

Abstract

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Edited by Matthew B. Sellers

THE EFFECT OF THE “ONCO-MOUSE” DECISIONS ON THE EXCEPTION TO PATENTABILITY FOR “ANIMAL VARIETIES” UNDER THE EUROPEAN PATENT CONVENTION

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I. Introduction

For biotechnological inventors of living-inventions, Article 53(b) is a particularly interesting provision of the European Patent Convention (EPC). Article 53(b) provides that “European patents shall not be granted in respect of... 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.”¹ This e-brief discusses recent and significant decisions in the European Patent Office (EPO) regarding an animal-related invention known as the “*Onco-mouse*” and provides guidance on how the exception to patentability for “animal varieties” under Article 53(b) has been interpreted and implemented with respect to animal-related inventions.

¹ The European Patent Convention (also known as the Convention on the Grant of European Patents), Oct. 5, 1973, as amended by the act revising art. 63 EPC of Dec. 17, 1991 and by decisions of the Administrative Council of the European Patent Organisation of Dec. 21, 1978, Dec. 13, 1994, Oct. 20, 1995, Dec. 5, 1996 and Dec. 10, 1998, art. 53(b) <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN> (last visited Feb. 20, 2004) [hereinafter EPC].

II. Background

Inventors of the *Onco-mouse* invention filed a European patent application entitled “Method for producing transgenic animals,”² claiming it was a method for producing a transgenic mammalian animal having an introduced oncogene sequence³—as well as the transgenic animal itself.⁴ Transgenic animals (particularly mice⁵), which had been genetically manipulated to have the oncogene sequence, were more likely to develop neoplasms (tumors), and thus could be utilized in experiments for cancer research.

III. Initial Examination

The Examining Division of the EPO⁶ denied the grant of a European patent for the *Onco-mouse* application. One of its main objections was raised against the claims to animals per se under Article 53(b), namely the “animal varieties” exception to patentability. The Examining Division interpreted the provision of Article 53(b) that “European patents shall not be granted in respect of... animal varieties” as referring not only to cases where a specifically designated variety was claimed, but also to cases where varieties were covered by a claim.⁷ It reasoned that

² European Patent Application No. 85 304 490.7 (filed June 24, 1985).

³ For example, method claim 1 read as follows:

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. Id.*

⁴ For example, product claim 17 (for a mammal) and claim 18 (more specifically for a rodent), read as follows:

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. Id.*

⁵ Although the patent application was directed to all mammals in general, the disclosure primarily described the use of oncogene sequences in mice. Thus, the invention was referred to as the “Onco-mouse”.

⁶ The Examining Divisions of the European Patent Office is responsible for the examination of European patent applications; see EPC, *supra* note 1, art. 18, <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>.

⁷ HARVARD/Onco-mouse, [1990] E.P.O.R. 4, 7.

the legislator's intention was not the exclusion of some particular group of animals, but rather the exclusion of animals in general.⁸

IV. Appeal to the Technical Board of Appeals

Harvard appealed the Examining Division's decision to the Technical Board of Appeals of the EPO.⁹ The Technical Board addressed the Examining Division's interpretation and application of the "animal varieties" exception of Article 53(b) to the *Onco-Mouse* patent application. It ultimately found the Examining Division's rejection unjustified.

In determining the scope of Article 53(b), the Technical Board first addressed the different terminology found in the three official texts of the EPC, which are written in German, English, and French. The English version of Article 53(b) excludes "animal varieties". The German version of Article 53(b) excludes "Tierarten". The French version excludes "races animals". Within these different languages, the terms have differing scopes. The German term "Tierarten" (animal species) is broader than the English term "animal varieties" and the French term "races animales" (animal races).¹⁰

Because it found that all three texts were equally authentic under the EPC, the Technical Board reasoned that there was a need to establish a common meaning as to the extent that animals are excluded from patentability under Article 53(b).¹¹ Although the Technical Board ultimately concluded that "[i]t [was] now the task of the European Patent Office to find a solution to the problem of the interpretation of Article 53(b) EPC with regard to the concept of 'animal varieties'", it did not accept the interpretation of the Examining Division that Article

⁸ *Id.*

⁹ The Technical Board of Appeals is responsible for the examination of appeals from the decisions of the Examining Divisions; see EPC, *supra* note 1, art. 21, <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>.

¹⁰ HARVARD/Onco-mouse (T19/90), [1990] E.P.O.R. 501, 509-10.

¹¹ *Id.* at 510.

53(b) excluded not only certain groups of animals from patentability, but in fact animals in general.¹²

The Technical Board noted that any exception to patentability under the EPC must be “narrowly construed”.¹³ The Technical Board further dismissed the possibility that the reference to certain categories of animals in Article 53(b), rather than to animals as such, was simply a mistake by the legislators, because nothing in the legislative history supported such an assumption.¹⁴ Rather, the Technical Board concluded that use of the terms “animal varieties”, “races animals” and “Tierarten” was a “clear indication” that Article 53(b) was not intended to cover animals as such.¹⁵ Furthermore, the Technical Board noted that Article 53(b) also contained in the same first half-sentence of the provision, a reference to “animals” (in general) with regard to essentially biological processes.¹⁶ Thus the Technical Board reasoned that because of its use of the different terms “animal varieties” (“races animals”, “Tierarten”) and “animals” (“animaux”, “Tiere”) in this way, the EPC legislator could not have meant “animals” in both cases.¹⁷

Therefore, the Technical Board found that the Examining Division was wrong in refusing the *Onco-mouse* application on the ground that Article 53(b) excludes the patenting of animals as such. The Technical Board held that “[t]he proper issue to be considered is, therefore, whether or not the subject-matter of the application is an ‘animal variety’ (‘race animale’, ‘Tierart’) within the meaning of Article 53(b) EPC.” The Technical Board then remitted the case back to the Examining Division for further prosecution. It instructed the Examining Division to “first

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

consider whether the subject-matter of the present application constitutes an ‘animal variety’, ‘race animale’ or ‘Tierart’ within the meaning of that provision. If it came to the conclusion that the subject-matter [was] not covered by any of these three terms, then Article 53(b) EPC would constitute no bar to patentability. If, however, it considered that any of these terms applie[d], then refusal of the application would only be justified if that specific term represents the proper interpretation of Article 53(b).”¹⁸

V. Re-examination by the Examining Division

After the case was remitted for further examination, the Examining Division considered whether the term “animal variety” or its counterparts (“race animale” and “Tierart”) covered the subject-matter of the *Onco-mouse* application, which was generically drafted to claim “mammals” and “rodents”. The Examining Division avoided specifically interpreting the scope of the term “animal varieties” by concluding that “[a]lthough the term ‘animal variety’ [was] not entirely clear, in particular in view of the differing wording in the three equally binding languages of the EPC, it nevertheless could be stated with certainty that rodents, or even mammals, constituted a taxonomic classification unit much higher than species (‘Tierart’). An ‘animal variety’ or ‘race animale’ is a sub-unit of a species and therefore of even lower ranking than a species.”¹⁹ Accordingly, the Examining Division found that the subject-matter of the claims to animals per se in the *Onco-mouse* application were not covered by the three terms of Article 53(b) of the EPC.²⁰

¹⁸ *Id.* at 511.

¹⁹ HARVARD/*Onco-mouse*, [1991] E.P.O.R. 525, 526.

²⁰ *Id.*

VI. Proceedings in the Opposition Division

Ultimately, a European Patent was granted for the *Onco-mouse* application.²¹ However, the *Onco-mouse* patent faced further scrutiny in the Opposition Division²² of the EPO. Several oppositions challenging the validity of the *Onco-mouse* patent were filed. Again, one of the main arguments raised by the opponents pertained to the patentability of animals under Article 53(b).

In addressing the patentability of animals in accordance with Article 53(b), the Opposition Division first reviewed recent developments in the Implementing Rules of the EPC, as well as in relevant case law. The Opposition Division first referred to Rule 23c(b)²³, which stipulates that inventions concerning plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.²⁴

The Opposition Division next noted that while appeals decisions addressing the issue of patentability of animals did not exist outside the *Onco-mouse* case, the decision from the Technical Board of Appeals did contain several legal considerations highly relevant to the present issue with regard to Article 53(b).²⁵ First, exceptions to patentability have to be construed narrowly.²⁶ Secondly, the appearance of “animals” (in general) and “animal varieties” in the same half-sentence of Article 53(b) is a clear indication that the legislator did not intend

²¹ European Patent No. 169672 (issued May 13, 1992).

²² The Opposition Division of the EPO is responsible for the examination of oppositions against any European patent filed by third parties challenging the validity of the granting of the patent; *see* EPC, *supra* note 1, art. 19, 99-100, available at <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>.

²³ Implementing Regulations to the Convention on the Grant of European Patents, Dec. 13, 2001, Rule 23c(b), <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG> (last visited Feb. 20, 2004) [hereinafter Implementing Regulations]. Rule 23c(b) provides: “Biotechnological inventions shall also be patentable if they concern... plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety.”

²⁴ *Onco-mouse/HARVARD*, OJ EPO 10/2003 – Decisions of the Opposition Division, at 497, para. 8.1.1. http://www.european-patent-office.org/epo/pubs/oj003/10_03/10_4733.pdf (last visited Apr. 12, 2004).

²⁵ *Id.* at 498, para. 8.1.2.

²⁶ *Id.*

the term “animal varieties” to cover animals in general or that the legislator meant “animals” in both cases.²⁷ Finally, if the subject-matter of the claims is not covered by any of the three terms “animal variety”, “race animale”, or “Tierart”, then Article 53(b) constitutes no bar to patentability.²⁸ The Opposition Board also noted that a recent decision relating to the patentability of plants under Article 53(b) had held that “[a] claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties.”²⁹

In light of these recent rules and case law, the Opposition Division concluded that “[l]iving matter and in particular plants and animals are accessible to patent protection.”³⁰ It found this to apply not only to process protection but also product protection.³¹ The Opposition Division also concluded that, as already established for plants under Rule 23c(b), if a grouping is characterized by a specific gene and not by its whole genome, then it is not excluded from patentability as a “variety”.³² In applying its conclusions to the *Onco-mouse* patent, the Opposition Division noted that “[t]here is no doubt that the invention as claimed is applicable to more than just varieties of mice... Therefore, the argument that the patent relates to particular mouse strains and therefore to animal varieties which are not patentable under Article 53(b) EPC must fail. The feasibility of the invention is not confined to a particular animal variety in the meaning of Rule 23c(b) EPC.”³³

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* at 498, para. 8.1.3 (citing Novartis/Transgenic Plant decision, (G01/98) [2000] E.P.O.R. 303).

³⁰ *Onco-mouse/HARVARD*, *supra* note 24, at 499, para. 8.2.1.

³¹ *Id.*

³² *Id.*

³³ *Id.* at 499, para. 8.2.2.

The Opposition Division also disagreed with the argument that it was the legislator's intention in Article 53(b) to not allow patents on animals in general. The Opposition Division first examined the applicability of case law which determined that, as far as plant varieties were concerned, the purpose of Article 53(b) was to comply with the ban on dual protection under a plant varieties protection scheme known as the International Union for the Protection of New Varieties of Plants (UPOV) Convention³⁴. The Opposition Division noted that the purpose in also excluding animal varieties was not clear since no equivalent protection was available at that time, or at present, for animal varieties as products of animal breeding.³⁵ However, it concluded that most obvious reason for this was that there was an intention to create, or at least keep open the possibility to create, such a law for the protection of animal varieties later on.³⁶ The Opposition Division found that if the legislator had in mind a different purpose for the exclusion of animal varieties than that for plant varieties, then the legislator would have had to make this very clear by using appropriate language in the EPC.³⁷ Since the legislator had not done so, the Opposition Division concluded that “[t]he equal linguistic treatment of plant and animal varieties in these bodies of law [was] a clear indication that the purpose of the exclusions must have been the same for both.”³⁸ Furthermore, the Opposition Division reasoned that because of the use of the different notions “animals” and “animal varieties” in the same half-sentence of Article 53(b),

³⁴ International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89, as Revised at Geneva on Nov. 10, 1972, on Oct. 23, 1978, and on Mar. 19, 1991, http://www.upov.int/en/publications/conventions/1991/act1991.htm#_14 (last visited Feb. 26, 2004).

³⁵ Onco-mouse/HARVARD, *supra* note 24, at 499, para. 8.2.3.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

the clear wording of the article itself indicated that its exclusion was limited to varieties only, and did not extend to animals in general.³⁹

Because it had found that the technical feasibility of the *Onco-mouse* invention was not confined to a particular animal variety, and that exclusion for “animal varieties” under Article 53(b) did not extend to animals in general, the Opposition Division ultimately held that Article 53(b) of the EPC did not constitute a bar to patentability for the subject matter claimed in the *Onco-mouse* patent.^{40, 41}

VII. Conclusion

In accordance with the *Onco-mouse* line of decisions, an inventor of an animal-related invention should consider the following:

- The exception for “animal varieties” under Article 53(b) of the EPC does not exclude animals in general from patentability.
- Inventions concerning plants and animals are patentable if the technical feasibility of the invention is not confined to a particular animal variety.
- The exclusion from patentability for animals under Article 53(b) is defined by the terms used within the three official texts of the EPC, which includes “animal varieties” (in English), “race animale” (in French) or “Tierart” (in German).
- Claims drafted to cover a taxonomic classification unit higher than species (“Tierart”), or the lower ranking subunits of animal variety or animal race (“race animales”), would not fall with the exclusion of Article 53(b).
- Interpretations EPC provisions and rules established with regard to plants may also be applicable with regard to animals since the equal linguistic treatment of plant and animal varieties in Article 53(b) indicates that the purpose of the exclusion is the same for both bodies of law.

In view of these guidelines, biotechnologists seeking protection in Europe under a European patent for animal-related inventions should not be apprehensive of the Article 53(b)

³⁹ *Id.* at 500, para. 8.2.5.

⁴⁰ *Id.* at 500, para. 8.3.

⁴¹ On July 6, 2004, the Technical Board of Appeal further restricted the *Onco-mouse* patent to apply only to mice, rather than the broader category, i.e. rodents, applicable before the decision. See *EPO – Press Release*, European Patent Office at http://www.european-patent-office.org/news/pressrel/2004_07_06_e.htm.

prohibition on “animal varieties”. As a practical matter, the application of the “animal varieties” exception appears to be strictly limited to animal-related inventions with subject matter claiming a specific animal variety. Thus, even with the “animal varieties” exception to patentability under Article 53(b), the European patent remains a viable option for biotechnologists with animal-related inventions.