirectly protects the transgenic animal. However, the Technical Board in Decision T 356/93 declared: "A claim is not allowable if the grant of a patent in respect of the invention defined in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability."[128] This statement resonates as an empty warning in view of the Enlarged Board's structural argument, in Decision G 01/98, that under the EPC, the national patent courts, which are already responsible for examining interpretation and infringement issues, shall apply the provisions of Article 64(2):

> The requirements on patentability to be examined by the EPO are contained in Part II, Chapter I EPC (Arts 52–57); Article 64 (2) EPC belongs to Part II, Chapter III, containing provisions concerning the effects of patents and patent applications and is to be applied by the courts responsible for deciding on infringement cases.[129]

Therefore, Article 64(2) also fails to raise a consequential obstacle to the allowance of Claim 48.

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126 NOVARTIS/Transgenic plant: G 01/98, *supra* note 104, § III (c), at 307.

127 EPC, *supra* note 12, art. 64(2).

128 PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, *supra* note 81, § 40.7, at 381.

129 NOVARTIS/Transgenic plant: G 01/98, *supra* note 104, § XI 4., at 320.

EPC Article 64 may not bar the allowance of Claim 48, but this article delineates the greatest controversy surrounding this claim. Indeed, if the national patent courts rule on matters of interpretation and infringement, then their decisions as to EP 0695351 Claim 48 may vary along with which of the three equally binding languages of the EPC they review. More specifically, the three versions of Claim 48 read: "A method of preparing a transgenic animal,"[130] "*Procédé de préparation d'un animal transgénique*,"[131] and "*Verfahren zur Herstellung eines transgenetischen Tieres*,"[132] in English, French and German respectively. The definition of the French term *animal* translates as "(general concept, including man) a living being gifted with sensibility and mobility, "[133] and the German term *Tier* as "living organism which nourishes itself from organic matter, and which is capable of moving and reacting to stimuli."[134] One of the definitions for the English term "animal" reads: "a multicellular organism of the kingdom Animalia, characterized by a capacity for locomotion, nonphotosynthetic metabolism, pronounced response to stimuli, restricted growth, and fixed bodily structure."[135] A second definition states: "an animal organism other than a human being."[136] Thus, absent the qualifier "non-human" in all three versions of Claim 48, there exists no single and definite interpretation, and Claim 48 may be read as: "A method of preparing a transgenic human animal" (i.e., a human clone) in all three texts[137] (contrary to the EPO's released statement which reported the possibility of such a reading for the English text only).[138]

The University of Edinburgh obtained EP 0695351 on December 8, 1999 and the EPO issued the following press release in January 2000:

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130 EP 0695351, *supra* note 10.

131 *Id.*

132 *Id.*

133 *(Concept général, incluant l'homme) Être vivant organisé, doué de sensibilité et de motilité.* LE NOUVEAU PETIT ROBERT 84 (3rd ed. 1996).

134 *Lebewesen, das sich von organischen Stoffen nährt u. sich bewegen u. auf Reize reagieren kann.* DEUTSCHES WORTERBUCH col. 3566 (2nd ed. 1971).

135 THE AMERICAN HERITAGE DICTIONARY 53 (3rd ed. 1993).

136 *Id.*

137 Note that the claims of the U.S. patent granted for the Harvard onco-mouse include the qualifier "non-human." U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

138 Press Release, European Patent Office, Declaration of the European Patent Office with regard to Patent No. EP 0695351 granted on 8 December 1999 (Feb. 22, 2000), *available at* http://www.european-patent-office.org/news/pressrel.

> The European Patent Office has already admitted this error and regrets that it has occurred. The Office will take every care to prevent such errors recurring in the future. Contrary to many accounts, and despite the omission of the qualifier "(non-human)," the scope of protection of Patent No. EP 0695351 does not extend to human cloning. That is because under Articles 69[139] and 84[140] of the European Patent Convention the patent claims must be supported by the patent description. This is not the case here.[141]

Nonetheless, the description for EP 0695351 seems to support this reading of Claim 48 in light of its sentence: "In the context of this invention, the term 'animal cell' is intended to embrace all animal cells, especially of mammalian species, including human cells."[142] Thus, if the term "animal cells" covers "human cells," then the words "animal" and "human" are to be equated throughout the description and claims. Further, the Enlarged Board in Decision G 01/98 declared that: "On the contrary, the Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions . . . establishes that promotion of innovation in this field is considered necessary in Europe."[143]

In conclusion of the analysis, EP 0695351 Claim 48 seems more the result of a calculated procedure by both sides (patentee and EPO) than the product of inadvertence. However, if the reader still believes Claim 48 was issued from an oversight of the EPO Examining Division, this Comment's conclusion evaluates whether the EPC provisions could rectify the dangerous precedent EP 0695351 will set if left in its presently granted form.

IV. CONCLUSION

Since the grant of EP 0695351 on December 8, 1999, the EPO has received fourteen notices of opposition to this patent (in brief,

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139 Article 69- Extent of protection

The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

EPC, *supra* note 12, art. 69.

140 Article 84- The claims

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

Id. art. 84.

141 EPO press release dated Feb. 22, 2000, *supra* note 138.

142 EP 0695351, *supra* note 10.

143 NOVARTIS/Transgenic plant: G 01/98, *supra* note 104, § 3.9, at 318–19.

from environmental agencies, religious groups, political parties, Germany's Ministry of Justice, Pro-Life groups, and the Government of the Republic of Italy).[144] The EPO informed the University of Edinburgh of the oppositions on December 27, 2000 and granted an eight-month reply period.[145] As of December 12, 2001, the EPO had ruled favorably on the admissibility of four such notices of opposition and scheduled oral proceedings for April 22, 2002.[146]

One or more of these opposition procedures may finally prove fatal to EP 0695351 Claim 48. Indeed, an attack on Claim 48 can rest on at least two grounds for opposition listed under Article 100: "the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art," or "the subject-matter of the European patent is not patentable within the terms of Articles 52 to 57."[147]

Under the first ground, an opponent would argue the broadest reading of Claim 48 covers a method of preparing all transgenic animals, which in the absence of the qualifier "non-human" includes transgenic human animals (or human cloning). However, the patent description focuses solely on mice as a preferred embodiment of the invention. Thus, the Opposition Division may decide that a person of ordinary skill in the art could not successfully extrapolate the method from production of transgenic mice to human cloning, and thus order the patentee to amend Claim 48 (revocation seems too strong of a remedy). However, the claimed invention relates to the isolation, selection and propagation of animal transgenic stem cells and not to the transgenic animal as such, so that the working examples using mice could suffice to enable the method of Claim 48.

Under the second ground of opposition, an opponent would argue most likely that Claim 48 violates EPC Article 53(a)'s "ordre

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[144] List of entities that filed notices of opposition: Greenpeace Deutschland e.V., PDS-Bundestagsfraktion, Ökumenischer Rat der Kirchen in Österreich, Bundesrepublik Deutschland Bundesministerium der Justiz z.H. Dr. E. Hucko, Alliance Pour les Droits de la Vie, Aktion Leben Österreich, Greenpeace e.V. Sammeleinspruch, Bündnis 90 Die Grünen-Bundestagsfraktion Dr. B. Laubach, Dr. Ruth Tippe "Kein Patente auf Leben," Het Koninkrijk der Nederlanden, Deutsche Forschungsgemeinschaft, Regierung der Republik Italien Unterstaatssekretär Dr. Enrico Micheli, Dr. Jürgen Kaiser, Bündnis 90/Die Grünen Ortsverband Vaihingen Kreisverband. European Patent Register, *at* http://www.epoline.org/register.html (last updated Dec. 12, 2001) (search for publication number EP0695351).

[145] *Id.*

[146] List of entities that filed admissible notices of opposition according to the EPO: Greenpeace Deutschland e.V., Ökumenischer Rat der Kirchen in Österreich, Bundesrepublik Deutschland Bundesministerium der Justiz z.H. Dr. E. Hucko, Regierung der Republik Italien Unterstaatssekretär Dr. Enrico Micheli. *Id.*

[147] EPC, *supra* note 12, art. 100.

public" or morality exception to patentability.[148] In its initial opinion rejecting the Harvard onco-mouse patent application, the Examining Division defined the purpose of the "ordre public" or morality limitation as serving "to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour."[149] Certainly, an interpretation of Claim 48 as covering human cloning will satisfy this definition. However, the Technical Board in Decision T 19/90 offered the following balancing test to guide the Examining Division in assessing Article 53(a) violations: "The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."[150] The description of EP 0695351 states the invention proposes a method for isolating stem cells from tissue samples using a selectable marker (e.g., an oncogene), which stem cells are then used for research or medical procedures.[151] Thus, the patentee may argue that the stem cells can be used to test suspected carcinogens and the protecting effect of antioxidants, so that like the Harvard onco-mouse, the invention contributes to the treatment of cancer.

The outcome of the opposition procedures is difficult to predict. Interestingly, the EPO revoked the Novartis patent (EP 0436257) on May 10, 2000, following oral proceedings. The Opposition Division justified its decision by stating the claims failed the novelty requirement under the EPC provisions because of public prior use in India.[152] Novartis had received its European patent shortly before the grant of EP 0695351, and together these patents rekindled the controversy over life-patents in Europe. Perhaps the only certainty related to Claim 48 rests in its possible invalidation through the national patent courts. For those nations outwardly banning human cloning, the hypothesized reading of Claim 48 as "A method for preparing a transgenic human animal" will bring its definite end.

The following oral statement by the President of the EPO, Mr. Ingo Kober, on June 27, 2000, like the above mentioned EPO press

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148 *Id.* art. 53(a).

149 HARVARD/Onco-mouse: Application 85 304 490.7, *supra* note 47, § 10.2, at 11.

150 HARVARD/Onco-mouse: T 19/90, *supra* note 49, § 5, at 513.

151 EP 0695351, *supra* note 10.

152 Press Release, European Patent Office, "Neem tree oil" case: European patent No. 0436257 revoked (May 10, 2000), *available at* http://www.european-patent-office.org/news/pressrel.

release acknowledging the EPO's mistake while prosecuting EP 0695351, illustrates that the controversy surrounding patent protection for genetically modified organisms in Europe may be more serious than the EPO initially envisaged:

> The patent system cannot decide whether a technology is permissible; the responsibility for considering and resolving such questions lies with quite different branches of the law. Nor do patent offices issue safety certificates. Dangerous or ethically questionable technology cannot be held in check with the help of patent law.
>
> . . . .
>
> The idea that the EPO has been deliberately breaking the law is also contradicted by the extensive system of checks via *opposition* and *appeal proceedings* after *grant* and *revocation proceedings* before national courts: in Germany, for example, before the Federal Patents Court at first instance, with the possibility of appeal to the Federal Court of Justice. Despite all claims to the contrary, European patents – and the activities of the European Patent Office – are subject to numerous independent controls and checks at both national and international level.[153]

Mr. Kober also invites critics to observe the recent changes in European patent law. He cites the E.C. Biotechnology Directive,[154] approved in its final form in 1998, which offers guidelines for the protection of biotechnological inventions and recognizes the fundamental importance of such inventions for the industrial development of Europe.[155] Furthermore, a Diplomatic Conference was held in late November 2000 to revise the EPC provisions.[156] Notably as a result of this Conference, the EPO will offer a patentee the option of electing a central procedure for limiting the protection afforded by the patent, should such a patent be found invalid, thus

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[153] Press Release, European Patent Office, Comments on genetic engineering (Excerpt from the address of the President of the EPO, Mr. Ingo Kober, on 27 June at the annual press conference of the Office in Munich) (June 27, 2000), *available at* http://www.european-patent-office.org/news/pressrel.

[154] *Id.*

[155] Council Directive 98/44 of 6 July 1998 on the legal protection of biotechnological inventions, 1998 O.J. (L 213) 1, *available at* http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0044.html (July 30, 1998).

[156] Press Release, European Patent Office, Opening of the Diplomatic Conference to revise the EPC (Nov. 20, 2000), *available at* http://www.european-patent-office.org/news/pressrel.

avoiding national patent offices and courts altogether.[157] The Chairman of the Administrative Council of the EPO explained: "This limitation option not only answers long-standing calls for such a procedure from experts in the field, but is also in the public interest, as evidenced by the controversy surrounding certain biotechnology patents. It will act as an incentive to amend incorrectly granted patents quickly and at low cost."[158] Nonetheless, the E.C. Biotechnology Directive demands that European countries comply with its text and the EPC contracting states have yet to ratify the Conference's new provisions.[159] Thus, until Europe can claim a complete harmonization of its patent laws, Europe seems destined to remain a second player to the United States in the biotechnology industry.

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[157] Press Release, European Patent Office, Statement by Dr Roland Grossenbacher, Chairman of the Administrative Council of the European Patent Organisation (Nov. 29, 2000), *available at* http://www.european-patent-office.org/news/pressrel.

[158] *Id.*

[159] *Id.*