

# **PLANT AND ANIMAL VARIETY**

The variety exceptions of the European Patent Organisation  
and the European Community assessed in relation to  
patentable subject matter

Kandidatnr: 566

Veileder: Morten Walløe Tvedt

Leveringsfrist: 10.11 2003

Til sammen 32750 ord

13/01/2004

# Contents

<b><u>1</u></b>	<b><u>INTRODUCTION</u></b>	<b><u>1</u></b>
1.1	RESEARCH QUESTION AND THE LEGAL LANDSCAPE	1
1.2	THE VARIETY EXCEPTIONS: A TOPIC OF CURRENT INTEREST	7
1.3	ADJOINING ISSUES NOT DISCUSSED IN THIS THESIS	9
1.4	BIOLOGICAL UNDERSTANDING OF <i>PLANT</i> AND <i>ANIMAL VARIETY</i>	12
<b><u>2</u></b>	<b><u>INTRODUCTION OF THE REGIMES</u></b>	<b><u>15</u></b>
2.1	THE EUROPEAN PATENT ORGANISATION	16
2.2	THE EUROPEAN COMMUNITY	18
2.3	THE WORLD TRADE ORGANISATION	21
2.4	THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS	21
<b><u>3</u></b>	<b><u>METHODOLOGICAL CHALLENGES</u></b>	<b><u>23</u></b>
3.1	PUBLIC INTERNATIONAL LAW	23
3.2	EC LAW –A METHODOLOGICAL CHALLENGE	24
3.3	OTHER TREATIES AS A SOURCE OF LAW	26
<b><u>4</u></b>	<b><u>PLANT AND ANIMAL VARIETY IN EPO AND EC</u></b>	<b><u>27</u></b>
4.1	WORDING	27
4.2	SUPERORDINATE TAXONOMICAL LEVELS	33
4.2.1	EPO CASE LAW –INTRODUCTION	33

4.2.2	THE CIBA GEIGY CASE AND THE LUBRIZOL CASE	35
4.2.3	THE ONCO-MOUSE CASE	38
4.2.4	THE PLANT GENETIC SYSTEMS CASE	42
4.2.5	OPINION G 3/95	44
4.2.6	THE NOVARTIS I CASE	46
4.2.7	THE NOVARTIS II CASE	49
4.2.8	CONSEQUENCES	51
4.2.9	OBJECT AND PURPOSE OF EPC AND THE DIRECTIVE	55
4.2.10	EPO ADMINISTRATIVE REGULATION	57
4.2.11	THE UNDERSTANDING OF THE EC DIRECTIVE AND THE INTERACTION WITH EPC	58
4.2.12	THE IMPACT OF THE COMMUNITY PLANT VARIETY RIGHTS REGULATION ON THE DIRECTIVE AND EPC	63
4.2.13	EPC AS A SOURCE OF LAW WHEN INTERPRETING THE EC PATENT DIRECTIVE 65	
4.2.14	PATENT PRACTICE AS A SOURCE OF LAW	67
4.2.15	CONCLUSION	68
<b>4.3</b>	<b>SUBORDINATE BIOLOGICAL LEVELS</b>	<b>68</b>
4.3.1	PLANT AND ANIMAL SPECIMENS IN RELATION TO <i>PLANT</i> AND <i>ANIMAL VARIETY</i>	69
4.3.2	THE DEMARCATION BETWEEN <i>CELLS</i> AND <i>PLANT</i> AND <i>ANIMAL VARIETY</i>	72
4.3.3	THE DELIMITATION BETWEEN <i>PROTEINS</i> AND <i>VECTORS</i> AND THE TERM <i>VARIETY</i> 79	
4.3.4	<i>GENES</i> IN RELATION TO <i>PLANT</i> AND <i>ANIMAL VARIETY</i>	81
4.3.5	CONCLUSION	88
<b>5</b>	<b><u>UPOV-91'S IMPACT ON THE INTERPRETATION OF EPC AND THE DIRECTIVE</u></b>	<b>89</b>

5.1	INTRODUCTION – <i>PLANT VARIETIES</i>	89
5.2	UPOV-91 AS A SOURCE OF LAW WHEN INTERPRETING EPC	89
5.3	UPOV-91 AS A SOURCE OF LAW WHEN INTERPRETING THE EC PATENT DIRECTIVE	95
5.4	THE DUAL PROTECTION BAN	96
5.5	DISCUSSION OF IDENTICAL INTERPRETATION – <i>PLANT VARIETIES</i>	98
5.6	CONSEQUENCES OF THE CESSATION OF THE DUAL PROTECTION BAN – <i>PLANT VARIETIES</i>	102
5.7	CONSEQUENCES FOR THE INTERPRETATION OF <i>ANIMAL VARIETIES</i>	106
<b>6</b>	<b><u>THE TRIPS AGREEMENT’S IMPACT ON THE INTERPRETATION OF EPC AND THE DIRECTIVE</u></b>	<b>108</b>
6.1	TRIPS AS A MEANS OF INTERPRETATION FOR EPC	108
6.2	TRIPS AS AN INTERPRETATION AID WHEN INTERPRETING THE EC PATENT DIRECTIVE	109
6.3	THE INTERPRETATION OF ARTICLE 27 (3) (B) TRIPS – <i>PLANT VARIETY</i>	111
6.3.1	WORDING	111
6.3.2	INFLUENCE FROM THE UPOV-91 CONVENTION	112
6.3.3	THE UNDERSTANDING OF THE TERM <i>PLANT</i> IN RELATION TO <i>PLANT VARIETY</i>	116
6.3.4	THE DEMARCATION BETWEEN <i>MICRO-ORGANISM</i> AND <i>PLANT VARIETY</i>	117
6.3.5	CONSEQUENCES FOR THE INTERPRETATION OF <i>PLANT VARIETY</i> IN EPC AND THE DIRECTIVE	118
<b>7</b>	<b><u>IMPLICATIONS</u></b>	<b>119</b>
<b>8</b>	<b><u>LITERATURE</u></b>	<b>121</b>

<u>9</u>	<u>TABLE OF CASES</u>	<u>128</u>
----------	-----------------------	------------

---

<u>10</u>	<u>TABLE OF LEGAL DOCUMENTS</u>	<u>129</u>
-----------	---------------------------------	------------

## 1 Introduction

### 1.1 Research question and the legal landscape

The point of departure in the patent law of the European Patent Organisation and the European Community is that all inventions are eligible for patent protection if they fulfil the patent requirements and not are explicitly exempted from patentability.<sup>1</sup> In the European Patent Organisation and the European Community *plant* and *animal varieties* are excluded from patentability.<sup>2</sup> The objective of this thesis is to discuss the legal understanding of the terms *plant variety* and *animal variety* in relation to patentable plant and animal subject matter. The distinction between patentable plant and animal subject matter and *plant* and *animal varieties* is important for to determine to what extent plants and animals can be patented. *Plant* and *animal varieties* are terms which are difficult to define precisely using the biological system of concepts.<sup>3</sup> Constructing the legal meaning of these terms therefore becomes essential. This thesis assesses the delimitation of *plant* and *animal variety* relative to more general categories of plants and animals on a superordinate taxonomical level, such as a plant or animal *family* or a plant or animal *species*.<sup>4</sup> Furthermore, the terms are delimited towards categories of plants and animals on subordinate levels.<sup>5</sup> This includes an assessment of the

---

<sup>1</sup> Article 52 (1) EPC and Article 3, first paragraph of the EC Patent Directive.

<sup>2</sup> Article 53 (b) EPC and Article 4, first paragraph, litra a of the EC Patent Directive.

<sup>3</sup> This is further discussed in Chapter 1.4.

<sup>4</sup> See Chapter 1.4 for a further explanation of superordinate taxonomical levels.

<sup>5</sup> See Chapter 1.4 for a further explanation of subordinate levels.

patentability of plant and animal specimens, cells, proteins, vectors and genes in relation to the variety exception. This implies that the term *variety* can be examined from two angles –the superordinate and the subordinate. The approach mirrors the structure of the thesis.<sup>6</sup>

The thesis discusses the interpretation of *plant* and *animal varieties* in the European Patent Convention and the EC Patent Directive where the legal understanding of the terms is considered. Hence, the question examined from the perspective of public international law and EC law. National legislation is therefore not assessed.

The legal documents to be examined are The European Patent Convention (EPC); and Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (the Patent Directive).<sup>7</sup> These documents are assessed because they apply the terms *plant* and *animal variety*. EPC states this:

‘European patents shall not be granted in respect of: ...plant and animal varieties....’<sup>8</sup>

The EC Patent directive offers a similar provision:

‘The following shall not be patentable: plant and animal varieties.’<sup>9</sup>

---

<sup>6</sup> See respectively Chapters 4.2 and 4.3.

<sup>7</sup> For details on these documents and the organisations from where they derive see Chapter 2.

<sup>8</sup> Article 53 (b) EPC.

<sup>9</sup> Article 4, first paragraph of the Directive.

The understanding of *plant* and *animal variety* in EPC and the Directive are discussed in Chapters 4, 5 and 6.

A patent is an exclusive legal right where the patent holder is granted the right to prohibit others from using the invention for commercial purposes within a limited period of time.<sup>10</sup> A patent system provides an incentive for investment in inventive activities and enhances technology transfer.<sup>11</sup> Considerable costs may be attached to such a contribution. Persons and companies who take on these costs must have a prospect of profit. Due to the monopoly rewarded the inventor, or his successor, a patent may give such outlook for future earnings.<sup>12</sup> The patent holder is given a time limited exclusive right, while society may prosper from development. After the expiration of the protection period, the knowledge devolves on society. In other words, the technology may be adopted in products and processes by everyone. Furthermore, patents facilitate disclosure of inventions. Subsequent to the issuing of a patent, there is less need to keep the invention a secret because the inventor does not have to physical control of the invention since a patent provides a judicial control.<sup>13</sup> Society is best served when everyone can prosper from the inventions created.

---

<sup>10</sup> Bently and Sherman 2001 p. 309.

<sup>11</sup> Lesser 2000 p.54.

<sup>12</sup> See for example Bently and Sherman 2001 p. 340.

<sup>13</sup> There are a set of different theories explaining the ideological basis for the patent system. One is based on the inventors natural right to an invention (the nature-law thesis), others are the reward-by-monopoly thesis and monopoly-profit-incentive thesis. Yet another is based on the notion that patents promote the exchange of secrets. For a more detailed introduction to these theories see for example Petrusson 1999, Moore 1997 and Stenvik 2001 pp. 92-137.



Several criteria must be met before a patent is granted. The subject matter has to be an invention, has to be new, involve an inventive step and be suited for industrial application. In addition to these criteria, the type of subject matter sought protection for has to be patentable.<sup>14</sup> The regulations concerning *plant* and *animal varieties* are exceptions from patentability.<sup>15</sup> Subject matter generally exempted from patentability in this manner is not put to the ordinary patent criteria test. It is rejected on a general basis even if the concrete subject matter might fulfil the other patent requirements. The exception at hand excludes one certain scope, namely *plant* and *animal variety*, from patentability.

Structurally, the patent system can be divided into three main stages: The subject matter has to be patentable; the product or process has to meet the patent criteria mentioned in the previous paragraph; and the scope of the patent claim has to be determined. The problem discussed in this thesis is, as outlined above, the legal understanding the terms *plant* and *animal varieties*. As a starting point, all products or processes are patentable. Any exception to this main rule must have a valid, legal basis as for example the exception for variety. Therefore, the question at hand structurally belongs in the first stage, patentability. The connection to the scope of the patent claim is interesting: patent examiners may limit the scope of the patent claims in each concrete case. In general, the scope of the patents is not supposed to exceed what is seen as an advantage for the technical development in society as a whole. The variety exception can be seen as a method to exclude one particular scope of subject matter from patentability *per se*

---

<sup>14</sup> For a detailed presentation of the patent criteria, see for example Bently and Sherman 2001 pp. 362-468 or Stenvik 1999 pp. 112-231.

<sup>15</sup> See Article 52 (1) EPC cf. Article 53 (b) EPC and Article 3, first paragraph in the EC Patent Directive cf. Article 4, first paragraph in the EC Patent Directive.

instead of limiting the patent claim of each patent application in relation to the assessments which gives the grounds for the current variety exception.<sup>16</sup> This thesis examines the limits and reasons for such an exception.

*Plant varieties* can be protected by plant breeder's rights. Plant breeder's rights are an alternative intellectual property rights system. The world leading plant breeder's rights system is constituted through The International Convention for the Protection of New Varieties of Plants, the UPOV Convention. Both the Patent Directive and EPC use the definition of *variety* used in the 1991 version of UPOV. The definition is used in the patent systems when identifying subject matter that is not patentable due to the exception for *plant* and *animal varieties* in Article 53 (b) EPC and Article 4, first paragraph, *litra a* in the EC Patent Directive. Furthermore, statements in EPC case law and legal theory indicates that the reason for constructing a variety exception in EPC and the Patent Directive was a practical division of work between UPOV and the patent systems.<sup>17</sup> UPOV contributed to this classification by introducing a double protection ban.<sup>18</sup> The ban forbids UPOV protection for subject matter which is patented. Consequently, both UPOV-61 and -78, EPC and the Directive all contribute to keeping the protection of *plant varieties* and other categories of plants apart. In the 1991 version of UPOV the double protection ban was not continued. An important question is how UPOV affects the patent systems. Specifically, in what manner the fact that the double protection ban no longer applies affects the interpretation of the term *variety* in EPC and

---

<sup>16</sup> This is discussed further in Chapter 7 in relation to the problematic aspects of too broad patent claims.

<sup>17</sup> See for example Paterson 1992 pp. 335-336, Bently and Sherman 2001 p. 396 and T 49/83, points 2 and 4 of the Reasons.

<sup>18</sup> Article 2 in UPOV-61 and UPOV-78.

the Directive. Thus, an assessment of the relationship between the patent systems and UPOV is carried out in Chapter 5.

In a broader context, the variety exception can be seen in relation to other international agreements. The Convention on Biological Diversity, CBD, seeks *inter alia* to facilitate 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources'.<sup>19</sup> This can, together with Article 15 CBD and the Bonn Guidelines<sup>20</sup>, be seen as a reflex of increased patenting of genetic resources.<sup>21</sup> The relation between patents and CBD has been addressed by CBD Conference of the Parties. It asked the World Intellectual Property Organisation, WIPO to comment on the issue. The WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore has discussed the relation between intellectual property rights and CBD, however it has not yet come to a clear conclusion on the posed question.<sup>22</sup> The International Treaty on Plant Genetic Resources for Food- and Agriculture, IT-PGRFA, was negotiated under the Food and Agriculture Organisation negotiations as a supplement to CBD on the issues of plant genetic resources for food and agriculture.<sup>23</sup> The relation between intellectual property rights and access to genetic resources is also important in this respect.<sup>24</sup> Thematically, the relation between patents and access and

---

<sup>19</sup> Article 1 CBD.

<sup>20</sup> Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.

<sup>21</sup> Nordic Gene Resource Council 2002, Chapter 2. See also Rosendal 1999 p. 97 and pp. 106-113 and Tvedt 2001 p. 19.

<sup>22</sup> Nordic Gene Resource Council 2002, Chapter 2.

<sup>23</sup> Ibid..

<sup>24</sup> Ibid..

benefit sharing regarding genetic resources falls outside that scope of this thesis. It is therefore not discussed further in any depth.

## 1.2 The variety exceptions: a topic of current interest

The question of patenting plants and animals has become a current issue of interest due to technological evolution. Modern biotechnology opens for manipulation of plants and animals which in turn renders fulfilment of the patent requirements possible.<sup>25</sup> For example, gene manipulation can make reproducible changes in plants and animals possible. Such techniques can implicate that the invention requirement can be fulfilled. The definition of *plant* and *animal varieties* contributes to the determination of to what extent plants and animals may be patented. This makes determining the scope of the variety exception important. Furthermore, the understanding of the scope of the variety exception has factual consequences. For example, the legal understanding of the variety exception may affect the technological progress in this field. On the one hand, a wide interpretation of the terms may result in hampering development because a large proportion of plant and animal subject matter is not patentable. In other words, a range of products and processes may not be invented or brought to market due to the lack of patent protection that could contribute to making the development profitable. This may especially be a challenge for subject matter which has no adequate alternative protection, such as subject matter defined as an *animal variety*.<sup>26</sup> Since there is no alternative intellectual property protection for such inventions, and a monopoly situation

---

<sup>25</sup> For details on biotechnology, see Chapter 1.4.

<sup>26</sup> See Chapter 5.7.

therefore is not afforded, the prospects of profit can be reduced. This may contribute to a situation where these inventions to a lower degree are brought to market.

On the other hand, a narrow interpretation of the variety exception may result in more patents being granted. This may contribute to a situation where research and development are limited due to patent stacking.<sup>27</sup> The theory is that the development cost increases beyond the point of profitability due to costs connected to licence charges. Consequently, some inventions may not be brought to market. An identification and assessment of these consequences requires an empirical examination of research and development materialising in patented inventions over an adequate period of time. To investigate this aspect an examination based on methodology other than a legal analysis is needed. Such an investigation would also be time-consuming. Therefore, due to methodical and volume reasons, this is beyond what can be presented in this thesis.

The European legal situation is in a development stage, and it therefore becomes interesting to assess the evolution. The Patent Directive has currently been implemented by seven countries out of a total of fifteen.<sup>28</sup> The low degree of implementation is partly connected to scepticism towards the EC approach to patentability of plant and animal subject matter.<sup>29</sup> The European Patent Convention is also in a process concerning patents for plants and animals. Both case law and

---

<sup>27</sup> See for example Heller and Eisenberg 1998.

<sup>28</sup> The Patent Directive is implemented by Denmark, Finland, the United Kingdom, Ireland, Spain, Portugal and Greece. See press release from the European Commission, IP/03/991. Available on [www.europa.eu.int](http://www.europa.eu.int). Accessed on 10 November 2003.

<sup>29</sup> See European Court of Justice, C-377/98R, *The Netherlands v. Council of the European Union and European Parliament*.

amendments made to the Convention in the Implementing Regulations, contribute to the development of the variety exception.<sup>30</sup> There is also an interesting relationship between EPC and the Patent Directive which implies that the understanding of the variety exception in one of the regimes may be affected by the other. This is further assessed in Chapters 4.2.11 and 4.2.13. The UPOV Convention is not a patent treaty. Based on the UPOV Convention, national authorities grant intellectual property protection for *plant varieties* which is less extensive than patents. The Convention's interface with the variety exception in EPC and the Patent Directive is, however, important for understanding the patent law on this particular issue. The relationship between plant breeder's rights and patents results in interesting dynamics in the interface between the systems since the UPOV understanding of *plant variety* can affect the understanding of the term in the patent systems. The manner in which the scope of the variety exception is affected by the scope of protection afforded by the plant breeder's rights system is therefore examined.<sup>31</sup> Since all members of the European Community and EPC are parties to the TRIPs Agreement, it is interesting to assess how the term *plant varieties* is understood in TRIPs and if this understanding can affect the interpretation of the term in EPC and the Directive.

### 1.3 Adjoining issues not discussed in this thesis

The thesis is limited to a discussion of the interpretation of the terms *plant* and *animal variety* in EPO and EC. Other agreements are not discussed in detail. However, due to the possible influence from UPOV and WTO on the interpretation of the terms in EPO

---

<sup>30</sup> See Chapters 4.2.1-4.2.8 and 4.2.10.

<sup>31</sup> See Chapter 5.

and EC, the UPOV Convention and the TRIPs Agreement are discussed in relation to the understanding of *plant* and *animal variety* under EPC and the Directive. Other regional patent systems based on public international law are not assessed since the focus of this thesis is the European approach to the patentability of plants and animals. Furthermore, the thesis presents patent law from the perspective of public international law. National patent law is thus not examined, neither national patent law from European states nor other countries. National patent law in European states is to a large extent based on the rules presented in EPC and the Patent Directive. The provisions do therefore not diverge to a large degree. However, the practice of the different states may be divergent. An assessment of European national patent laws regarding patentability of plants and animals is therefore, besides falling outside an investigation of inter- and super-national patent regulations, too extensive for the size of this thesis.

The presentation does not include an examination of the part of Article 53 (b) EPC and Article 4 first paragraph litra b of the Patent Directive which excludes ‘essentially biological processes for the production of plants and animals’ from patentability. The thesis is also delimited regarding examining the patentability of ‘microbiological and other technical processes and the products thereof’.<sup>32</sup> This is an exception to the exception that ‘essentially biological processes for the production of plants and animals’ are non-patentable subject matter.<sup>33</sup> Based on an ordinary understanding of the wording, both the exception and the exception to the exception are related to process claims and derived product claims. The variety exception concerns ‘*plant and animal varieties*’.<sup>34</sup>

---

<sup>32</sup> Article 4 paragraph 3 of the Directive and Article 53 (b) EPC, cf. Rule 23c (c) of the EPC Implementing Regulations.

<sup>33</sup> Article 4 paragraph 1 (b) of the Directive and Article 53 (b) EPC.

<sup>34</sup> Article 4 paragraph 1 (a) of the Directive and Article 53 (b) EPC.

The wording of this exception indicates that it is limited to product claims. Since the above mentioned provisions concerns process claims, while the variety exception concerns product claims, the thesis does not therefore assess ‘essentially biological processes for the production of plants and animals or microbiological and other technical processes and the products thereof’.

In both EPC and the Patent Directive, there is a provision excepting from patentability subject matter which is contrary to *ordre public* and moral. This exception is not covered by this thesis presentation. The *ordre public* rule is distinct from the variety exception because it does not, like the latter, exclude one particular subject matter from patentability. It functions as a security clause. It gives the patent granting authorities and competent courts an opportunity to avoid granting patents for inventions unwanted by society. It may be argued that this is not a task for the patent authorities. Patents give a right to exclude others from using the patented invention for certain purposes. It cannot be seen as permission to make use of the invention. This is, in principle, left to other legislation to decide. Nevertheless, an *ordre public* rule is present in EPC and the Patent Directive, and hence in most national patent legislation in Europe.<sup>35</sup> Even though the *ordre public* rule is not examined, it is important to be aware of a link between the two exceptions. If the object and purpose of the variety exception is to except ethically questionable inventions from patentability, the interface between the two exceptions may be overlapping. However, strong indications suggest that the object and purpose of

---

<sup>35</sup> Not all countries in the world have an *ordre public* rule in their patent legislation. See for example the Canadian Patent Act which can be accessed on [www.sice.oas.org/int\\_prop/nat\\_leg/Canada/ENG/lippec.asp](http://www.sice.oas.org/int_prop/nat_leg/Canada/ENG/lippec.asp). Accessed on 10 November 2003.



the variety exception, at least for plants, is not based on ethical consideration, but rather the relationship to *sui generis* plant variety protection.<sup>36</sup>

This thesis does not address questions related to patenting of human subject matter. Although humans may be considered as animals in a biological sense, certain features require a distinct legal status for humans. In particular, ethical questions must be assessed in view of the special position held by the human race. The results of these considerations may diverge from the results for other animals. Furthermore, there are, *de lege lata*, provisions specifically regulating patenting of human subject matter.<sup>37</sup> These provisions indicate that animal or *animal variety* is not to be understood as to include human subject matter.<sup>38</sup>

#### 1.4 Biological understanding of *plant* and *animal variety*

In this thesis the legal concept, and not the biological concept, of *plant* and *animal variety* is examined. Based on an intuitive understanding of the terms *plant* and *animal variety* used in EPC and the Directive, it may be natural to assume that the legal understanding of the terms are founded on the biological understanding of the terms. As it turns out, however, these two understandings of the terms might not be coherent because there is no clear biological understanding of the terms.<sup>39</sup> Nevertheless, there is a

---

<sup>36</sup> See Chapter 4.2.9.

<sup>37</sup> See for example Article 6 (2), litra a-c of the Directive, Article 53 (c) EPC and Article 27.3 (a) TRIPs.

<sup>38</sup> Nuffield Council on Bioethics 2002 p. 34.

<sup>39</sup> Hellstadius 2001 p. 41.

close relation between them. Therefore, in order to understand the basis for the legal argumentations and the problems they create, there is a need to address the biological meaning of the terms.

It is important to note that this chapter, concerning biology, is not intended to hold any position as a source of law. The discussions are merely background material for the assessment of legal questions and are based on communication with experts on the field of biology, presented as I have understood them.<sup>40</sup>

In this and the following paragraph the biological understanding of *plant variety* and *animal variety* are outlined. The term *plant variety* is, in biology, a term which expresses a group of plants with certain common traits. There are also a number of other scopes of plant categories. Each category constitutes a *taxonomical level*, also known as a *rank*. The taxonomical system is a method for classification and naming living organisms.<sup>41</sup> The system has a hierarchic structure.<sup>42</sup> The higher and more general category comprises the lower categories. The taxonomical system for plants is presented below, starting with the highest level:

‘Kingdom

Phylum

---

<sup>40</sup> This chapter is mainly based on personal communication with Director of the Nordic Genebank for Domesticated Animals Erling Fimland, Professor Åsmund Bjørnstad from the Norwegian School of Agriculture and Senior Advisor Håkon Sønju from the Norwegian Agricultural Inspection Service on 20 February 2003.

<sup>41</sup> Robinson 1996 p. 447.

<sup>42</sup> For a brief introduction to the character of this hierarchy, see Mayr 1982 p. 205.

Class

Order

Family

Genus

Species

Variety'.<sup>43</sup>

As the list of the categories shows, the term *variety* has the lowest rank. The term *variety* is not used by all taxonomists. Some regard *species* as the base rank, but recognise *variety* as an infraspecific rank below that of *subspecies*.<sup>44</sup> Biologically, *plant variety* is therefore not clearly defined.<sup>45</sup> *Variety* has been the relevant taxonomical category for the production of new plants and thus important for the industry more so than for taxonomists. The definition used by the plant production industry today has evolved through an interaction between biology and the industry. This definition has been the basis for the legal definition of *plant variety* used in the UPOV-91 Convention, EPC and the EC Patent Directive.<sup>46</sup>

The taxonomical system for animals is in many ways similar to the one for plants. There are, however, some major differences. First of all the relevant category for animal

---

<sup>43</sup> See for example Wilson 1993 p. 144 and the World Biodiversity Database on [www.eti.uva.nl/database/WBD.html](http://www.eti.uva.nl/database/WBD.html). Accessed on 10 November 2003.

<sup>44</sup> See for example Judd...(et al.) 2002 p. 553.

<sup>45</sup> Hellstadius 2001 p. 41.

<sup>46</sup> Article 1 (vi) of UPOV-91, Article 53 (b) EPC cf. Rule 23b (4) of EPC Implementing Regulation and Article 2, third paragraph of the Patent Directive cf. Article 5 of the EC Community Plant Variety Rights Regulation.

breeders is *breed* and not *variety*. The term *breed* is widely used to classify animals with common characteristics on a taxonomical level lower than species. There is no clear definition of the term. Generally, *breed* is closer to individuals than *varieties*. The concept of *variety* is based on a certain degree of uniformity within the selection. Animals cannot have this high degree of uniformity. The reason for this is that animals are more exposed to the negative effects of inbreeding. Plants seem not to be affected by such problems to the same extent. This is related to the methods of reproduction. Some plants are clones (e.g. potato), some cross-pollinate (e.g. flowers), while yet others are self-pollinating (e.g. corn). Furthermore, the size and monetary value of each individual may also explain the different approaches for plants and animals. One animal individual is generally more economically profitable than one plant individual. An operational unit needs fewer animal individuals than plant individuals to be profitable. This is mirrored in the way the individual is recognised and valued. Animal individuals are generally the centre of the breeder's attention. The breeder is interested in the characteristics of a particular animal. Mating this individual with his stock, he hopes that the desired properties will be introduced in the new generation of animals. The focus on animal individuals reduces the need to classify animals in groups. A legitimate question is then why *animal variety* is exempted from patentability. This question is discussed further in Chapter 4.2.9.

## **2 Introduction of the regimes**

In this chapter the European Patent Organisation, the European Community, the World Trade Organisation and the International Union for the Protection of New Varieties of Plants are introduced. This is done to establish a platform of general information needed

for the subsequent discussions and to emphasise why the presented regimes are relevant to this thesis.

## 2.1 The European Patent Organisation

The European Patent Organisation was established in 1978 to strengthen cooperation on patent protection between European states.<sup>47</sup> Currently, the Organisation has 19 member states.<sup>48</sup> The European Patent Organisation consists of the Administrative Council and the European Patent Office, hereinafter EPO.<sup>49</sup> The Organisation is concerned with the granting of European patents. Thus, the organisation assesses the validity of patents, but is not involved in the enforcement.<sup>50</sup> The latter is dealt with on the national level. The legal basis for the cooperation is the Convention on the Grant of European Patents, commonly referred to as the European Patent Convention or EPC. EPC was signed in 1973 and entered into force in 1978. One of the exceptions examined in this thesis is found in Article 53 (b) EPC. This provision, which make EPC relevant to the present

---

<sup>47</sup> See the first paragraph of the preamble of EPC.

<sup>48</sup> See [http://www.european-patent-office.org/epo/facts\\_figures/facts2001/pdf/facts\\_figures\\_01.pdf](http://www.european-patent-office.org/epo/facts_figures/facts2001/pdf/facts_figures_01.pdf). Accessed on 10 November 2003. Norway has signed, but not ratified EPC. According to Protocol 28 EEC Art. 3 (4), however, Norway must fulfil its material content. See Stenvik 1999 p. 33.

<sup>49</sup> Article 4 EPC. The Organisation and the Office are sometimes confused because there seems to be no uniform understanding of the abbreviations. EPO is used for both the Organisation and the Office. In many cases it is not necessary to distinguish between the two. Therefore, a distinction will only be made when required to understand the point of law being discussed. In these situations the Organisation's and Office's full names are used.

<sup>50</sup> Paterson 1992 p. 2.

thesis, complements the main rule of patentability in Article 52 EPC, as it exempts *plant* and *animal varieties* from patent protection.

EPC provides an opportunity for a two instance examination of all patent applications made to EPO. The first instance consists of various sections and divisions. Relevant for the assessment of EPO case law are the Examining Division and the Opposition Division. The second instance is the Boards of Appeal. Case law from the Boards of Appeal is one source of law contributing to a basis for the interpretation of *plant* and *animal variety* in EPO.<sup>51</sup> This is taken into account, and EPO case law is discussed in Chapters 4.2.1-4.2.8. The Boards of Appeal is normally made up of three members with both legal and technical background. When made up of three members the second instance is called Technical Board of Appeal. If a Technical Board of Appeal is uncertain how to interpret EPC on a particular point of law, it can refer the question to the Enlarged Board of Appeal. The Enlarged Board of Appeal has five members instead of three, but the Enlarged Board of Appeal is not a separate instance of appeal. Even though decisions and opinions from the Enlarged Board of Appeal gives no formal precedence, in the sense that the subsequent Enlarged Boards of Appeal, Technical Boards of Appeal, and first instance organs are obligated to comply with the rulings, they have a tendency to do so if there are no good reasons not to. This is a consequence of EPO's hierarchic structure and the fact that EPO aims to instil confidence by making their practice predictable.<sup>52</sup> Consequently, case law from the Technical- and Enlarged

---

<sup>51</sup> Article 31, second paragraph, litra b of the Vienna Convention.

<sup>52</sup> This paragraph is based on EPC Part I, Chapter III and IV, The Rules of Procedure of the Boards of Appeal (RPBA) and Paterson 1992 pp. 45-56. A more detailed introduction with further references to the structure of EPO is presented in Paterson 1992 on the mentioned pages.

Boards of Appeal may be applied as sources of law in the assessments of the interpretation of *plant* and *animal variety* in EPC.

The Implementing Regulations to the European Patent Convention give supplementing rules to EPC. According to Article 164 (1) EPC, the Implementing Regulations are an integral part of the Convention. In case of conflict between provisions in EPC and the Implementing Regulations, the Convention shall prevail.<sup>53</sup> The Implementing Regulations can therefore be seen as a source of law relevant to the interpretation of *plant* and *animal variety* under EPO.<sup>54</sup> The Examining Divisions often base their practice on the Guidelines for Examination in the European Patent Office.<sup>55</sup> The Guidelines are not binding to the Technical- and Enlarged Boards of Appeal.<sup>56</sup> Nevertheless, the Guidelines are of some value as source of law since the Examining Divisions can, in most cases, be expected to follow them.<sup>57</sup>

## 2.2 The European Community

The European Community presently lacks a common patent system for its members. Attempts have been made through the establishment of the Community Patent Convention, CPC. This convention was signed by nine member states in 1975. Due to

---

<sup>53</sup> Article 164 (2) EPC.

<sup>54</sup> Paterson 1992 p. 5.

<sup>55</sup> Paterson 1992 p. 6.

<sup>56</sup> Article 23 (3) EPC and for example T 162/82.

<sup>57</sup> Paterson 1992 p. 6.

political reasons CPC has not entered into force.<sup>58</sup> There is an ongoing process which may result in a future introduction of a Community Patent.<sup>59</sup> When this process will materialise into a functioning system is unclear. Instead the European Community, hereinafter EC, has decided to further harmonise the patent legislation regarding biotechnological invention within the EC through Directive 98/44/EC. The Directive, also referred to as the Patent Directive, is relevant to this thesis because the patentability of *plant* and *animal varieties* is regulated in Article 4, first paragraph, litra a of the Directive. According to the provision *plant* and *animal varieties* are exempted from patentability. This is an exception from the main rule in Article 3, first paragraph of the Directive.

The Directive is controversial, and only implemented by seven states.<sup>60</sup> The Netherlands summoned the European Council and the European Parliament before court trying to suspend the legislation.<sup>61</sup> The Netherlands argued that, amongst other, the directive does not eliminate the uncertainty related to the interpretation of terms in relevant, international conventions. On the contrary, they argued, it merely created a new, separate body of law inconsistent with conventions regulating the field.<sup>62</sup> Stenvik argues that the controversy related to 98/44/EC had, and still has, its basis in a general, emotive scepticism towards manipulation of plants and animals,<sup>63</sup> and consequently, also

---

<sup>58</sup> Paterson 1992 p. 22 and Commission Green Paper 2002 p. 2.

<sup>59</sup> Commission Green Paper 2002 p. 4.

<sup>60</sup> These are: The United Kingdom, Denmark, Finland, Greece and Ireland. Portugal and Spain.

<sup>61</sup> European Court of Justice, C-377/98R.

<sup>62</sup> Point 12 of the judgement, C-377/98R.

<sup>63</sup> Stenvik 1999 II p. 257.



towards the legal protection of the products of such acts.<sup>64</sup> In contrast to Stenvik, Fauchald does not agree that a general, scarcely substantiated scepticism is the only argumentation which can be applied against the Patent Directive. In Fauchald 2001 he argues that the relation to access to genetic resources and benefit sharing of the profit of products based on such resources may suffer under a strong patent regime.<sup>65</sup> This may in turn affect the possibility to legally obtain genetic material needed for the development of new products and thus a patent system can actually weaken the very development it is set to promote. However, the Court did not find that the Directive should be suspended. The European Council is currently summoning EC members reluctant to implement the Directive before the European Court of Justice.<sup>66</sup>

The conflict within the European Community is strictly speaking not relevant to the assessments in this thesis because the Directive, in spite of the conflict, expresses the current legal situation on these points of law on the Community level. How the Directive is implemented in the national legislation of the EC member states is not discussed in this thesis since a delimitation is made regarding assessment of national patent legislation.<sup>67</sup>

---

<sup>64</sup> C-377/98R point 9 of the Judgement.

<sup>65</sup> Fauchald 2001.

<sup>66</sup> See press release from the Commission, IP/03/991, available on [www.europa.eu.int](http://www.europa.eu.int). Accessed on 10 November 2003.

<sup>67</sup> See Chapter 1.3.

### 2.3 The World Trade Organisation

The Agreement on Trade Related Aspects of Intellectual Property Rights, TRIPs, is a convention under the World Trade Organization, WTO. It was negotiated between 1986 and 1994 as a part of the Uruguay Round.<sup>68</sup> The TRIPs Agreement is included as Annex 1c of The Marrakesh Agreement Establishing the WTO. As of April 2003 there were 146 WTO member countries.<sup>69</sup> Relevant in relation to the questions discussed in this thesis is Article 27 (3) (b) TRIPs. The provision sets minimum standards for intellectual property protection for plant and animal subject matter and is an exception from the main rule of patentability in Article 27 (1) TRIPs.

### 2.4 The International Union for the Protection of New Varieties of Plants

The International Union for the Protection of New Varieties of Plants, UPOV, is not a patent system and is not directly examined in this thesis which has a patent perspective. Nevertheless, a short introduction to UPOV is given here. As the discussions in the thesis show, there are strong connections between EPC and the Directive on the one hand and UPOV Convention on the other.<sup>70</sup> In the assessment of the variety exception in EPC and the Directive, the interface between the patent systems and UPOV is essential since the variety exceptions in EPC and the Directive are based on the delimitation

---

<sup>68</sup> See Matthews 2002 p. 29-45.

<sup>69</sup> [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm). Accessed on 10 November 2003.

<sup>70</sup> See Chapter 5.

towards *plant varieties* protectable under the UPOV regime.<sup>71</sup> In relation to TRIPs, the UPOV Convention is relevant when discussing the basis for the understanding of the term *plant variety* in TRIPs.<sup>72</sup>

The UPOV Convention, administered by UPOV, provides intellectual property protection for the subject matter *plant varieties* and is referred to as one type of a *sui generis* system.<sup>73</sup> The typical applicant is a plant breeding company which is interested in commercial exclusivity for their new *plant variety*. The plant breeder's rights afforded by UPOV resemble patent protection in that an exclusive commercial right is granted the applicant. However, the scope of this right and the requirements to obtain it diverge from those of EPC and the Patent Directive. The UPOV Convention was first signed in 1962. Since then it has been revised in 1972. In 1978 a new convention was negotiated. 28 of a total of 53 UPOV members are bound by these older versions and have not accepted the newer ones. 25 states have ratified the revised convention of 1991. In this latest revision, this system is evolving closer to patent protection. This is also why so many of the contracting parties of the 1978 convention have not ratified the 1991 convention. The assessments in this thesis are based on the 1991 version of the UPOV Convention, hereinafter UPOV-91.

---

<sup>71</sup> See Chapter 4.2.9.

<sup>72</sup> See Chapter 6.3.2.

<sup>73</sup> The term is Latin and means *of a specific kind*. This indicates that UPOV is a system of intellectual property protection for subject matter of a specific kind –*plant varieties*.

### 3 Methodological challenges

#### 3.1 Public international law

The topic of this chapter is what methodology applies to the understanding of the legal questions that are to be assessed when interpreting the terms *plant* and *animal variety* in EPC. Although the basis for its interpretation is not mentioned explicitly in EPC, it is generally assumed that this convention is to be interpreted in accordance with customary rules of interpretation of public international law.<sup>74</sup> The term *plant varieties* in the TRIPs Agreement is not interpreted independently in this thesis, but is examined as an auxiliary source of law to the understanding of the term *plant variety* in EPC and the Directive.<sup>75</sup> It is therefore also relevant to assess the methodology applied in the interpretation of WTO law. Articles 3, second paragraph and 7 of the WTO Dispute Settlement Understanding emphasises that the methodology of public international law is to be applied in the interpretation of the TRIPs Agreement.<sup>76</sup> Therefore, both EPC and TRIPs are treaties of public international law which are to be interpreted in accordance with customary rules of interpretation of public international law.

The point of departure in public international law is that the sources of law are determined by the state's practice.<sup>77</sup> A widely used codification, which is generally

---

<sup>74</sup> Paterson 1992 p. 24.

<sup>75</sup> See Chapter 6.

<sup>76</sup> See also Palmeter and Mavroidis 1998 p. 399.

<sup>77</sup> Oppenheim 1992 p. 25.

authoritative because it reflects state practice, is Article 38 (1) of the Statutes of the International Court of Justice.<sup>78</sup> This provision indicates that conventions, customs and general principles of law are primary sources of law, while judicial decisions and teachings of the most highly qualified experts on international law are considered subsidiary means of interpretation. While the Statutes of the International Court of Justice express the codification of legal sources in public international law, the Vienna Convention on the Law of Treaties, hereinafter the Vienna Convention, expresses the codification of customary law related to the interpretation of treaties.<sup>79</sup> The interpretation of EPC and TRIPs is based on the text in the Vienna Convention.<sup>80</sup> The methodological background for the discussions concerning EPO and WTO is therefore the customary rules of interpretation of public international law and the customary rules of interpretation of treaties. The methodical challenges involved in comparing public international law with EC law is addressed in Chapter 3.2.

### 3.2 EC Law –A methodical challenge

European Community law is based on treaties between the EC member states.<sup>81</sup> In that respect EC law is public international law.<sup>82</sup> Secondary legislation, such as the Patent

---

<sup>78</sup> Ibid.

<sup>79</sup> Articles 31 and 32 of the Vienna Convention.

<sup>80</sup> For EPO: The Enlarged Board of Appeal applied this approach in case G 5/83. See also Paterson 1992 p. 25. For WTO: e.g. United States –Standards for Reformulated and Conventional Gasoline, WTO Doc. AB-1996-1, WT/DS2/AB/R, at 17 (May 20, 1996), 35 ILM 603 (1996) and Palmetier and Mavroidis 1998 p. 406.

<sup>81</sup> See for example the Rome Treaty.

<sup>82</sup> Kapteyn and Themaat 1998 p. 77.

Directive has, however, more the character of internal law common to the member states.<sup>83</sup> In this relation EC law deviates from public international law. The question is on the basis of which principles EC Directives are to be interpreted. As a starting point it can be said that the interpretation of EC Directives is based on the same principles as in Article 31, first paragraph of the Vienna Convention. This means that the wording, context and objectives of the Directive are to be taken into account. Such an understanding implicates that the basis for interpretation of public international law and EC law is similar to one another.<sup>84</sup> Nevertheless, due to the EC's aim to harmonise legislation within the Community underscored in Recital 5 of the Preamble of the Rome treaty, the European Court of Justice emphasises the advantages of a teleological approach to the interpretation of Directives and EC law in general.<sup>85</sup> This does however not deviate considerably from the general aim to harmonise patent law which EPC is one result of.<sup>86</sup> On this background the terms *plant* and *animal variety* in the EC Patent Directive and EPC are discussed simultaneously and, as a point of departure, interpreted on the basis of the same principles throughout the thesis. Where the approaches of EPO and EC are deviating, the differences are emphasised.

When interpreting international law as an integral part of EC law the international agreement is, according to the European Court of Justice in the *Polydor* case, interpreted in accordance with the customary rules of international law on interpretation of treaties

---

<sup>83</sup> Ibid..

<sup>84</sup> Borgli and Arnesen 1993 p. 116.

<sup>85</sup> Ellis and Tridimas 1995 p. 563.

<sup>86</sup> Recital 1 and 2 of the preamble of EPC.

as codified in Article 31 and 32 of the Vienna Convention.<sup>87</sup> This approach is therefore applied when discussing the Patent Directive in relation to EPC and TRIPs.

### 3.3 Other treaties as a source of law

A reoccurring question in this thesis is whether one provision or term in a treaty can be taken into account as a source of law when interpreting a similar provision or term in another treaty. During the work on the thesis, this methodological question in particular has emerged and been necessary to assess in order to interpret the terms *plant* and *animal variety*. The question is important and of current interest due to the relationship between patent systems and plant variety protection which exists on the field of intellectual property protection of plants and animals. The answer to the question determines how EPC and the Patent Directive are discussed in relation to each other. It also determines how TRIPs and UPOV-91 affects the understanding of *plant* and *animal variety* in both EPC and the Directive. The approach to discuss this question and the conclusions of these discussions varies depending on which legal document is assessed in relation to EPC or the Directive. A presentation of this methodological issue is therefore not given here, but rather in relation to the chapters where the material legal questions are discussed.

---

<sup>87</sup> C-270/80, Polydor Ltd & RSO Records Inc v. Harlequin Record Shops Ltd & Simons Records Ltd, (1982) ECR 329. See also Bourgeois 2000 p. 97.

## 4 Plant and animal variety in EPO and EC

In this chapter the understanding of the terms *plant and animal variety* in the European Community and the European Patent Organisation is discussed. Thus, the question is what plant and animal subject matter is not seen as a *plant* or *animal variety* and therefore escapes the variety exceptions. The variety exceptions in the two patent systems are assessed and compared to each other. A simultaneous presentation is made since, as the assessment shows, the variety exceptions of EPC and the Directive are quite similar. Prospective divergence between the two exceptions is emphasised. In relation to the question in this chapter, the thesis assesses the limits of the variety exceptions. Hence, the challenge is to examine the limits of the terms in relation to patentable subject matter. Therefore, the presentation is divided into two parts: first, the variety exception is discussed in relation to patentable plant and animal categories superordinate to the variety level. Second, the terms *plant* and *animal variety* are delimited towards patentable subordinate categories.

### 4.1 Wording

Here, the question is how the terms *plant* and *animal variety* are understood in EPC and EC. The point of departure for the interpretation is the wording of the texts.<sup>88</sup> Article 53 (b) EPC makes this statement:

‘European patents shall not be granted in respect of: plant or animal varieties....’

---

<sup>88</sup> The Vienna Convention Article 31, first paragraph.



And Article 4, first paragraph, litra a of the Directive spells out this emphasis:

‘The following shall not be patentable: Plant and animal varieties;....’

According to the Vienna Convention, the ordinary meaning of the *plant and animal varieties* has to be established. The methodology of EC law does not diverge from this point of departure.<sup>89</sup> First, it is emphasised that a contextual understanding of ‘*plant and animal variety*’ means that the term *variety* refers both to *plant* and to *animal*. The term *variety* is normally used in relation to taxonomical classification.<sup>90</sup> *Variety* is then delimited towards other taxonomical levels. A linguistic approach, therefore, implies that the exception covers *varieties* as opposed to categories of plants and animals on other taxonomical levels.

The provisions have to be examined in accordance within their context.<sup>91</sup> Article 53 (b) EPC and Article 4, first paragraph, litra a of the Directive are exceptions to the general rule in Article 52 (1) EPC and Article 3, first paragraph of the Directive. The point of departure is that all subject matter which fulfils the patent criteria and is not explicitly excluded from patentability shall be granted protection.<sup>92</sup> This follows from Article 52 (1):

---

<sup>89</sup> See Borgli and Arnesen 1993 p. 116.

<sup>90</sup> See Chapter 2.

<sup>91</sup> The Vienna Convention Article 31, first paragraph.

<sup>92</sup> It is important to note that the substance, and not only the form of the claim is assessed. This indicates that applicants will not be granted a patent if they try to adapt the claim with mere linguistic alterations to comply with the requirements. See Bently and Sherman 2001 p. 397.

‘European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.’<sup>93</sup>

The Directive’s statement is similar:

‘...inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable...’<sup>94</sup>

This implies that the exception is not to be interpreted widely. The taxonomical levels that delimit *variety*, for example *species* or *subspecies*, are not defined in either EPC or the Directive. Consequently, little assistance can be found in these terms. The term *plant variety* is on the other hand defined in both texts. In the *Implementing Regulations to the Convention on the Grant of European Patents*, Rule 23b, *plant variety* is defined.<sup>95</sup> Its paragraph 4 makes this statement:

“‘Plant variety’ means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of plant variety right are fully met, can be:

defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

---

<sup>93</sup> Article 52 (1) EPC.

<sup>94</sup> Article 3, first paragraph of the Directive.

<sup>95</sup> The Implementing Regulations are viewed as part of the relevant context the convention is to be assessed in. This is emphasised in Enlarged Board of Appeal case G 5/83 and in Paterson 1992 p. 24.

distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regards to its suitability for being propagated unchanged.’

In Article 2, third paragraph of the Patent Directive there is a reference to a definition given in Regulation (EC) No 2100/94 on Community plant variety rights.<sup>96</sup> The Directive states that the term is to be interpreted in accordance with the definition in the Regulation. *Plant variety* is defined in the Regulation Article 5 (2):

‘For the purpose of this Regulation, “variety” shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be defined by the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged.’

This definition is almost identical to the wording in the Implementing Regulation. One divergence is, however, found in the opening part of the definitions. In EPC the opening words are “‘*Plant variety*” means...’, in EU it is stated that ‘For the purpose of this Regulation “*plant variety*” shall be taken to mean...’. These introduction phrases hold no legal meaning. In substance the two definitions are identical. Both definitions are also identical to the definition of *plant variety* as applied in UPOV from which they

---

<sup>96</sup> Even though the scope of the Regulation is delimited to plant breeder’s rights, the definition given there is relevant due to the reference in the Directive.

originate.<sup>97</sup> This emphasises the relation between patent protection and plant breeder's rights.

The term *animal variety* is not defined in either EPC or the Directive. This may be due to the fact that *breed* and not *variety* is the relevant category for animals.<sup>98</sup> Furthermore, *plant varieties* may be protected by the UPOV Conventions. As for *animal varieties* no such alternative protection is available. The term *plant variety* is defined in UPOV-91.<sup>99</sup> The definitions of *plant variety* in EPC and the Directive have been inspired by the understanding of the term in UPOV.<sup>100</sup> Since there is no alternative intellectual property protection for animal subject matter, a link to a *sui generis* system similar to the one for *plant varieties*, is missing for *animal varieties*. This may also contribute to explaining why *animal variety* is not defined in EPC or the Directive.

Some scholars have discussed whether the definition of *plant variety* can be applied analogously to contribute to the understanding of the term *animal variety*.<sup>101</sup> On the one hand, the terms are quite similar in that both terms are called *variety*. Thus, according to an ordinary meaning of the wording in Article 53 (b) EPC and Article 4, first paragraph, *litra a* of the Directive, an analogous interpretation is an option. This can imply that the two terms are to be defined identically. On the other hand, it is necessary to emphasise the fact that no alternative intellectual property protection for *animal varieties* exists. Taking into account that the definition of *plant variety* is closely linked to the definition

---

<sup>97</sup> Westerlund 2001 p. 322.

<sup>98</sup> See Chapter 1.4.

<sup>99</sup> Article 1 (vi) UPOV-91.

<sup>100</sup> Westerlund 2001 p. 322 and p. 324.

<sup>101</sup> See for example Westerlund 2001 p. 388.

in UPOV-91, and the desire to avoid protection for identical subject matter under both plant breeder's rights and the patent systems, it is possible that the term *animal variety* should be interpreted differently since dual protection is not an issue for animal subject matter.<sup>102</sup> Moreover, it is also possible that the actual and biological differences between plants and animals may give good reasons for interpreting the two terms in different ways.<sup>103</sup> These two arguments suggest that an analogical interpretation of the term *animal variety* should not be applied. Based on this discussion, the following presentation is not grounded on an analogical application of the term *plant variety* for the interpretation of *animal variety*. This feature will pervade the discussion of object and purpose.<sup>104</sup>

As seen in this chapter, the wording of the variety exception in EPC and the Directive does not determine the exact understanding of the exception. In the subsequent discussions other sources of law are assessed. In the following presentation *variety* is approached from two angles. The term *variety* is first assessed in relation to more general categories of plants and animals such as *species* and *family*. Because they are on a higher taxonomical level than *variety* these categories are as a collective term called *superordinate taxonomical levels*. This is examined in Chapter 4.2. Second, in Chapter 4.3, the term is discussed in relation to biological levels subordinate to *variety*, such as individual specimens of plants and animals and microbiological material.

---

<sup>102</sup> See Chapter 5.

<sup>103</sup> This argument is emphasised by Westerlund 2001 p. 389.

<sup>104</sup> See Chapter 5.

## 4.2 Superordinate taxonomical levels

In the previous chapter the wording of the variety exceptions in relation to both the superordinate and the subordinate limitation was in focus. The question here is how the limits of *plant* and *animal variety* is determined in relation to categories of plant and animal subject matter on superordinate taxonomical levels. The understanding of the exceptions in relation to categories of superordinate taxonomical rank was first outlined in EPO case law. The variety exception has later been specified in accordance with the case law in both the EPC Implementing Regulations and the EC Directive. To give a chronological presentation, the case law is examined in the Chapters 4.2.1-4.2.8, before the codifications are assessed. The object and purpose of the limitation of the variety exception regarding categories of plants and animals of higher taxonomical rank is assessed in Chapter 4.2.9.

### 4.2.1 EPO case law –introduction

The topic here is to investigate how the term *plant* and *animal variety* has been interpreted in the case law of the Technical Board of Appeal and the Enlarged Board of Appeal. Seven cases from the European Patent Organisation particularly contribute to the understanding of the legal situation on this matter.<sup>105</sup> The cases are the Ciba Geigy decision,<sup>106</sup> the Lubrizol decision,<sup>107</sup> the Onco-mouse decision,<sup>108</sup> the Plant Genetic

---

<sup>105</sup> In accordance with the Vienna Convention Article 31, second paragraph, *litra b* practice from EPO is examined.

<sup>106</sup> Ciba-Geigy/Propagating Material Application, T 49/83 (1979-85) C EPOR 758.

<sup>107</sup> Lubrizol/Hybrid plant, T 320/87 (1990) EPOR 173.

Systems decision,<sup>109</sup> Opinion G 3/95<sup>110</sup>, the Novartis I decision<sup>111</sup> and the Novartis II decision<sup>112</sup>. The cases are important for the understanding of *de lege lata* because they discuss the issue of *variety* directly. One of the cases, the Onco-mouse case, concerns the term *animal variety*, while the other cases discuss the interpretation of *plant variety*. According to the Technical Board of Appeal, the Onco-mouse case is also relevant for the interpretation of *plant variety* due to the quality of the arguments presented.<sup>113</sup> The Novartis II case is the most recent judgement assessing plant subject matter and can thus be expected to give an indication of the present legal situation for plants. The other cases give, to a various degree, alternative approaches and solutions to the questions. The question is if a *plant variety* or *animal variety* not specified in the patent application can be covered by patent regulation when the claims are related to a category of plants and animals on a higher taxonomical level. The cases are presented in the following chapters. To emphasise their importance and due to the attention given to them in terms of textual volume, the cases are assessed on the same level of heading as the other sources of law.

---

<sup>108</sup> Harvard/Onco-mouse, T 19/90 (1990) EPOR 501.

<sup>109</sup> Plant Genetic Systems/Glutamine synthetase inhibitors, T 356/93 (1995) EPOR 357.

<sup>110</sup> Inadmissible referral, G 3/95 (1995) EPOR 505.

<sup>111</sup> Novartis/Transgenic plant, T 1054/96 (1999) EPOR 123.

<sup>112</sup> Novartis/Transgenic plant, G 1/98 (2000) EPOR 303.

<sup>113</sup> T 356/93 point 30 Of the Reasons.

#### 4.2.2 The Ciba Geigy case and the Lubrizol case

In 1979 a company called Ciba Geigy applied for a patent on chemically treated plants for the purpose of making the plants resistant to agricultural chemicals. The application was first refused, but that decision was later appealed to the Technical Board of Appeal in 1983. The question in the Ciba Geigy case was to what extent patent claims which are not confined to one particular *plant variety* are patentable. In other words, if the exception in Article 53 (b) EPC is applicable when a patent is claimed for categories of plants on a higher taxonomical level. The Technical Board of Appeal made this argument:

‘... the subject-matter of claims 13 and 14 is not an individual variety of plant distinguishable from any other variety, but the claims relate to any cultivated plants in the form of their propagating material which have been chemically treated in a certain way. However, Article 53 (b) EPC prohibits only patenting of plants or their propagating material in the genetically fixed form of the plant variety.’<sup>114</sup>

As the quotation indicates, the Technical Board of Appeal ruled that only claims confined to one single *plant variety* were to be excluded from patentability. This implicates that applications covering more than one *plant variety* are patentable. They based this conclusion on the wording of Article 53 (b) EPC and on the reasons for creating the exception:

---

<sup>114</sup> T 49/83 point 3 of the Reasons.



‘Plant varieties were excluded from European patent protection mainly because several of the signatory states to the European Patent Convention have developed special protection for plant breeding at national and international level.’<sup>115</sup>

The Technical Board of Appeal refers to one reason for excluding *plant varieties* from patentability: the unfavourable possibility for dual protection. It would mean that the rightholder was granted a too extensive a right, bringing the interplay between rightholder and society out of balance. Since there was a system of protection for *plant varieties*, they were exempted from patentability. Moreover, the 1961 and 1978 versions of the UPOV Convention had introduced an explicit double protection ban.<sup>116</sup>

The Technical Board of Appeal then looked at the Strasbourg Patent Convention of 27 November 1963 which is the predecessor of the European Patent Convention.<sup>117</sup> Article 53 (b) EPC strictly adhered to the wording of Article 2 (b) of the Strasbourg Patent Convention.<sup>118</sup> With regard to the legal situation at the time of construction of the Strasbourg Patent Convention the Technical Board of Appeal made this statement:

‘Even at that time the majority of the States represented on the Council of Europe were already of the opinion that plant varieties should be protected not by patents but by a special industrial property right.’<sup>119</sup>

---

<sup>115</sup> T 49/83 point 4 of the Reasons.

<sup>116</sup> See Article 2 (1) in both conventions.

<sup>117</sup> See for example Paterson 1992 p. 16.

<sup>118</sup> See the Strasbourg Patent Convention Article 2 (b) cf. Article 53 (b) EPC.

<sup>119</sup> T 49/83, point 4 of the Reasons.

This statement supports the notion that the problems connected with dual protection were decisive in the creation of the variety exception. In accordance with the Vienna Convention, the Technical Board of Appeal can apply this understanding in their argumentation.<sup>120</sup> The object of the provision is used in its interpretation. This leads to an interpretation of *plant variety* in accordance with the ordinary meaning of the term. The reference to the object and purpose of the provision was repeated in second of these two cases, the Lubrizol decision.<sup>121</sup> This case concerned a certain kind of hybrid seed and the resulting plants. The Technical Board of Appeal came to the conclusion that the claimed product was not encompassed by the term *plant variety*. The patent application was therefore remitted to the Examining Division for further prosecution.

The Ciba Geigy case refers to the object and purpose of the exception. These considerations were connected only to plants. Thus, the legal situation for animals remained uncertain since plant variety protection only is available for one particular subject matter, namely *plant variety*. The question is how the variety exception for animals is delimited contrary to the plant variety exception. The fact that there is no alternative protection system for animals requires that the dual protection ban argumentation cannot be applied for this group. The question was not addressed until 1990, when the refusal of the Onco-mouse patent application was appealed before the Technical Board of Appeal.

---

<sup>120</sup> See the Vienna Convention Article 31, first paragraph: ‘A treaty shall be interpreted... in the light of its object and purpose.’

<sup>121</sup> T 320/87 point 12 of the Reasons.

### 4.2.3 The Onco-mouse case

The Onco-mouse is a genetically modified mouse especially constructed to be exposed to cancer. The mice are used in cancer research as test animals. They are named after the gene introduced through genetic engineering; the onco gene. The patent claims were expressed more widely than one mouse variety. The inventors claimed patent rights for all non-human mammals with the inserted onco gene. The patent was ultimately granted for all rodents with the inserted onco gene.<sup>122</sup> This scope is broader than a mouse, but narrower than all non-human mammals. The question was if an invention with such a scope was excluded from patentability. The Technical Board of Appeal expressed the view:

‘In the decision under appeal the Examining Division interpreted Article 53 (b) EPC as excluding not only certain groups of animals from patentability but, in fact, animals as such. The Board is unable to accept this interpretation.’<sup>123</sup>

The Technical Board of Appeal was of the opinion that only *animal variety*, and not categories of animals in other taxonomical levels, is excluded from patentability. The statement indicates that the Technical Board of Appeal chose to apply an interpretation in compliance with the ordinary meaning of the wording and parallel to the interpretation of *plant variety* presented in the previous chapter. The Technical Board of Appeal emphasised this point:

---

<sup>122</sup> See [www.european-patent-office.org/news/pressrel/2001\\_11\\_07\\_e.htm](http://www.european-patent-office.org/news/pressrel/2001_11_07_e.htm), accessed on 10 November 2003.

<sup>123</sup> T 19/90 point 4.4 of the Reasons.

‘...Article 53 (b) EPC is an exception, for certain kinds of inventions, to the general rule under Article 52 (1) EPC that European patents “shall be” granted for all inventions which are susceptible of industrial application, which are new and involve an inventive step. Any such exception must, as repeatedly pointed out by the Boards of Appeal, be narrowly constructed.’<sup>124</sup>

The Technical Board of Appeal stresses that an exception, under normal circumstances, is to be interpreted not only in the light of the wording, but also with respect for the main rule from which the exception derives. Consequently, when the main rule is widely formulated and only delimited by explicit exceptions, there is reason to adopt a restrictive and narrow understanding of the exceptions.

As the examination above shows, the term *animal variety* is delimited negatively by the Technical Board of Appeal, in that it emphasises the terms relation to patentable subject matter. *Plant variety* on the other hand is, in addition to a negative delimitation, positively defined.<sup>125</sup> The question to be posed here is whether *animal variety* was given a positive content by the Technical Board of Appeal which can contribute to the delimitation of the term towards categories of animals on superordinate taxonomical ranks. The Technical Board of Appeal says this:

‘It is 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", providing a proper balance between the interest of inventors in this field in obtaining

---

<sup>124</sup> T 19/90 point 4.5 or the Reasons.

<sup>125</sup> See EPC Implementing Regulations Rule 23b, litra d where a positive definition of the term is given.

reasonable protection for their efforts and society's interest in excluding certain categories of animals from patent protection.’<sup>126</sup>

Here, the Technical Board of Appeal gives an indication of the frames for defining the term. It emphasised the need for a definition which is balanced between the interests of the inventor and society. The Technical Board of Appeal did not, however, go any further with the assessment of the question at hand. Moreover, the Technical Board of Appeal discussed the comparison of the three original language versions of EPC. In the French version *animal variety* is called *raças animales*, while in the German version *Tierarten*. The ordinary meaning of the term in the latter version diverges from the other two by encompassing the superordinate taxonomical rank *species*. Without being more concrete about the positive delimitation of *animal variety*, this understanding of the term was rejected by the Technical Board of Appeal. They did not give any clear reason for this argumentation. However, it was probably based on the principles laid down in Article 33, paragraph 4 of the Vienna Convention which regulates conflicts between equally authoritative language versions of a treaty. Some conventions may be written in different language versions that are all authoritative, in other words equally binding for the contracting parties. The question is what happens when the different versions give different results based on the interpretation of the wordings. Such conflicts are regulated in Article 33, paragraph 4 of the Vienna Convention.<sup>127</sup> It is emphasised that the version

---

<sup>126</sup> T 19/90 point 4.7 of the Reasons.

<sup>127</sup> Article 33, paragraph 4 of the Vienna Convention: ‘Except where a particular text prevails in accordance with paragraph 1, when a comparison of the authentic text discloses a difference of meaning which the application of articles 31 and 32 does not remove, the meaning which best reconciles the texts, having regard to the object and purpose of the treaty, shall be adopted.’

best promoting the object and purpose of the treaty is to make the basis for the interpretation. This means that teleological considerations are relevant when the versions cannot be harmonised. The version that brings the treaty closest to its intentions will prevail. It is also important to note that this article only comes into effect if harmonization is not possible. Many differences may be solved using Article 31, paragraph 1 of the Vienna Convention, where it is emphasised that treaties are to be interpreted in their context and in the light of their object and purpose. In this case the biological and ordinary meaning of the term *Tierarten* is, as discussed above, diverging from the terms used in the two other language versions. On this basis, it is possible that the Technical Board of Appeal founded their decision on such considerations.

Even though it also here had the opportunity to examine the positive delimitation of *animal variety*, the Technical Board of Appeal did not do so. These two arguments show that contrary to *plant variety*, the term *animal variety* has not been positively defined by EPO. One consequence may be that the understanding of the two terms drift apart, opening for diverging practice of the variety exception for plants and animals. This could implicate that the limits of the plant variety exception may deviate from the limits of the plant variety exception.

Even though the Onco-mouse decision concerns the term *animal variety*, the reasoning connected to the delimitation of the variety exception towards superordinate taxonomical levels has been regarded effective also for the understanding of the term *plant variety*.<sup>128</sup> The Ciba Geigy case, the Lubrizol case and the Onco-mouse case seemed to clarify the understanding of the situation where the patent claims

---

<sup>128</sup> See for example Westerlund p. 339 where T 19/90 is discussed in relation to the understanding of *plant variety*.

encompassed more than one *plant variety* so that such subject matter is not comprised by the variety exception.

#### 4.2.4 The Plant Genetic Systems case

Uncertainty was created in the wake of the Plant Genetic Systems case.<sup>129</sup> A patent was granted in 1990 by the Examining Division for specific plant cells resistant to glutamine synthetase inhibitors made by genetic engineering.<sup>130</sup> In plain English, the invention comprised, among other claims, a genetically modified tobacco plant resistant to herbicides. The applicant was Plant Genetic Systems N.V.. Greenpeace opposed the granting of the patent. The case was admitted to the Technical Board of Appeal in 1993 as case T 356/93. Their conclusion was that the invention was patentable, although in an altered form. The claims were limited in accordance to the Technical Board of Appeal's ruling and protection was awarded the applicant.<sup>131</sup>

The question relevant in this perspective was if and to what degree it was possible to grant patents for inventions encompassing plant varieties. To avoid the exclusion for *plant varieties* in Article 53 (b), the applicant claimed protection for a wider scope than a specific *plant variety*. The patent claims focus on '...non-variety specific enzymatic activity....'<sup>132</sup> This means that the claims include more than the tobacco plant mentioned above. It is more general in its formulation, and not confined to one

---

<sup>129</sup> See G 3/95 point II of the Summary of the procedure.

<sup>130</sup> See the title of the application. Application number: 87400141.5.

<sup>131</sup> T 356/93 point 44 of the Reasons.

<sup>132</sup> T 356/93 point 40.3 of the Reasons.

particular *plant variety*. With regards to the patentability of such claims the Technical Board of Appeal made this argument:

‘A claim is not allowable if the grant of a patent in respect of the invention defines in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability.’<sup>133</sup>

This means that the Technical Board of Appeal wanted to avoid a situation where of the linguistic skills of the patent attorneys determines which patents can be granted.

Furthermore, the Technical Board of Appeal emphasises that:

‘Given the fact that Claim 21 encompasses plant varieties..., it follows therefore, that Claim 21 is only allowable, if the exception to patentability under Article 53 (b) EPC, first half-sentence, concerning plant varieties does not apply, because the subject-matter of this claim is to be regarded as the product of a microbiological process....’<sup>134</sup>

The Technical Board of Appeal states that one cannot obtain protection for a *plant variety* merely because the claim also encompasses more than, and is more general than, a specific *plant variety*. The only situation where a patent can be granted is, according to the Technical Board of Appeal, where the subject matter is a product of a microbiological process and thus falls in under the exception from the variety exception in Article 53 (b), second half sentence.<sup>135</sup> This was not the case for the Plant Genetic

---

<sup>133</sup> T 1054/96 point 40.7 of the reasons.

<sup>134</sup> T 1054/96 point 40.8 of the reasons.

<sup>135</sup> Article 53 (b) EPC, second half sentence: ‘...this provision shall not apply to microbiological processes and the products thereof.’



Systems application. Consequently, patent protection was not granted to Plant Genetic Systems for the invention in this general form.

The Plant Genetic Systems case seems to take a stand opposite to the previous cases.

The Ciba Geigy case, the Lubrizol case and the Onco-mouse case conclude that *plant varieties* are not patentable, while superordinate categories for plants are patentable.

The results are based on diverging argumentation. Unlike the Technical Boards of Appeal in the Ciba Geigy case and the Lubrizol case, the Technical Board of Appeal in the Plant Genetic Systems case does not assess the object and purpose of the provision. Instead the question of evasion of the exception is brought into examination. The Onco-mouse decision concerns animals, for which there is no alternative intellectual property protection. Since the object and purpose of the *animal variety* exception for that reason differs from that of the *plant variety* exception, the Onco-mouse decision can not be based on the same argumentation as the Ciba Geigy case and the Lubrizol case. The Onco-mouse decision is based on the variety exception's relation to the main rule in Article 52 (1) EPC. The question of evasion was not touched upon. This divergence of both argumentation and result created uncertainty with regard to the legal situation on this point.

#### 4.2.5 Opinion G 3/95

The President of EPO expressed uncertainty with regard to the case law from the Technical Board of Appeal. In his opinion the result in the Plant Genetic Systems case stood in contradiction to the results in the Ciba Geigy case and the Onco-mouse case.<sup>136</sup>

---

<sup>136</sup> G 3/95 point VI of the Summary of the procedure.

According to Article 112 (1) (b) EPC, the President of EPO can refer a point of law to the Enlarged Board of Appeal where two Technical Boards of Appeal have given different decisions on a question. Therefore, on the 28 of July 1995 the President of EPO referred a question to the Enlarged Board of Appeal.<sup>137</sup> He asked the Enlarged Board of Appeal to comment on the legal situation subsequent to the apparently conflicting decisions from the Technical Boards of Appeal in the Ciba Geigy case<sup>138</sup> and the Onco-mouse case<sup>139</sup> on the one hand and Plant Genetic Systems case<sup>140</sup> on the other. The President's question was this:

‘Does a claim which relates to plants or animals but wherein specific plant or animal varieties are not individually claimed contravene the prohibition of patenting in Article 53 (b) EPC if it embraces plant or animal varieties?’<sup>141</sup>

The Enlarged Board of Appeal's conclusion was that the cases were not conflicting.<sup>142</sup> They argued that the legal issues in the two groups of cases are in fact different.<sup>143</sup> In the Plant Genetic Systems decision, the Enlarged Board argued, the Technical Board of Appeal reasoned that the genetically modified plant itself complied with the definition of a *plant variety* in the UPOV-91 Convention and was thus not patentable within the meaning of Article 53 (b) EPC. In other words, the claimed invention did not include

---

<sup>137</sup> G 3/95.

<sup>138</sup> T 49/83.

<sup>139</sup> T 19/90.

<sup>140</sup> T 356/93.

<sup>141</sup> G 3/95 point I in the summary of the procedure.

<sup>142</sup> G 3/95 point 8 of the Reasons.

<sup>143</sup> G 3/95 point 8 of the Reasons.

within its scope more than one *plant variety*, but was in fact a *plant variety*. The two other cases dealt, according to the Enlarged Board of Appeal, with the question of more than one *variety* within the scope of a patent. Consequently, the President's question was answered with the notion that there was no contradiction between the cases. Furthermore, that the Ciba Geigy case and the Onco-mouse case expressed the legal situation with regard to inventions encompassing more than one *variety*. In other words, inventions comprising more than one *variety* are patentable.

An important question to assess is how this opinion was interpreted in subsequent case law from the Technical Board of Appeal and the Enlarged Board of Appeal. As explained in Chapter 2.1, there is no formal precedence in EPO. Nevertheless, a practice from the Enlarged Board of Appeal is continued if there are no particular reasons not to do so. Thus, strong reasons have to indicate an alternative argumentation or result. In this case the Enlarged Board of Appeal expressed quite clearly how this point of law is to be interpreted. This points towards a coherent understanding of subsequent practice from the Technical Board of Appeal and the Enlarged Board of Appeal.

#### 4.2.6 The Novartis I case

Even though the Enlarged Board of Appeal was of the understanding that the legal situation was unambiguous, others, such as the company Novartis AG, were not so certain of the legal content of Article 53 (b) EPC. A patent application was submitted by Novartis for genetically modified plants containing transgens making them resistant to fungi. The patent application was launched as a test patent after the strict ruling, from

plant innovators' point of view, in the Plant Genetic Systems case.<sup>144</sup> The patent application would, if granted, give the applicant, Novartis, patent protection for non-specifically claimed plant varieties embraced by the patent claims. Novartis calls this the 'more than a single variety' approach.<sup>145</sup> The patent application, with application number No. 91810144.5, was refused by the Examining Division because it was covered by the exception in Article 53 (b) EPC. This decision was appealed by the applicant and was admitted by the Technical Board of Appeal in 1996 as case T 1054/96. In the Plant Genetic Systems case the Technical Board of Appeal held that, as explained above, patent protection was not granted for patents encompassing *plant varieties*.

Consequently this meant, according to the Examining Division, that a patent could not be granted for an invention like the Novartis application where a *plant variety* was part of the invention, but not specifically claimed. The Technical Board of Appeal took the same stand in this statement:

'To deduce from this wording of Article 53 (b) EPC that a patent shall not be granted for a single plant variety but may be granted if its claims cover more than one variety, does not appear to comply with the normal rules of logic.'<sup>146</sup>

This means that the Technical Board of Appeal objected to the 'more than a single variety' approach.<sup>147</sup> However, the Technical Board of Appeal was uncertain of this

---

<sup>144</sup> See a brief comment on the case in the European Intellectual Property Report, 2000 p. N-49.

<sup>145</sup> T 1054/96 point 32 of the Reasons.

<sup>146</sup> T 1054/96 point 36 of the Reasons.

<sup>147</sup> T 1054/96 point 32 of the Reasons.

reasoning.<sup>148</sup> They therefore referred four questions to the Enlarged Board of Appeal, one of which is relevant in this context:<sup>149</sup>

‘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?’<sup>150</sup>

The question is identical in content to the question referred by the President of EPO to the Enlarged Board of Appeal in Opinion G 3/95 discussed above. On that occasion the Enlarged Board of Appeal avoided commenting to a great extent on its opinion in this matter. The Enlarged Board of Appeal concluded, however in accordance with *Ciba Geigy* case and the *Onco-mouse* case that patents embracing *plant varieties* are covered by the exception in Article 53 (b) EPC. In the *Novartis I* case the Technical Board of Appeal came to no formal conclusion other than referring questions to the Enlarged Board of Appeal. However, in their argumentation they suggested that categories of plants on taxonomical levels superordinate to *plant variety* should be covered by the variety exception.<sup>151</sup>

---

<sup>148</sup> T 1054/96 point 37 of the Reasons.

<sup>149</sup> The answers to the questions are given in Opinion G 1/98 which is discussed in the following chapter. See Article 112 (1) (a) EPC.

<sup>150</sup> T 1054/96 point 31 of the Reasons.

<sup>151</sup> T 1054/96 point 36 of the Reasons.

#### 4.2.7 The Novartis II case

On this background the question was referred to the Enlarged Board of Appeal in 1998 and assessed as case G 1/98.<sup>152</sup> The Enlarged Board of Appeal made a contrasting argument to the Technical Board of Appeal in Novartis I:

‘If the intention to exclude plants as a group embracing in general varieties as products, the provision would use the more general term plants as used for the processes.’<sup>153</sup>

This means that According to the Enlarged Board of Appeal, the ordinary meaning of the wording does not indicate that categories of plants on superordinate taxonomical levels are exempted from patentability. The Enlarged Board of Appeal assumes that the contracting parties of EPC would not use the category *plant variety* if their intention was to except all forms of plants from patentability.

The Enlarged Board of Appeal also emphasised the historical background of the variety exception. In the view of the Enlarged Board of Appeal, the relationship to the UPOV Convention speaks in favour of a narrow interpretation of the exception.<sup>154</sup> Furthermore, they pointed out practical reasons for limiting the variety exception to comprise only *plant varieties*:

---

<sup>152</sup> The Novartis II case.

<sup>153</sup> G 1/98 point 3.3.1 of the Reasons.

<sup>154</sup> G 1/98 points 3.4 to 3.7 of the Reasons.

‘The inventor would not obtain appropriate protection if he were restricted to specific varieties for two reasons: first, the development of specific varieties will often not be in his field of activity and, second, he would always be limited to a few varieties even though he had provided the means for inserting the gene into all appropriate plants.’<sup>155</sup>

If EPC patent protection could not be obtained for any category of plants, the only possible protection would be afforded for *plant varieties* by the UPOV Convention. These reflections contribute to the rest of the argumentation presented by the Enlarged Board of Appeal. To interpret Article 53 (b) EPC as excluding all categories of plants would create an insufficient opportunity for inventors to protect their products. It would also leave subject matter with no possible intellectual property protection. Categories of plants on taxonomical levels superordinate to *variety* would not be protectable by either plant breeder’s rights or patent. The Enlarged Board of Appeal did not find that such a situation was intended.<sup>156</sup> After considering the above mentioned arguments, the Enlarged Board of Appeal came to the conclusion 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*.<sup>157</sup>

Consequently, they agreed with the thought of the so called ‘more than a single variety’ approach which requires that patents encompassing *plant varieties* not individually claimed may be granted. This conclusion stands in contrast to the findings in the Plant Genetic Systems case and the Novartis I case. However, the decision in the Novartis II case is delivered by the Enlarged Board of Appeal which is the last instance of appeal in

---

<sup>155</sup> G 1/98 point 3.8 of the Reasons.

<sup>156</sup> G 1/98 point 3.7 of the Reasons.

<sup>157</sup> G 1/98 point 2 of the Conclusion.

the EPO system. Furthermore, the Novartis II decision is the latest case considering this point of law. This entails that the decision expresses the current legal understanding of Article 53 (b) EPC.

#### 4.2.8 Consequences

The consequence of the Novartis II ruling is that the organs that are given the competence to interpret EPC, the Technical Board of Appeal and the Enlarged Board of Appeal, have chosen an approach which emphasises the relation between the patent system and plant breeder's rights at the expense of an understanding of Article 53 (b) EPC that excludes plants and animals from patentability on a broad scale. A method of restricting patents for such subject matter is to interpret the variety exception to include categories of plants and animals of all taxonomical ranks. The Enlarged Board of Appeal in the Novartis II case, on the other hand, argued that the term *plant variety* should be interpreted narrowly to include only the taxonomical rank of *variety*, allowing superordinate ranks to be patentable. Therefore, the gap in the intellectual property protection of plants is avoided. As explained above, if the variety exception is understood to include plants on all taxonomical levels, there will be subject matter with no protection available.<sup>158</sup> The taxonomical rank *variety* can be protected by plant breeder's rights while categories of plants on superordinate taxonomical levels have no alternative protection to the patent system. This is avoided when applying the approach chosen by the Enlarged Board of Appeal in the Novartis II decision. The implications of this approach to interpreting Article 53 (b) EPC may be that patent protection is

---

<sup>158</sup> See the Novartis II discussion.



afforded a wider range of plant subject matter than with the more restrictive approach, thus contributing to wider patent claims.

The relationship between patents and plant breeder's rights does not concern the understanding of the term *animal variety*. Inventors cannot obtain intellectual property protection for animals through plant breeder's rights. Nevertheless, the Technical Board of Appeal in the Onco-mouse case came to the conclusion that the variety exception does not comprise taxonomical levels superordinate to *animal variety*.<sup>159</sup> They came to the same conclusion as the Enlarged Board of Appeal later did in the Novartis II case. Since they could not base their argumentation on EPC's relationship to UPOV, they applied a different reason for the conclusion. In particular, the Technical Board of Appeal in the Onco-mouse case argued that the exceptions relation to the main rule was an important reason for a narrow interpretation of the variety exception.<sup>160</sup>

As pointed out in the examination of the Onco-mouse case above, the Technical Board of Appeal argued that the term *animal variety* has to be defined according to the interface between the interests of the inventor and the interests of society.<sup>161</sup> When it is determined that the term *animal variety* does not include animals as such, and there is no alternative intellectual protection for *animal varieties* it is, in my opinion, unclear what particular interest society has in excluding *animal variety* from patentability. It will be interesting to follow the future case law from EPO on this point of law.

---

<sup>159</sup> See T 19/90.

<sup>160</sup> See T 19/90.

<sup>161</sup> See Chapter 4.2.3 and T 19/90 point 4.7 of the Reasons.

Even though the Boards of Appeal applied divergent reasons for their decisions, they came to the same conclusion both for plants and animals. The use of different argumentation may indicate that the objectives for exempting *plant variety* and *animal variety* are not identical. The object(s) and purpose(s) of the variety exceptions are assessed in Chapter 4.2.9. At this point in the presentation it is sufficient to note that there is a difference in the possibilities for attaining intellectual property protection for plants and animals. Moreover, factual differences in the biological composition of plants and animals may possibly affect the need for intellectual property protection.<sup>162</sup>

Since the reasoning and factual situation differs for plants and animals, the variety exception may possibly be interpreted differently for plants and animals in the future. This might be the case, for instance, if the withdrawal of the dual protection ban in UPOV-91 affects the interpretation of the term *plant variety* in EPC.<sup>163</sup> This is discussed in detail below.<sup>164</sup> For the purpose of this discussion, it is sufficient to point out that even though references to the UPOV-91 Convention have been made, EPC case law has not yet taken the revocation into consideration.<sup>165</sup> UPOV-91 did not enter into force until 24 April 1998. None of the examined case law has been based on patent applications submitted prior to that date. Consequently, according to public international

---

<sup>162</sup> For a further presentation see Chapter 1.4.

<sup>163</sup> The dual protection ban implicates that the same subject matter can not be protected by both patent and plant breeder's rights. In UPOV-61 and -78 there is a ban against such dual protection. The ban was not continued in UPOV-91. For a further presentation on this point of law see Chapter 5.

<sup>164</sup> The impact of the abolishment of the dual protection ban for EPC and the Directive is discussed in Chapter 5.6.

<sup>165</sup> It is referred to the UPOV-91 Convention in for example G 3/95 point 3 (2) of the Reasons.

law it is methodologically correct for the Boards of Appeal to keep to the older versions of the UPOV Convention.<sup>166</sup> Thus, they have not had any occasion to assess the consequences of the removal of the dual protection ban. For future cases to be tried before the Boards of Appeal, however, there are at least three alternative approaches to how the withdrawal of the UPOV dual protection ban may affect the interpretation of Article 53 (b) EPC. First, the Boards of Appeal may come to the conclusion that the UPOV-91 Convention does not affect the interpretation of EPC at all. In that case, the Boards of Appeal can uphold the current legal situation by resting on other legal arguments that lead to the same conclusion. For example, they may use the argumentation applied for animals in the Onco-mouse case. There they have pointed out that a narrow interpretation of Article 53 (b) EPC derives from the relationship between the exception and the main rule in Article 52 (1) EPC.<sup>167</sup> Moreover, the Boards of Appeal may argue that plant breeder's rights are more suitable for protection of *plant varieties* than patent, and therefore leave the protection of such subject matter to UPOV without seeing the abolishment of dual protection as a decisive legal argument. Second, that EPC is not affected by the changes in UPOV until all contracting parties of EPC have become affiliated to UPOV-91. This can, as the discussion in Chapter 5.2 indicates, be the result of an interpretation of Article 31, third paragraph, *litra c* of the Vienna Convention. Third, that the Boards of Appeal consider the changes in UPOV as making the variety exception in Article 53 (b) EPC obsolete and unnecessary. Plant varieties were excluded from European patent protection mainly because several of the signatory States to the European Patent Convention had developed special protection for plant breeding at national and international level and because UPOV prohibited double

---

<sup>166</sup> As a main rule, a treaty does not apply until it enters into force. This can be deduced from Article 18 (b) of the Vienna Convention.

<sup>167</sup> See Chapter 4.2.3.

protection.<sup>168</sup> Thus, the Boards of Appeal could argue that it would be unreasonable to uphold an exclusion in EPC when double protection is not forbidden in UPOV. It may be methodologically difficult for the Boards of Appeal to disregard the wording of the variety exception, but they may at least send a signal to the competent body that amendments are necessary. It is impossible to say with certainty what alternative the Boards of Appeal will choose. This concludes the discussion of EPO case law. In the following chapter the subsequent administrative rules based on the reviewed case law are assessed.

#### 4.2.9 Object and purpose of EPC and the Directive

The relevance of a treaty's object and purpose as a source of law is established in Article 31, first paragraph of the Vienna Convention. A teleological interpretation is also according to EC law a means of interpretation.<sup>169</sup> This means that for EPC and the Directive a teleological interpretation is relevant for the understanding of the terms *plant* and *animal variety*. The question in this chapter is how the terms *plant* and *animal variety* of EPC and the Directive are affected by their object and purpose.

In a historical perspective, the exception of plant and animal subject matter originates from the conclusion of the Strasbourg Patent Convention, the predecessor of EPC, in 1963. Article 2 of the Strasbourg Patent Convention states that *plant* and *animal varieties* were not patentable. Just a few years earlier, in 1961, the UPOV Convention was signed by most of the European states which later entered into the Strasbourg

---

<sup>168</sup> See T 49/83 point 4 of the Reasons.

<sup>169</sup> Ellis and Tridimas 1995 p. 563.

Patent Convention. UPOV-61 emphasised that dual protection, that is intellectual property protection by both plant variety protection and patent law for one particular product, was banned.<sup>170</sup> The parties of the Strasbourg Patent Convention therefore excluded *plant varieties* from patentability. The object and purpose of the variety exception in EPC and the Directive is to exclude subject matter which is eligible for protection under UPOV.<sup>171</sup> This means that the reason for exempting plant subject matter is a division of labour between the patent law and plant variety protection. The object and purpose therefore indicates that the plant variety exception is to be interpreted in a manner that excludes subject matter eligible for protection under UPOV, while other categories of plants are not encompassed by the variety exception. This interpretation is in line with the understanding presented in EPO case law, EPC Implementing Regulation and the EC Directive.<sup>172</sup>

The objective presented above does not cover the exclusion of *animal variety*. There is no alternative intellectual property protection for *animal varieties*. The reason for exempting *animal varieties* from patentability is therefore not clear.<sup>173</sup> The uncertainty entails that, based on a teleological interpretation of the *animal variety*, the understanding of the term is unclear.

---

<sup>170</sup> Article 2 (1) UPOV-61.

<sup>171</sup> Paterson 1992 p. 336 and Grubb 1999 p. 252.

<sup>172</sup> See Chapters 4.2.8, 4.2.10 and 4.2.11.

<sup>173</sup> Paterson 1992 p. 338.

#### 4.2.10 EPO Administrative regulation

The question of the variety exceptions' scope in relation to superordinate taxonomical levels is addressed in EPC Implementing Regulations Rule 23c (b). The rule was passed administratively in 2001. The Implementing Regulations are an integrated part of the Convention, and must therefore be taken into account.<sup>174</sup> However, the Implementing Regulations are subsidiary sources of European patent law, and in case of conflict the Articles in the main EPC document prevail.<sup>175</sup> The provision is formulated as follows:

'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;....'

The ordinary meaning of this is that the variety exception in EPC is delimited towards claims which comprise more than one *variety*, or in other words to claims which identify subject matter that is superordinate to the term *variety*. This can be seen as a clarification of the delimitation of Article 53 (b) EPC, and is in line with the 'more than a single variety' approach presented in the Novartis II decision.<sup>176</sup> This points in the direction of excluding only one taxonomical unit from patentability, namely *varieties*.

---

<sup>174</sup> Article 164 (1) EPC. See also Paterson 1992 p. 5.

<sup>175</sup> See Article 164 (2) EPC and Paterson 1992 p. 5.

<sup>176</sup> G 1/98 point 2 of the Conclusion.

#### 4.2.11 The understanding of the EC Directive and the interaction with EPC

In Chapter 4.1 the wording of the EC variety exception was interpreted. Subsequent to that examination the thesis addresses how EPO case law and administrative regulations affect the understanding of the EPC variety exception. Here, an assessment of how other sources of law than the wording of the Directive influence the interpretation of the EC variety exception is given. The understanding of the Directive can be important for two reasons. First, because the interpretation is crucial for the understanding of EC law itself. And second, due to the Directive's impact on the understanding of EPC. Before looking into the interpretation of the Directive regarding the terms *plant* and *animal variety* in relation to superordinate taxonomical ranks, its role as a supplementary means of interpretation to EPC is discussed.

Rule 23b (1) of the EPC Implementing Regulations states that:

‘... Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.’<sup>177</sup>

This entails that the Patent Directive is to be taken into account as a supplementary means of interpretation to EPC. According to Article 32 of the Vienna Convention, supplementary means of interpretation are to be applied when the interpretation of other sources of law are inadequate for concluding on the particular point of law, or if the interpretation based on the principal means of interpretation leads to unreasonable or

---

<sup>177</sup> Implementing Regulation to the Convention on the Grant of European Patents, Rule 23b (1), second sentence.

absurd results.<sup>178</sup> The interpretation of EPC sources results, however, in a relatively clear understanding of the variety exception in relation to superordinate taxonomical ranks.<sup>179</sup> Nevertheless, the Directive can still be a source of law because supplementary means of interpretation are, according to the International Law Commission, to be viewed in conjunction with other sources of law as a whole.<sup>180</sup> The question is what is to be taken into account when interpreting EPC, the EC understanding of *plant* and *animal variety* at the point when Rule 23b (1) was established or the at all times prevailing EC interpretation of the terms. This is therefore a question of how dynamical EPC can be interpreted in relation to the EC Directive. One statement in the Official Journal of EPO from August and September 1999 exemplifies the ambiguousness of the situation. It is stated that:

‘Rule 23b (4) adopts the definition of the concept of “plant variety” from Article 5 (2) of Regulation (EC) No. 2100/94 on plant variety rights, which is binding in accordance with Article 2 (3) of the Directive.’<sup>181</sup>

This statement indicates that the EC Patent Directive is relevant to the understanding of EPC. The meaning of the word *adopts* is, however, unclear. The word does not give a

---

<sup>178</sup> Article 32 of the Vienna Convention.

<sup>179</sup> See Chapters 4.2.8, 4.2.9 and 4.2.10.

<sup>180</sup> Brownlie 1998 p. 633.

<sup>181</sup> See the EPO Official Journal: OJ EPO 8-9/1999, p. 579, point 18. According to the Vienna Convention Article 31, 2 (b), instruments made by the contracting parties are seen as relevant means of interpretation. EPO is the executive body of EPC established to implement the content of the convention. Consequently, it may be seen as such an instrument. Hence, the Official Journal issued by EPO may have relevance as a means of interpretation of the EPC.



clear indication of on which basis the supplementary means of interpretation can be used in the understanding of EPC. It can either be on the basis of the understanding of the Directive as it was when it was decided that the Patent Directive was to be a supplementary means of interpretation, or on the basis of the at all times present understanding of the Directive. Here, the interest of sovereignty of state has to be balanced towards the interests of effectiveness and dynamics. The balance between these considerations determines the states' ability to control the content of their international obligations. The question is therefore how the interests are to be balanced. An objective for EPO is harmonisation of European patent law. This is stated in the Preamble of EPC.<sup>182</sup> The same consideration is, as a general principle, put forward by the European Community in the Rome treaty.<sup>183</sup> This indicates that the EPC may be interpreted dynamically to contribute to the harmonisation. On the other hand, the EPC member states' sovereignty may limit the degree of dynamical interpretation even though this can lead to a less efficient interpretation in relation to harmonisation. This indicates a restrictive application of the Directive as a supplementary means of interpretation to EPC. Exactly how these considerations are balanced is not easy to determine.

EPO has decided to give the EC Directive status as a supplementary means of interpretation. This indicates that EPO and its member states are willing to take the risk that the understanding of the Directive develops in a direction of which EPO is uncomfortable with since such understanding can contribute to an interpretation of EPC which is unwanted by EPO and its members. Furthermore, since both EPO and the EC are eager to harmonise European patent law, the possibility of deviating interpretation is

---

<sup>182</sup> Recital 1 of the EPC Preamble.

<sup>183</sup> Recital 5 of the preamble of the Rome treaty.

limited. Moreover, it has to be taken into consideration that EC Directive would be one of several sources of law being assessed. This means that the impact of a supplementary means of interpretation is limited. These features indicates that the at all times present understanding of the EC Directive can be taken into consideration as a supplementary means of interpretation when interpreting EPC.

This means that the EC Directive is relevant as a supplementary means of interpretation for EPC and that the at all times present understanding of the Directive is to form the basis for the interpretation. How EPO assesses this question is, however, determined through future practice by the Technical Board of Appeal and the Enlarged Board of Appeal.

This concludes the discussion on how the Directive is to be assessed in relation to the interpretation of EPC. In the following, the focus turns towards discussing the interpretation of the EC Directive. In the previous chapter, the question was how the EPC terms *plant* and *animal variety* are delimited towards categories of plants and animals on superordinate taxonomical levels. This topic is also addressed in the EC Directive:

‘Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.’<sup>184</sup>

Article 4 second paragraph is substantially identical to the provision in the Implementing Regulations of EPC. The ordinary meaning of this provision is, as in EPC, that while *variety* is excluded from patentability, claims which identify subject

---

<sup>184</sup> Article 4 second paragraph of the EC Directive.

matter that is superordinate to the term *variety* is patentable. This suggests that in the European Community also, the reason for the variety exception is to delimit the patent systems from the plant breeder's rights systems, and not to prevent overly wide patent scopes.

The preamble of the Directive, recital 31, is a means of interpretation and can indicate how the variety exception is to be understood.<sup>185</sup>

‘Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;’<sup>186</sup>

The statement indicates that categories of plants of superordinate taxonomical rank are patentable, while only inventions delimited to one particular *plant variety* is excluded from patentability. This is in line with the EPO understanding of the term *plant variety* presented in the Novartis II decision.<sup>187</sup> The statement does not, however, consider the situation for *animal varieties*. This may indicate that the exceptions for *plant* and *animal varieties* shall be interpreted differently. However, seen in conjunction with the wording of Article 4, second paragraph, discussed in the previous paragraph, the Directive opens for patentability of inventions expressing subject matter on taxonomical levels superordinate to both *plant* and *animal variety*. This has, as discussed above, consequences also for the interpretation of EPC. The interpretation of the Directive

---

<sup>185</sup> The preamble is a relevant source of law according to the Vienna Convention Article 31 first paragraph, cf. second paragraph.

<sup>186</sup> Recital 31 of the preamble of the Patent Directive.

<sup>187</sup> G 1/98 point 2 of the Conclusion.

supports and strengthens the results of other EPC sources of law. Thus, this is an example of the interaction between EPC and the Directive.

#### 4.2.12 The impact of the Community Plant Variety Rights Regulation on the Directive and EPC

The Community Plant Variety Rights Regulation regulates the protection of new plant varieties within the EC.<sup>188</sup> The question in this chapter is to what extent the understanding of *plant variety* in the Regulation affects the interpretation of the term first of all in the Directive, but also indirectly the impact on EPC through the application of the Directive as a supplementary means of interpretation. First, the Regulation's potential impact on the Directive is examined.

The point of departure is that the intention of the EC secondary legislation is, among other, to harmonise, in fully or partially, the national legislation of the member states.<sup>189</sup> Thus, it would be unfortunate if the secondary legislation is reciprocally divergent. This may lead to problems in the practice of the EC law at the national level. Furthermore, the use of coherence considerations in EC law indicates that the Patent Directive is to be interpreted in the light of the Plant Variety Regulation.<sup>190</sup> This means that the Regulation is generally relevant in the interpretation of the Directive. However, it has to be noted that generally there is no automatic connection between the interpretation of a term in one document and a similar term in another. For instance, different object and

---

<sup>188</sup> EC Regulation NO2100/94.

<sup>189</sup> Recital 5 of the preamble of the Rome treaty.

<sup>190</sup> Arnesen 1992 pp. 27-29.

purpose may lead to diverging understandings. In this case, however, it is referred from the Directive to the Regulation for the definition of *plant variety*.<sup>191</sup> On the one hand, this can indicate that the Directive is interpreted in accordance with the Regulation on this point of law. On the other hand, the reference can also mean that only the wording of the definition in the Regulation, and not the interpretation of the provision as a whole, is to be taken into account when interpreting the term in the Directive. In Article 5 of the Regulation this statement is made:

‘For the purpose of this Regulation, “variety” shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be defined by the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged.’<sup>192</sup>

The wording of this definition is substantially identical to the definition of *plant variety* in both the EPC Implementing Regulation and the UPOV-91 Convention.<sup>193</sup> The objective of the Regulation is to harmonise the plant variety protection in EC member states.<sup>194</sup> Taking into account that the EC members are also members of UPOV, it is natural that the UPOV understanding of *plant variety* is similar to the understanding of

---

<sup>191</sup> Article 2, third paragraph of the Directive, cf. Article 5 of the Regulation.

<sup>192</sup> Article 5 of the Regulation.

<sup>193</sup> Rule 23b (4) of the EPC Implementing Regulation and Article 1 (vi) UPOV-91.

<sup>194</sup> Recital 2 of the preamble of the Regulation.

the term in the Regulation and thus also in the Directive. The conclusion is therefore that Regulation affects the understanding of the term *plant variety* in the Directive, but that the understanding of the Regulation on this point of law is founded on the UPOV understanding. Therefore, the effect of Regulation is in practice limited.

The next question is if also the term *plant variety* used in EPC is affected by the understanding of the term in the Regulation. The EPC Implementing Regulations Rule 23b (1) states that the Directive has status as a supplementary means of interpretation to the EPC. Since the Directive refers to the definition of *plant variety* in the Regulation, and the Directive is to be interpreted in the light of this definition, the Regulation is, as discussed in the previous paragraph, *de facto* relevant for the interpretation of the term in the Directive. And because the Directive is relevant for the interpretation of EPC, the Regulation is indirectly relevant to the understanding of EPC. The understanding of *plant variety* in the Regulation is as seen in the previous paragraph based on the UPOV-91 definition. The practical impact of the Regulation is therefore limited since EPC is, as discussed in Chapter 5, affected by the UPOV definition of *plant variety*.

#### 4.2.13 EPC as a source of law when interpreting the EC Patent Directive

All the members of EC are also parties to EPC, but the European Community as such is not a party to EPC.<sup>195</sup> International obligations only become a part of EC law when the Community as such has taken on the obligations.<sup>196</sup> This means that EPC is not an integral part of EC law. This indicates that EPC cannot affect the understanding of the

---

<sup>195</sup> See [www.european-patent-office.org/epo/members.htm](http://www.european-patent-office.org/epo/members.htm). Accessed on 10 November 2003.

<sup>196</sup> Bourgeois 2000 p. 92.

Patent Directive. However, the European Court of Justice sometimes takes international law into account as an auxiliary source of law when interpreting EC law.<sup>197</sup> There is not yet any practice from the European Court of Justice addressing the question of EPC as a means of interpretation for understanding the Patent Directive. However, the objective of the Directive is to harmonise the legal situation in the EC member states on the issue of patentability of plants and animals.<sup>198</sup> The national patent legislation in the EC member states are to a great extent based on EPC also on the question of patentability of plants and animals.<sup>199</sup> This connection on the national level means that the states are given frames within which the national patent law is passed and practiced. The states have to take into consideration both EPC and the Directive. Thus the close connection between EPC and the Directive with regard to harmonisation of patent law on biotechnology indicates that EPC can play a role in the interpretation of the Directive. The question of applying EPC in the understanding of the Directive is not clarified. However, based on the connection between presented above, the thesis has as a premise that EPC can be used in the interpretation of the Directive.

There is not yet any case law from the European Court of Justice determining how the EPC understanding of *plant* and *animal variety* can affect the interpretation of *plant* and *animal variety* in the Directive. The effect of this methodological situation is not clear. However, the situation indicates that if the EPC understanding changes, the

---

<sup>197</sup> See for example C-10/61 Commission v. Italy, (1962) ECR 1. See also Kapteyn and Themaat 1998 p. 280.

<sup>198</sup> Recital 9 of the preamble of the Directive.

<sup>199</sup> Paterson 1992 p. 37. Here the understanding of UK patent law in relation to EPC is given as an example.

understanding in the Directive may be affected by the potential change. This is yet an example of how EPC and the Directive are likely to be influenced by each other.

#### 4.2.14 Patent practice as a source of law

In this chapter the question is whether patent practice from the first instance of EPO is to be regarded as a source of law. This is of importance for the examinations of the legal situation *de lege lata* in the discussions presented in this thesis. The practice is formed through the grant and refusal of patent applications directed to EPO.

There are two alternative approaches to the question of the position of first instance patent practice as a source of law. Either patent practice expresses the current legal situation and is therefore a source of law, or it can be seen merely as practice of *de lege lata* as e.g. a patent examiner or an Opposition Division sees it and thus not a source of law. On the one hand, there are a vast number of patent applications, granted and refused, which can give an indication of how the EPC is to be understood. This indicates that practice should be assessed as a source of law. On the other hand, there are numerous patent examiners and Opposition Divisions. It can therefore be difficult for such a large number of people to have an overview of earlier practice and coordinate with concurrent practice. This complexity indicates that the practice of first instance should not be seen as a source of law. The conclusion to the question of the position of first instance practice as a means of interpretation cannot be said to be clear. However, since it is difficult to find a representative collection of first instance practice, such practice is not examined in this thesis. This conclusion applies to the discussion in Chapter 4.2 as well as Chapter 4.3.



#### 4.2.15 Conclusion

The main question at hand has been whether the terms *plant* and *animal variety* applied in Article 53 (b) EPC and Article 4 first paragraph in the EC Patent Directive are to include categories of plants and animals of superordinate taxonomical rank, or if they are limited to one taxonomical level, namely the variety level. The ordinary meaning of the wording of the provisions suggested that the legal scope was delimited to the variety level. The EPO case law was to some extent staggering. However, the latest decision, *Novartis II*, indicates that the understanding of *plant variety* does not include categories of plants of superordinate taxonomical levels. For *animal varieties*, the same is suggested in the *Onco-mouse* decision. An interpretation of provisions and recitals in the EPC Implementing Regulations and the Directive points in the same direction. Also the object and purpose of the exception suggests that it is confined to the rank *variety*. An examination of the sources of law leads to the conclusion that the terms *plant variety* and *animal variety*, as applied in the European Patent Organisation and the European Community, do not comprise categories of plants and animals of superordinate taxonomical ranks, but are confined to the variety level.

#### 4.3 Subordinate biological levels

In the previous chapter the term *variety* was examined in relation to categories of plants and animals of superordinate taxonomical ranks. In this chapter the question of patentability of expressions of plants and animals on levels subordinate to *variety* are examined. The examination assesses patentability of individual specimens of plants and animals and microbiological expressions such as cells, proteins, vectors, and genes. It can be asked whether granting patents for individual specimens and microbiological

levels of plants and animals in fact constitutes protection of a *variety*. In the following chapters these scopes are therefore discussed in order to determine the limits of the variety exception in EPC and the Directive.

As pointed out in the introduction, this thesis aims to contribute to the understanding of the term *variety*. It is therefore necessary to delimit the term towards adjacent expressions of plants and animals. As the pointed out above in Chapter 1.4, the taxonomical system is hierarchic.<sup>200</sup> This can also be said to be the case for the biological levels subordinate to *variety*. The structure relevant for patent applications is, in descending hierarchic order, individual specimen, cells, proteins, vectors and genes. The inventive step of an invention can be on any of these levels. In the following chapter the questions related to individual specimens are examined.

#### 4.3.1 Plant and animal specimens in relation to *plant* and *animal variety*

In this chapter the question is whether patent claims regarding specimens of plants and animals is interpreted as encompassed by the plant and animal variety exception in EPC and the Directive. In this context specimen can be understood as one particular plant or animal individual. The answers to the questions discussed in this chapter are not clarified in either EC law or in EPO. Hence, the assessments presented here can only be seen an indication of a possible approach to patentability of specimens related to the variety exception. The presentation is based on relevant sources of law.

---

<sup>200</sup> Mayr 1982 p. 205.

The fulfilment of the patent requirements, especially reproduction, novelty and inventive step, may be problematic in relation to plant and animal specimens. This thesis is delimited towards the patent requirements. The questions in this thesis are related to the eligibility of different types of subject matter in relation to the variety exception. This delimitation is, of course, also applied in this chapter. Therefore, as in the rest of this thesis, the patent requirements invention, novelty, inventive step and industrial application are not discussed.

As pointed out above, the question is whether or not it is possible to limit the patent claims regarding a specimen so that a *variety* is not encompassed. Or more precisely, whether it is possible to limit the patent claims to the traits which are exclusive to that specimen and not typical for a group, a *variety*. To limit the patent claims to one specimen, it is necessary to describe the characteristics which appear in that particular specimen, but which are not present in other specimens. By comparing the genetic constellation of the specimen described in the patent claim with other specimens, this may be possible. This suggests that it might be possible that a specimen is patentable without conflicting with the variety exception.

A problem occurs, however, in relation to the limits of such a claim. Therefore, the next question is to what extent the patent claim encompasses not only one particular specimen, but also other specimens for example its offspring. This can be divided into two questions. First, whether it is possible for the characteristics of the specimen specified in the claims to remain intact in that particular combination when passed on to other specimens. Second, how that situation would relate to the variety exception. Using sexual propagation as means of reproduction, the offspring will at least have some characteristics diverging from the patented parent since such propagation requires reproductive cells from two specimens. It is thus possible that such offspring may not be

comprised by the claim. Cloning techniques, techniques used to produce clones, might present another situation. A clone is ‘a group of cells, an organism, or a population of organisms arising from a single ancestral cell. All members of a particular clone are genetically identical.’<sup>201</sup> This means that a clone may be covered by the claim characterising the traits of the original specimen.

The second question is, as indicated above, how such a claim relates to the variety exception. In the plant variety definition of the Directive and EPC it is stated that a *variety* is ‘a plant grouping’ with certain common characteristics.<sup>202</sup> Even though the patent claims are delimited towards *plant variety* concerning the original specimen, the clones may fulfil the requirements for *plant variety* because they can be seen as a group, not as a specimen. This indicates that at some point the clones derived from the original specimen may be considered to be a *plant variety* and may thus not be patentable. There is no definition of *animal variety* in either EPC or the Patent Directive. It is therefore difficult to see animal clones in relation to the variety exception.

---

<sup>201</sup> Martin and Hine 2000 p. 128. Cloning can occur naturally, by means of traditional techniques (e.g. cutting) and by advanced gene-technology.

<sup>202</sup> See Article 2, third paragraph of the Patent Directive cf. Article 5, second paragraph of the Regulation, Rule 23b forth paragraph of the EPC Implementing Regulation.

#### 4.3.2 The demarcation between *cells* and *plant* and *animal variety*

##### ***Point of departure –the wording of the variety exception in EPC and the Directive***

The question in this chapter is whether plant and animal cells in some cases are comprised by the term *plant* or *animal variety*.<sup>203</sup> The patentability of plant and animal cells in relation to the variety exception is not explicitly mentioned in the provisions of EPC and the Directive. This could either imply that it is evident that plant and animal cells are considered to be comprised by the terms *plant* or *animal variety* or, on the contrary, that such subject matter is patentable. Hence, the wording does not give any clear indication of how the posed question should be answered. However, taking into consideration that the point of departure in patent law is that exceptions from patentability have to be explicitly formulated, the silence regarding cells indicates that plant and animal cells are not comprised by the variety exception.

##### ***Other EPO sources***

The question of patentability of plant cells has been discussed in EPO case law. The Plant Genetic Systems case states:

‘Plant cells as such...cannot be considered to fall under the definition of a plant or a plant variety.’<sup>204</sup>

---

<sup>203</sup> Cell: ‘The structural and functional unit of most living organisms. .... Each cell contains a mass of protein material...which contains DNA.’. Martin and Hine 2000 p. 103.

<sup>204</sup> T 356/93 point 23 of the Reasons.

This means that as long as the claims in the patent application are limited to comprising one or more plant cells, and do not make a *plant variety* the scope of the claim, the patent will not be affected by the variety exception. The tenet was put into practice in relation to the application's Claim 14. The appellant stated that Claim 14, a claim covering plant cells, should be regarded not to be patentable because the claim *de facto* encompassed a plant variety. The Technical Board of Appeal did not agree:

'...the Board cannot agree with the Appellants' submission that this claim covers *de facto* plant varieties and that,...,it is not allowable under Article 53 (b) EPC, because,...,plant cells as such may not be considered to fall under the definition of a plant or a plant variety.'<sup>205</sup>

The Technical Board of Appeal consequently came to the conclusion that the subject matter of the claim did not represent an exception from patentability under Article 53 (b) EPC.

The Technical Board of Appeal does not explicitly explain the reasoning for the statement. One possible reason is, in my opinion, that the Technical Board of Appeal considered the object and purpose of the variety exception for plants. As examined in Chapter 4.2.9, the reason for excluding *plant varieties* was to avoid granting double protection for identical subject matter under both the patent systems and the UPOV Convention. Plant cells as such are not eligible for protection under the UPOV Convention.<sup>206</sup> Since dual protection will not occur, it is not necessary to exclude such subject matter. When the main rule of patentability states that all subject matter which is

---

<sup>205</sup> T 356/93 point 40.2 of the Reasons.

<sup>206</sup> See Article 1 (vi) of UPOV-91.

not explicitly excluded is patentable, claims confined to plant cells should be patentable.<sup>207</sup> This understanding is in line with the approach taken by the Technical Board of Appeal when assessing the legal situation for taxonomical ranks superordinate to *variety*.<sup>208</sup> The Technical Board of Appeal emphasised that the exception is limited to *variety* while expressions of plants and animals on superordinate taxonomical levels are patentable. Based on the legal sources of EPO, the conclusion is that plant cells are patentable when the claims are limited to cells and not a *plant variety*.

### ***Other EC sources***

The examination above assesses plant cells in relation to the variety exception in EPC. In this paragraph the focus turns towards the legal situation under the Directive. The introduction to this chapter points out that no provision in the Directive explicitly deals with the question at hand. However, there may be a provision which touches upon the patentability of plant cells in relation to the variety exception. Article 4, second paragraph of the Directive reads:

‘Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.’<sup>209</sup>

As discussed in Chapter 4.1, the provision is as a point of departure concerned with the relationship between *varieties* and superordinate taxonomical levels. The question to be posed here is whether the provision can be said to include the relationship between plant cells and the variety exception. The provision states that ‘the invention is not confined

---

<sup>207</sup> Article 52 (1) EPC.

<sup>208</sup> See for example G 1/98 assessed in Chapter 4.2.7.

<sup>209</sup> Article 4, second paragraph of the Directive.

to a particular plant or animal variety'. The ordinary meaning of the word *confined* is *limited or restricted*.<sup>210</sup> It seems that this understanding implies that the variety exception does not comprise expressions which include more than one variety, while expressions on a level subordinate to *variety* are not discussed in this provision. This suggests that the provision is intended to concern only the relation between the variety exception and superordinate taxonomical levels. Article 4, second paragraph of the Directive is therefore not applicable with regards to the situation discussed in this paragraph.

Perhaps the object and purpose of the Patent Directive can shed light on the legal situation at hand given the wording of the preamble:

'...effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investments in the field of biotechnology.'<sup>211</sup>

According to this recital, the main objective of the Directive is to harmonise the patent regulations within the European Community. Since all members of the EC are contracting parties to EPC, it is natural to be certain that the practice from EPO is implemented on the national level through the codifications of the European Patent Office practice in the EC Patent Directive. Taking this into account, it is possible that the patentability of cells in relation to the variety exception is to be understood according to the interpretation of the same question in EPC. This means that cells as such are patentable if the claims are limited to cells but not comprising a *plant variety*. However, the EC is not obligated to take on the interpretations of the EPO since these

---

<sup>210</sup> Hornby 1974 p. 178.

<sup>211</sup> Recital 3 of the Preamble of the Directive.



are two autonomous legal systems. The legislator of the European Community bases its legislation on an independent assessment of how it wants to develop patent law within the EC. As pointed out, this does not prevent the EC legislator from being inspired by EPC and EPO practice. The question of patentability of cells in relation to the variety exception has seemingly not, as the examination above shows, been assessed by the EC legislator. However, it is possible that the EC, when they do take a stand in this question, will be inspired by the legal situation in EPO. Such an influence can contribute to the dynamics between the two patent systems: the EC through its objective of harmonising the legislation in member states, and the EPC because the Directive is a supplementary means of interpretation.<sup>212</sup> This dynamic effect can lead to a situation where the two systems push each other in one direction. Nevertheless, there are limitations to this dynamic effect. Article 3, first paragraph 1, litra h of the Rome Treaty states the limit:

‘For the purposes set out in Article 2, the activities of the Community shall include, as provided in this Treaty and in accordance with the timetable set out therein: the approximation of the laws of Member States to the extent required for the functioning of the common market;’<sup>213</sup>

This indicates that it is possible that the EC attempts to harmonise national legislation within the Community only as long as the harmonisation promotes the functioning of

---

<sup>212</sup> EC: Recital 5 of the preamble of the Rome treaty. EPO: Implementing Regulation to the Convention on the Grant of European Patents, Rule 23b (1), second sentence.

<sup>213</sup> Article 3, first paragraph, litra h of the Rome Treaty.

the common market.<sup>214</sup> If the interpretations of EPC are in conflict with the promotion of the common market it may be that the Directive not be interpreted in accordance with EPC. In the continuation of this discussion, it has to be pointed out that the basic objectives of the EC can affect the interpretation, possibly creating divergence from the understanding of the legal situation in EPC. One of the most important objectives of the EC is to promote trade between the member states.<sup>215</sup> This objective diverges from the object and purpose of the EPC. There, the object and purpose is confined to the classical intention of patent law, namely promoting invention in the best interest of both the inventor and society.<sup>216</sup> Since the object and purpose of the EC are to be taken into consideration, they can effect the interpretation of the Directive. However, it can be said that the objectives of the two systems are not that dissimilar. Promoting trade and promoting inventions can be seen as two sides of the same argument both promoting the common market. This means that a conflict would not come into existence between the objectives. Consequently, for the EC legislators to be inspired by the interpretation of plant cells in relation to the variety exception would not be in conflict with the Rome Treaty.

Therefore the question how patentability of plant cells is to be considered in relation to the variety exception in the Directive cannot be answered with certainty. However, based on the discussions above, it is likely that the question will be interpreted in accordance with the understanding set forth by EPO. Consequently, that plant cells are

---

<sup>214</sup> See Kapteyn and Themaat 1998 p. 778 where it is pointed out that patent law is one example of a legal field which influences the functioning of the common market.

<sup>215</sup> See Article 2 of the Rome Treaty.

<sup>216</sup> Bently and Sherman 2001 p. 313.

not included in the variety exception and that the main rule in Article 3, first paragraph of the Directive prevails.

***Special circumstances affecting the interpretation of animal cells in relation to the variety exception***

In the previous paragraphs, plant cells were discussed. Here, the question is whether animal cells as such are patentable. The reason for exempting *plant varieties* from patentability is related to the protection of such subject matter under the UPOV Convention. For *animal varieties*, there is no such alternative protection. Consequently, the concern with dual protection for identical subject matter cannot give grounds for exempting *animal varieties* from patentability.<sup>217</sup> As the object and purpose of the *plant variety* exception and *animal variety* exception are divergent, the argumentation applied for plant cells cannot be fully implemented in the discussion of animal cells. A separate presentation is therefore needed.

All subject matter which is not explicitly excluded from patentability is patentable. Consequently, if an animal cell is to be excluded from patentability the action has to be based on a legal authority. The wording of the variety exception in EPC and the Directive states that *animal varieties* are exempted from patentability. The ordinary meaning of this wording cannot be said to exempt animal cells. The wording has to be interpreted in accordance with its context. Therefore, it is relevant to consider the connection between the animal variety exception and the plant variety exception. The exception of *plant varieties* is based on the relationship between patent law and plant breeder's rights; they are exempted from patentability to avoid double protection of identical subject matter under both the patent systems and the UPOV Convention. For

---

<sup>217</sup> See Chapter 4.2.9 and 5.

*animal varieties*, there is no such alternative protection, and double protection is thus no problem. It seems as if the variety exception in both EPC and the Directive is based on the need for an operational interface between patent and plant breeder's rights but not for *animal varieties*.<sup>218</sup> As a point of departure, it can be said that a rule should be practiced in accordance with its object and purpose.<sup>219</sup> *Animal varieties* are excluded from patentability even though there is no alternative protection available. The exception is therefore practiced without any clear object and purpose. It would therefore be questionable if animal cells were to be excluded from patentability in relation to the variety exception, when their plant counterparts were patentable. Thus, the conclusion is, in accordance with the main rule of patentability, that animal cells are patentable in relation to the variety exception.

#### 4.3.3 The delimitation between *proteins* and *vectors* and the term *variety*

A protein can be defined as any of a large group of organic compounds found in all living organisms.<sup>220</sup> In other words, proteins are the products of the genetic recipe in genes. Proteins are used by the organisms mainly to turn on or off a chemical reaction that controls a specific trait. A vector is a vehicle used in gene cloning to insert a foreign DNA fragment into the genome of a host cell.<sup>221</sup> The question is whether proteins and

---

<sup>218</sup> Westerlund 2001 p. 388.

<sup>219</sup> See Article 31, first paragraph of the Vienna Convention.

<sup>220</sup> Martin and Hine 2000 p. 488.

<sup>221</sup> Martin and Hine 2000 p. 616. More on vectors: 'The foreign DNA is spliced into the vector using specific restriction enzymes and DNA ligases to cleave the vector DNA and join the foreign DNA to the two ends created. In some phage vectors, part of the viral genome is enzymically removed and replaced with the foreign DNA. Retroviruses can be effective vectors

vectors are patentable in relation to the variety exception. This is relevant to this thesis because the inventive step of the inventions on both the protein and vector levels in some cases might be said to *de facto* comprise the *variety* level, even though the claims are formally limited to the protein and vector levels. The wording of the variety exception in EPC and the Directive state that *plant and animal varieties* are not patentable subject matter. The ordinary meaning of these terms cannot be said to include inventions on the protein and vector level. This indicates that such subject matter is patentable in relation to the variety exception.

Cells and genes are in general patentable.<sup>222</sup> This means that levels on either hierarchic boundary of proteins and vectors are patentable. Considering the relationship between the different levels of microbiological subject matter, it would serve the consistency of patentability if inventions on the protein and vector levels are patentable in relation to the variety exception.

A limited number of available legal sources concern the patentability of proteins and vectors. Despite inquiries, I have not found any practice from the EPO Technical Board of Appeal or the Enlarged Board of Appeal that discusses the patentability of subject matter on the protein and vector levels.<sup>223</sup> On the one hand this can indicate that it may

---

for introducing recombinant DNA into mammalian cells. In plants, derivatives of the tumour-inducing plasmid of the crown gall bacterium, . . . , are used as vectors.’. Martin and Hine 2000 p. 616.

<sup>222</sup> T 356/93 point 23 of the Reasons.

<sup>223</sup> The inquiries consist of searching for Technical- and Enlarged Board of Appeal cases where the patent claims are limited to the protein and vector levels in the EPO database on

be considered as obvious, and thus not contested by the appeal instance of EPO, that such subject matter is not patentable in relation to the variety exception. On the other hand it may indicate the opposite; that it is obvious that inventions are patentable on the protein and vector levels and that the question of such subject matter's relation to the variety exception therefore has not been assessed by the Technical Board of Appeal or the Enlarged Board of Appeal. Based on the relation to the cell and gene levels and the ordinary understanding of the wording of the variety exception, the latter alternative seems plausible. On the basis of the sources of law examined in the discussion above, the conclusion is thus that inventions on the protein and vector levels are not comprised by the exception from patentability presented in the variety exceptions of EPC and the Directive.

#### 4.3.4 *Genes in relation to plant and animal variety*

A gene is a unit of heredity composed of DNA.<sup>224</sup> In general genes are patentable.<sup>225</sup>

This is for example stated in the preamble of the Directive:

---

[http://legal.european-patent-office.org/dg3/search\\_dg3.htm](http://legal.european-patent-office.org/dg3/search_dg3.htm) and [http://www.european-patent-office.org/dg3/g\\_dec/index.htm](http://www.european-patent-office.org/dg3/g_dec/index.htm). Accessed on 10 November 2003.

<sup>224</sup> Martin and Hine 2000 p. 251. DNA: 'The genetic material of most living organisms, which is a major constituent of the chromosomes within the cell nucleus and plays a central role in the determination of hereditary characteristics by controlling protein synthesis in cells.' Martin and Hine 2000 p. 183.

<sup>225</sup> Article 52 (1) EPC, Article 3, first paragraph of the Directive and Recital 22 of the preamble of the Directive.

‘according to this Directive, the granting of a patent for such inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application;....’<sup>226</sup>

The requirements for obtaining a patent are mentioned as criteria to grant patents for genes, while general exclusion of such subject matter is not emphasised. This can be interpreted to mean that genes shall not be excluded from patentability on a general basis, but be the subject of an assessment according to the ordinary patent requirements. What has been disputed, however, is whether naturally occurring genes can be patentable. This depends on how the requirement *inventive step* shall be assessed in relation to genes. According to EPO case law and the Directive genes have been considered patentable if isolated from their natural environment.<sup>227</sup> The question presented above exceeds the scope of the thesis since the question does not relate to the variety exception and will therefore not be discussed further.

### ***Point of departure –the wording***

The question to be posed in this chapter is whether plant and animal genes, in one occasion, can be said to be comprised by the variety exception. In other words, whether or not a gene is patentable when the trait of the gene which is to be patented is what makes a plant or animal grouping different from other groups, thus creating a new *plant* or *animal variety*. According to the main rule in Article 52 (1) EPC and Article 3, first paragraph of the Directive, all subject matter which fulfils the patent requirements is

---

<sup>226</sup> Recital 22 of the preamble of the Directive.

<sup>227</sup> See Howard Florey/Relaxin T 74/91 (1995) EPOR 541 and Article 3, paragraph 2 of the Directive.

patentable if not explicitly exempted. The patentability of genes in this relation is not discussed in neither the provisions of EPC nor the Directive. This implies that the main rule prevails and that genes whose traits entail the creation of a new *plant* or *animal variety* are patentable.

The wording of the variety exception in both EPC and the Directive is that *plant and animal varieties* are not patentable.<sup>228</sup> Even though the patentability of genes is not mentioned, the ordinary meaning of these provisions is that whatever is comprised by the terms *plant* and *animal varieties* are exempted from patentability. This indicates that genes, whose traits entail the creation of a new *plant* or *animal variety*, are encompassed by the terms and thus exempted from patentability. If such an interpretation is in accordance with the other sources of law is discussed below.

In the following presentation, the legal situation for plant genes under the Directive are discussed before proceeding with plant genes under EPC and finally examining the legal situation for animal genes in both EPC and the Directive. The division is done due to the divergence in the legal sources other than the wording of the variety exception.

### ***Plant genes –the Directive***

In the preamble of the Directive the patentability of plant genes is mentioned. The variety exception in Article 4, first paragraph, *litra a* has to be interpreted in light of the preamble.<sup>229</sup> Recital 31 states that:

---

<sup>228</sup> Article 53 (b) EPC and Article 4, first paragraph, *litra a* of the EC Patent Directive.

<sup>229</sup> See Article 31, second paragraph of the Vienna Convention.



‘Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new plant varieties.’<sup>230</sup>

The recital at hand explicitly states that a group of plants which are divergent from other groups due to traits caused by a particular gene are patentable on one condition, despite the fact that the grouping encompasses *plant varieties*. The condition is that the scope of the patent claim is limited to the gene holding the particular traits and not the plant grouping’s entire genetic composition, the genome. The tie to the *sui generis* protection of *plant varieties*, for example as found in the UPOV Convention, is put forward in this recital. The statement can, in accordance with the ordinary meaning of the wording, be interpreted to mean that there is a close connection between patent protection in the Directive and the protection under the UPOV Convention: Because plant groupings characterised by one particular gene, and not the entire genome, cannot be protected by plant breeder’s rights, such subject matter is patentable in relation to the variety exception. As discussed in Chapter 4.2, that examines the variety exception’s relation to superordinate taxonomical levels, a strict understanding of the wording in Article 4, first paragraph, *litra a* of the Directive may suggest that the provision can be interpreted to mean that only *plant varieties*, and no other category of plants is to be exempted from patentability. The wording of Recital 31 is, as suggested above, based on the connection to the UPOV Convention. Under the UPOV Convention, protection is granted new *plant varieties*, while all other categories of plants fall outside the scope of the convention. Hence, the wording in this recital can indicate that the term *plant variety* has to be interpreted strictly in accordance with the wording of the Article 4, first paragraph, *litra a* of the Directive.

---

<sup>230</sup> Recital 31 of the preamble of the Patent Directive.

In this relation it is possible to draw a line to the object and purpose of the variety exception. In Chapter 4.2.9 the conclusion was that the object and purpose of the exception was to prevent double protection for identical subject matter. This indicates that the dual protection argument can be applied to the distinction between non-patentable varieties and patentable genes. The interpretation of the wording presented above is therefore in accordance with the object and purpose of the variety exception. This suggests that a gene is patentable under the Directive if the claims are limited to that particular gene, and not the entire genome, even if the trait of the gene is what makes a plant grouping different from other groups, thus creating a new *plant variety*.

### ***Plant genes –EPC***

The discussion above has focused on the legal situation in the Directive. The question now is how Article 53 (b) EPC is to be interpreted. In the paragraph above, called *point of departure –the wording*, the variety exception is interpreted in light of its wording. Here, other sources of law are assessed. In the Onco-mouse case, the Technical Board of Appeal came to the conclusion that the variety exception should be interpreted narrowly in respect for the main rule in Article 52 (1) EPC.<sup>231</sup> Even though the Onco-mouse case concerns superordinate taxonomical ranks and this discussion focuses on genes as one subordinate biological level, the argumentation of the Technical Board of Appeal can still be said to be of relevance because of the general nature of the statement. According to the methodology of public international law, wide interpretations of provisions are not the main rule in international law due to the principle of sovereignty of state.<sup>232</sup> This means that since a state is only obligated to

---

<sup>231</sup> T 19/90 point 4.5 of the Reasons.

<sup>232</sup> Brownlie 1998 p. 290.

adhere to commitments it has assumed, the state will typically be interested in interpreting these duties as narrowly and thus as near to the ordinary meaning of the wording as possible. Even though this does not give any concrete indication of how the term is to be understood in this situation, it may give some direction for the interpretation. This suggests that a wide interpretation of *plant variety* is not applied in the EPC understanding of the term.

EPC has no recital in its preamble similar to Recital 31 of the Directive nor does it have any other provision concerned with this issue. This may indicate that plant genes are not patentable in relation to the variety exception. However, the relationship between EPC and the Directive has to be taken into account. In the Implementing Regulations to EPC it is stated that:

‘Directive...shall be used as a supplementary means of interpretation.’<sup>233</sup>

This implies that when the primary sources of law do not give a clear answer, or the results are ambiguous or obscure, the Directive is to be used as a supplementary means of interpretation in addition to those mentioned in Article 32 of the Vienna Convention. In this case, the question of patentability of genes in relation to the variety exception cannot be said to be clear. Therefore, the understanding of Recital 31 of the Directive’s preamble in the interpretation of the question at hand in EPC is relevant. For this discussion it is referred to the examination above. Consequently, this argument indicates that particular genes are patentable if the claims are limited to particular genes and not the entire genome. In addition to this argument, the object and purpose of the variety exception in EPC and the Directive are identical with regards to their relation to the

---

<sup>233</sup> EPC Implementing Regulation, Rule 23b (1).

UPOV Convention. Therefore, it is also for this argumentation referred to the discussion above. Thus, the object and purpose indicates that a particular gene is patentable if the claims are limited to the gene and not the whole genome. The conclusion drawn from this discussion is that the variety exception in EPC is to be understood as allowing patents encompassing a particular gene which characterises a plant grouping, even if the trait creates a new plant variety.

### ***Animal genes under EPC and the Directive***

The discussions above have focused on the legal situation for plants. In this paragraph the question is whether an animal grouping distinguished from other groupings by a trait controlled by a particular gene is patentable in EPC and the Directive. For *animal varieties* there is no alternative intellectual property protection. The interface between the patent systems and a *sui generis* system cannot therefore, explain the exception for *animal varieties*. The argumentation applied above regarding the object and purpose of the variety exception related to plants cannot therefore, be used in this context. On the contrary, the fact that the variety exception for animals cannot be explained with a reference to a *sui generis* system may indicate that a gene which controls a trait distinguishing an animal grouping from other groupings is not to be patentable. Thus, that the variety exception is to be interpreted wider for *animal varieties* than for *plant varieties*. However, taking into account the legal history of the variety exception, it would have to be considered somewhat inconsistent that the variety exception for animals would be given a wider scope than the *plant variety* exception for which the exception was intended.<sup>234</sup> At least for the interpretation of EPC the argument in relation to the principle of sovereignty of states can be used as an argument for allowing patents

---

<sup>234</sup> Paterson 1992 p. 336 and p. 338. See also Chapters 4.2.9 and 5.

for genes which characterises an animal grouping.<sup>235</sup> Furthermore, it can be argued that, in respect for the main rule, the demand for a narrow interpretation of the exception may lead to patentability for these particular genes.<sup>236</sup> To conclude, it can be said that based on the sources of law presented here, the legal situation for animal genes in this respect is more uncertain than for plants. Nevertheless, the most probable conclusion is that an animal grouping characterised by particular genes holding traits which makes the patent claim comprise one or more *animal varieties* is patentable.

#### 4.3.5 Conclusion

The discussions above have shown that, though on partly divergent grounds, both plant and animal individual specimens and plant and animal microbiological material are not excluded from patentability due to the variety exception under both EPC and the Directive. This may imply that the variety exception in EPC and the Directive, on this point of law, does not reflect a wide rule. Thus, this opens for a wide access to patent categories of plants and animals.

---

<sup>235</sup> See the discussion above.

<sup>236</sup> T 19/90 point 4.5 of the Reasons.

## 5 UPOV-91's impact on the interpretation of EPC and the Directive

### 5.1 Introduction –*plant varieties*

As pointed out above, there is an international system for the protection of plant varieties. In this Chapter, the main question is how the cessation of the dual protection ban in UPOV affects the plant and animal variety exception in EPC and the Directive. before going into that issue it is necessary to discuss whether UPOV can be used as a source of law in the understanding of EPC and the Directive. In this chapter and Chapters 5.4 to 5.6 the focus is directed at *plant varieties*, while Chapter 5.7 discusses UPOV-91's impact on the term *animal variety* as applied in EPC and the Directive. *Animal varieties* are assessed in a separate chapter because such subject matter cannot be protected by the UPOV Convention.

### 5.2 UPOV-91 as a source of law when interpreting EPC

The question is if UPOV-91 can be used as a source of law in the interpretation of *plant variety* in EPC. Basically, the assessment of UPOV's possible influence on EPC is founded in the balancing of the interests of sovereignty of state on the one hand and on the other hand effectiveness and dynamics qualities of treaties. In this context, sovereignty of state implicates that a state shall only be bound by obligations it has

explicitly taken on through the ratification of a treaty or through state practice.<sup>237</sup> The principle of effective interpretation means that a treaty should not be left meaningless or ineffective relative to the object and purpose of the treaty following an interpretation.<sup>238</sup> In this relation dynamic interpretation means that a treaty is understood in accordance with evolvement towards a particular objective. Typically, this kind of interpretation leads to results which go beyond the ordinary and contextual meaning of the provision at hand, but which is in line with the object and purpose of the treaty. In other words, dynamic interpretation and the principle of effectiveness are based on a teleological view of approaching legal questions. The principle of sovereignty of state, on the other hand, typically favours a narrow interpretation also in relation to the use of other treaties in the interpretation.<sup>239</sup> In relation to the understanding of *plant varieties*, the principle of sovereignty of state promotes an interpretation based on sources which can be deduced from what has been agreed between the members of EPO. Dynamic interpretation and the principle of effective interpretation, on the other hand, encourage application of the UPOV Convention in the interpretation of EPC.

The point of departure in public international law is that a state is only bound by obligations it has undertaken or custom not actively opposed through state practice.<sup>240</sup> As mentioned in the previous paragraph this displays one side of state sovereignty and is expressed in Article 34 of the Vienna Convention where it is stated that:

---

<sup>237</sup> Bernhardt 1995 p. 900 and Ballreich 1995 p. 945.

<sup>238</sup> Oppenheim 1992 p. 1280.

<sup>239</sup> Bernhardt 1995 II p. 1419 and Oppenheim 1992 p. 1274 on the rule of *in dubio mitius*.

<sup>240</sup> Bernhardt 1995 p. 900 and Ballreich 1995 p. 945.

‘A treaty does not create either obligations or rights for a third State without its consent.’<sup>241</sup>

Applying the UPOV-91 understanding of *plant variety* in the interpretation of the term *plant variety* EPC may create obligations which cannot be derived from the treaties themselves. This entails that as a point of departure an understanding of a term in one treaty cannot be applied in the interpretation of a similar term in another treaty.

The next question is if there are exceptions to this point of departure. In Article 31, paragraph 3, litra c of the Vienna Convention it is stated that:

‘There shall be taken into account, together with the context:  
any relevant rules of international law applicable in the relations between the parties.’<sup>242</sup>

There are two cumulative criteria that have to be met in order to apply the understanding of a term to the interpretation of a similar term in another treaty. First, the rule (term) which is to be applied has to be a ‘relevant rule[...] of international law’ to the treaty at hand. Second, the two treaties have to be applicable ‘between the parties’.

‘A rule of international law’ can in this respect be understood as an obligation or a right taken on through agreement or state practice. This rule also has to be ‘relevant’ to the term being interpreted. One approach is to take the objectives of the treaties into consideration. A basic principle is that a convention shall be interpreted along the lines

---

<sup>241</sup> Article 34 of the Vienna Convention.

<sup>242</sup> Article 31, paragraph 3, litra c of the Vienna Convention.



of its object and purpose.<sup>243</sup> The objectives of a treaty may influence the interpretation of its provisions. For instance, the wording in two treaties may be identical even though the background for and objectives to the creation of the agreements is different. This kind of differences may constitute a basis for a diverging interpretation result. When applying this principle to Article 31, paragraph 3, *litra c* a comparison of the treaties' objectives can give an indication of the source treaty's suitability as a source of law. The more similar the objectives are, the more suitable the treaty is. Consequently, a treaty's relevance may depend on its objective compared to the object and purpose of the treaty at hand. As discussed in Chapter 4.2.9, the object and purpose of the UPOV-91 and EPC are closely related since the variety exception in the latter is established to create a division of protectable subject matter between the two systems of protection. Furthermore, the definition of *plant variety* in Rule 23b (4) EPC Implementing Regulations is in substance identical to the definition in Article 1 (vi) UPOV-91.<sup>244</sup> This indicates that the term *plant variety* in UPOV-91 is a 'relevant rule of international law' in relation to the interpretation of *plant variety* in EPC.

The next question is how the second criterion, applicable 'between the parties', is understood in public international law. It can have at least two meanings. On the one hand, it may indicate that only the two parties involved in a particular dispute have to be parties of the two treaties. On the other hand, it can be understood as to mean that the treaty being used as a source must be signed by all of the states that are part of the treaty being interpreted. The first interpretation is particularly practical when two bilateral treaties, between the same two states, are at hand. However, many treaties are multilateral. This lowers the probability of two treaties having identical set of parties.

---

<sup>243</sup> See Article 31, paragraph 1 of the Vienna Convention.

<sup>244</sup> See G 1/98 point 3.1 of the Reasons.

The wording can be said to open for both alternatives. Thus, according to the ordinary meaning of the wording the provision appears to be unclear on this point of law.<sup>245</sup>

As mentioned above, state sovereignty and effectiveness are key objectives in the public international law. It can be argued that interpreting a term in one convention applying the understanding of a similar term in another treaty may lead to effective results even though the contracting parties are not identical. The principle of state sovereignty suggests that states only are bound by rights and obligations they have agreed to and that all parties therefore have to be identical. The reason for this is that the interpretation will create a special understanding of the obligation. This interpretation of the term will have to be taken into account by all parties to the treaty at hand when interpreting the treaty on a later occasion. This effect holds a particular significance when the treaty at hand is interpreted by an authoritative institution, such as the EPO Boards of Appeal (Technical or Enlarged), which argumentation and result is often followed by these institutions later and therefore also by subordinate instances.<sup>246</sup> They will therefore be committed to an interpretation of the provision which they have not accepted as binding to them. Hence, to interpret a term in one treaty based on the interpretation of a similar term in another treaty with a different set of parties is therefore problematic in relation to basic principals of international law. Consequently, it is not sufficient that the two parties involved in the conflict are the same. Furthermore, the EPO Legal Board of Appeal emphasises that all members of both treaties have to be identical in order to apply Article 31, third paragraph of the Vienna Convention.<sup>247</sup> This case was related to

---

<sup>245</sup> Palmeter and Mavroidis seems to be of the opinion that 'parties' refers to the parties of the particular dispute. See Palmeter and Mavroidis 1998 p. 411.

<sup>246</sup> See Paterson 1992 p. 8.

<sup>247</sup> The united cases AstraZeneca/Priority from India J9/98 and J10/98 point 4.2 of the Reasons.

the application of the Patent Co-operation Treaty priority rights based on the TRIPs Agreements impact on the interpretation of EPC. The situation here and in the present case is therefore not identical. Moreover, this understanding of Article 31, third paragraph of the Vienna Convention is not completely clarified since the Legal Board of Appeal referred the question of interpretation and direct effect of TRIPs in EPC to the Enlarged Board of Appeal.<sup>248</sup> They are yet to answer the question posed to them. However, the case gives an indication on how EPO sees this point of law. The Technical Board of Appeal stated that in order to apply Article 31, third paragraph, litra c the parties of the treaties at hand had to be identical.<sup>249</sup> Thus, the requirement applicable ‘between the parties’ entails that all parties have to be identical.

The question is therefore if the parties of EPO are all parties to the UPOV-91 Convention. 14 of 27 EPC members are not parties to UPOV-91. This shows that the requirement of identify is not fulfilled and that, on the basis of Article 31, paragraph 3, litra c, the UPOV-91 understanding of *plant variety* cannot, according to Article 31, third paragraph, litra c, be applied to the interpretation of *plant variety* in EPC. Even though UPOV-91, according to customary international law codified in the Vienna Convention, is not a source of law in this situation EPO seems to take the relationship with UPOV-91 into consideration. Thus, the thesis discusses how the relation between UPOV-91 and EPC is viewed by EPO in Chapter 5.5.

---

<sup>248</sup> J9/98 and J10/98 point 2 of the Order. The case is pending under reference Nos. G 2/02 and G 3/02.

<sup>249</sup> J9/98 and J10/98 point 4.2 of the Reasons.

### 5.3 UPOV-91 as a source of law when interpreting the EC Patent Directive

The European Community is not as such party to the UPOV-91 Convention.<sup>250</sup>

International obligations only become a part of EC law when the Community as such has taken on the obligations.<sup>251</sup> UPOV-91 is therefore not an integral part of EC law.

However, the European Court of Justice sometimes takes international law into account as an auxiliary source of law when interpreting EC law.<sup>252</sup> In Chapter 4.2.13 it was

argued that due to the close relation between EPC and the Directive and since all EC members are parties to EPC, EPC could be applied in the interpretation of the Directive.

The plant variety exception in the Directive is based on the relation between patent law and plant breeder's rights.<sup>253</sup> This indicates that there is a strong relationship between

the Directive and UPOV-91. However, 9 of 15 EC members are not parties to UPOV-91. This indicates that UPOV-91 cannot be used as a means of interpretation of the EC

Patent Directive. Based on these arguments it is difficult to determine UPOV-91's status as a source of law in relation to the Directive. However, since 9 of the EC member

states are not parties to UPOV-91, the most probable conclusion is that UPOV-91 cannot be used as a source of law when interpreting the Directive. Just as for EPC it

seems that the European Community takes into account the relationship between the

Directive and UPOV-91 even though the latter is not seen as a source of law in EC law.

---

<sup>250</sup> See [www.upov.org/en/about/members/pdf/members.pdf](http://www.upov.org/en/about/members/pdf/members.pdf). Accessed on 10 November 2003.

<sup>251</sup> Bourgeois 2000 p. 92.

<sup>252</sup> See for example C-10/61 Commission v. Italy, (1962) ECR 1. See also Kapteyn and Themaat 1998 p. 280.

<sup>253</sup> See Article 2, third paragraph of the Directive cf. Recital 27 of the preamble of the EC Plant Variety Rights Regulation.

This relationship is assessed in Chapter 5.5. Before addressing that issue it is necessary to assess the background for the relationship. This is done in the following chapter.

#### 5.4 The dual protection ban

The dual protection ban, also referred to as the double protection ban, prohibits the protection of subject matter which falls within the definition of *plant variety* as applied in UPOV in other intellectual property protection systems. In Article 2 of UPOV-61 and UPOV-78 it is stated that:

‘Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent.

Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species.’<sup>254</sup>

This means that identical subject matter cannot be protected both by patent and by plant breeder’s rights without breaking with the obligations of UPOV-61 and UPOV-78. This was taken into account when the predecessor of EPC, the Strasbourg Patent Convention, was formed, and continued in EPC and the Directive by excepting *plant varieties* from patentability. The ban was, however, not pursued in the 1991 version of the UPOV Convention. This was done because the majority of the contracting states of UPOV-91 did not wish to attempt to give rules on forms of protection other than plant breeder’s

---

<sup>254</sup> Article 2 (1) of UPOV-61 and -78.

rights.<sup>255</sup> Moreover, the parties were of the opinion that the question of deciding intellectual property protection for *plant varieties* was best left in the hands of the national legislatures.<sup>256</sup> In addition, it was emphasised that several of the contracting parties had national legislature opening for patenting of *plant varieties*. These states would therefore have problems complying with the dual protection ban.<sup>257</sup> Adjustments had been done earlier when revising the Convention in 1978. The United States practiced double protection. To satisfy the US, the double protection ban was softened by the new Article 37 (1) which stated that parallel protection is acceptable if notification is given to the Secretary-General when signing or ratifying.<sup>258</sup> This amendment was seen as insufficient by the states which opted for patenting of *plant varieties* when revising the Convention in 1991. It was also pointed out that the dual protection ban could keep potential future member states from taking on the obligations of the Convention.<sup>259</sup> The double protection ban was therefore not taken into the UPOV-91 Convention. If the understanding of *plant variety* in the patent systems, EPC, and the Directive, and UPOV-91 are identical and identical subject matter cannot be protected by both systems, the dual protection ban will imply that the interpretation of the term will affect what subject matter can be protected by each system. A wide interpretation of *plant variety* will mean that fewer categories of plants can be patented due to the

---

<sup>255</sup> See the Minutes of the Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, points 251.1, 256.2 and 259.

<sup>256</sup> *Ibid.*, points 254.1, 257.1, 260 and 261.

<sup>257</sup> *Ibid.*, point 254.2.

<sup>258</sup> Marin 2002 p. 33.

<sup>259</sup> See the Minutes of the Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, point 254.1.

variety exception, while more subject matter may be protectable under the UPOV Convention –and vice versa. In the next chapter the discussion centres on whether the understanding of *plant variety* is identical in the patent systems and the UPOV Convention. Chapter 5.6 and 5.7 assesses the consequences of not continuing the dual protection ban in UPOV-91.

## 5.5 Discussion of identical interpretation –*plant varieties*

As mentioned in the introduction to this chapter, the main question is how the cessation of the dual protection ban in UPOV affects the variety exception in EPC and the Directive. Before this can be discussed, one additional topic must be addressed: Namely if the interpretation of *plant variety* in EPC and the Directive are identical to the understanding of the term in UPOV-91.

The Implementing Regulations to the EPC Convention,<sup>260</sup> Rule 23b (4) defines the term *plant variety* in EPC. The wording is identical to the wording in UPOV-91. This is also emphasised in the EPO Official Journal, the definition's relation to other legal documents is commented on and explained:

‘The definition follows the wording of the concept of variety as set forth in Article 1 (vi) of the 1991 UPOV Convention.’<sup>261</sup>

---

<sup>260</sup> The provisions concerning biotechnological inventions in these regulations entered into force on 1 September 1999.

<sup>261</sup> OJ EPO 8-9/1999, p. 579, point 18.

The quotation suggests that the term is to be understood identically in both EPC and UPOV-91. This is supported by another sentence in the same Official Journal:

‘The EPO boards of appeal have hitherto always used the UPOV Convention’s concept of variety as the basis for implementing Article 53 (b) EPC (see T 49/83, T 320/87 and most recently T 356/93).’<sup>262</sup>

Here, it is stated that, based on practice from the Technical Boards of Appeal, the term *plant variety* is to be interpreted identical to the understanding of the term in UPOV-91. In T 49/83, one of the cases referred to in the quotation above, the Technical Board of Appeal furthers the application:

‘This definition is reflected in the International Convention for the Protection of New Varieties of Plants of 2 December 1961,...’<sup>263</sup>

This indicates that the Technical Board of Appeal also sees the definition in the 1961 UPOV Convention to be consistent with the one in EPC. In T 320/87, the Lubrizol case, this argumentation is repeated.<sup>264</sup> In relation to the UPOV-91 Convention, the Technical Board of Appeal in the Plant Genetic Systems case refers to the definition of *plant variety* in UPOV-91 when defining the term in EPC.<sup>265</sup> This implies that the understanding of the term in EPC is to be interpreted identically to the interpretation in

---

<sup>262</sup> Ibid..

<sup>263</sup> T 49/83 point 2 of the Reasons.

<sup>264</sup> T 320/87 point 13 of the Reasons.

<sup>265</sup> T 356/93 point 23 of the Reasons.



UPOV-91. The quotations above give the impression that that the term *plant variety* in EPC and UPOV is to be interpreted identically.

In the previous paragraph the centre of attention has been EPC. In the following, the focus changes to cover the discussion from the perspective of the European Community. The question is if the definitions of *plant variety* in the Directive and UPOV-91 are interpreted identically. *Plant variety* is defined in the Community Plant Variety Rights Regulation.<sup>266</sup> The wording of the definition is identical to the definition presented in UPOV-91. The Regulation is relevant because the Directive refers to it for the definition of plant variety.<sup>267</sup> This indicates that the definitions are to be interpreted identically. The relationship to other intellectual property protection systems is discussed in the preamble of the Regulation:

‘...Whereas this definition is not intended to alter definitions which may have been established in the field of intellectual property rights....’<sup>268</sup>

Applied to the question here, the quotation can mean that the legislature of the European Community does not intend to alter the interface between patent protection and plant variety protection. This indicates that the definition in the Community Plant Variety Rights Regulation, and consequently also in the Directive, and UPOV-91 are identical. The statement presented here may be seen as a result of the underlying principle of

---

<sup>266</sup> EC Regulation NO2100/94.

<sup>267</sup> Article 2, third paragraph of the Patent Directive.

<sup>268</sup> Recital 9 of the preamble of EC Regulation NO2100/94.

harmonisation of EC members' legislation.<sup>269</sup> This objective is also emphasized in the following citation from the same preamble:

'...Whereas it is however highly desirable to have a common definition in both fields; whereas therefore appropriate efforts at international level should be supported to reach such a common definition;...'<sup>270</sup>

Even though the principle of harmonisation is put forth here, the perspective is different. The text can be interpreted as an indication that there currently is no common understanding of the term *plant variety* in the Directive and UPOV-91. Harmonisation is wanted, but not yet achieved. Seemingly, there is a conflict between the two quoted excerpts. The first indicates identity between the Directive and UPOV-91, while the second does the opposite. In my opinion, the first quotation is clearer and more unambiguous than the latter. This speaks in favour of looking at the understanding of the definitions as identical.

Another approach is to ask what the legislature means when it wants to achieve a 'common definition'.<sup>271</sup> The EC law is not statically connected to the legal situation today. New legislation as well as new interpretations of existing legislation can contribute to this dynamics.<sup>272</sup> There may be developments changing the balance between the different protection systems. For instance, case law may result in a change in how *plant variety* is understood. It can be argued that the meaning of identical terms

---

<sup>269</sup> Recital 5 of the preamble of the Rome treaty.

<sup>270</sup> Recital 10 of the preamble of EC Regulation NO2100/94.

<sup>271</sup> Ibid.

<sup>272</sup> Kapteyn and Themaat 1998 p.115 and p. 289.

can, within certain frames, be dynamical in relation to the others. Consequently, there is not *one* common definition, only definitions evolving together. In harmony with this, the conclusion is that the interpretations of *plant variety* in the Directive and UPOV-91 are identical today.

The conclusion, based on the discussions above, is that the definitions of *plant variety* in EPC, the Directive and UPOV-91 are to be interpreted identically as well as having an identical wording. This feature is taken into consideration when identifying the consequences of the cessation of the dual protection ban.

#### 5.6 Consequences of the cessation of the dual protection ban –*plant varieties*

As mentioned in the introduction to this chapter, the main question in this chapter is what consequences may occur in the cessation of the dual protection ban in UPOV-91. In other words the question is whether the cessation starts a process which results in that the variety exception changes or no longer applies. To illustrate, two extreme scenarios are presented. The first is that *plant varieties* can be patented under the EPO and EC patent regimes because they no longer have to take into account what is to be protected under the UPOV regime. The second is that EPC and the Directive are to be interpreted as before because they are not affected by the cessation of the dual protection ban. In the following presentation the reasoning for these two alternatives is discussed.

It can be said that the grounds for exempting *plant varieties* from patentability under EPC and the Directive begin to fade when the dual protection ban in UPOV-91 is removed. As presented above, the reason for exempting *plant varieties* from patentability was that a system for protecting such subject matter already existed and

that there was a ban against double protection.<sup>273</sup> When the dual protection ban is taken away, the explanation is no longer valid and there is less need to except *plant variety* as understood in the UPOV Convention from patentability.<sup>274</sup> This indicates that the understanding of *plant variety* in EPC and the Directive may be affected by the cessation of the dual protection ban.

However, it can be argued that the contracting parties of the Strasbourg Patent Convention, the predecessor of EPC, chose to exempt *plant varieties* due to the possibility of protecting such subject matter through a *sui generis* system regardless of the dual protection ban.<sup>275</sup> The contracting parties may have considered the UPOV system better suited for protecting *plant varieties* than the patent system and thus exempting such subject matter from patentability. In the continuation of this argumentation it should be noted that the dual protection ban was problematic for states which opted for patent or other protection other than UPOV protection for *plant varieties*. Australia, for example, opposed the dual protection ban because it meant that their legislation was in conflict with their obligations taken on through the UPOV Convention.<sup>276</sup> For the parties to the EPC and members of the EU, which excluded *plant varieties* from patentability, there was no problem of that kind. These arguments can indicate that removal of the dual protection ban does not affect the interpretation of *plant variety* in EPC and the Directive.

---

<sup>273</sup> See Chapter 4.2.9.

<sup>274</sup> Westerlund seems to take this stand. See Westerlund 2001 p. 446.

<sup>275</sup> Paterson 1992 p. 336.

<sup>276</sup> See the Minutes of the Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants, point 254.1.

Furthermore, several of the members of the EC are not parties to the UPOV-91 Convention. Austria, Belgium, Spain, France, Ireland, Italy and Portugal have ratified older versions of the UPOV Convention. Greece and Luxembourg are not parties to any UPOV version. These states are also parties to the EPC. In addition to these there are also some EPC states which are not members of the EC, that are parties to older versions of the UOPV Convention (Switzerland and Slovakia) and some that are not party to any UPOV Convention (Cyprus, Liechtenstein and Monaco). This means that if a change in the UPOV Convention were to affect the interpretation of *plant variety* in EPC and the Directive, states which are obligated to ban double protection and states which have no relation to UPOV will have to take on responsibilities they have not wanted. Both these consequences are problematic with regards to the principle of sovereignty of state.<sup>277</sup> The states that are parties of older versions of UPOV will *de facto* be forced to relate to the provisions they have objected to through the new interpretations in the patent regimes. The states that are not part of any UPOV Convention should not have their obligations in the patent systems affected by treaties to which they have no relation. This indicates that the changes in UPOV-91 do not affect the understanding of *plant variety* in EPC and the Directive.

The current interpretation of the term *plant variety*, not encompassing categories of plants of superordinate taxonomical rank as well as subordinate biological levels, makes the variety exception for plants relatively narrow.<sup>278</sup> Today it is possible for inventors to apply for plant variety protection on the *variety* level and patent protection on superordinate taxonomical levels such as the *family* level or having subordinate

---

<sup>277</sup> See Chapter 5.2.

<sup>278</sup> Bently and Sherman 2001 p. 550.

biological levels, e.g. the gene level, as the scope of the patent claim.<sup>279</sup> If this trend is continued it may lead to an erosion of the variety exception even though *plant variety* is to be interpreted identically in both UPOV and the two patent systems because the systems may overlap to a greater extent now that the dual protection ban is taken out of the UPOV Convention.<sup>280</sup> This argument indicates that the cessation of the dual protection ban may affect the interpretation of *plant variety* in EPC and the Directive.

In the continuation of this argument, Bently and Sherman states that due to the cessation of the dual protection ban, the patent systems and the UPOV system are no longer mutually exclusive and that this may lead to overlap between the systems.<sup>281</sup> However, it may very well be that the patent systems and the plant variety protection system are mutually exclusive even though the dual protection ban was not continued in UPOV-91. *Plant varieties* are protected by UPOV.<sup>282</sup> *Plant varieties* are exempted as patentable subject matter from EPC and the Directive.<sup>283</sup> Due to the reasons for the exception of *plant varieties* EPO and EC have, at least up until today, built their interpretation of *plant variety* on the UPOV understanding/definition.<sup>284</sup> Based on this argumentation, the two systems are mutually exclusive. Hence, this indicates that the cessation of the dual protection does not affect the interpretation of *plant variety* under EPC and the Directive.

---

<sup>279</sup> See Chapter 4.

<sup>280</sup> Bently and Sherman 2001 p. 550.

<sup>281</sup> Ibid..

<sup>282</sup> Article 2 UPOV-91.

<sup>283</sup> See Article 53 (b) EPC and Article 4, first paragraph, litra a of the Directive.

<sup>284</sup> See for example T 49/83 point 4 of the Reasons.

Having said this, it must be noted that since one of the reasons for excepting *plant varieties* from patentability was that dual protection was forbidden by the earlier versions of the UPOV Convention, and this reason is fading because of UPOV-91, it is possible that the interpretation of *plant variety* in EPC and the Directive may be different in the future. This possibility can result in the two systems no longer being mutually exclusive and indicates that the cessation of the dual protection ban may affect the understanding of *plant variety* under EPC and the Directive.

The discussion above gives numerous arguments in the discussion of the dual protection ban's possible impact on the interpretation of *plant variety* under EPC and the Directive. Nevertheless, a clear conclusion is difficult to deduce from the examination. However, some considerations that are important to the assessment may be indicated. The answer may lie in the balancing of two important considerations. First, the interface between the patent systems and the plant breeder's rights system depends on what division of labour the contracting parties to UPOV and EPC and the members of the EC choose to apply. Second, the interface may be determined by how much emphasis is put on the sovereignty of the contracting states.

## 5.7 Consequences for the interpretation of *animal varieties*

In the previous chapter the consequences of the dual protection ban's cessation for the term *plant variety* as understood in EPC and the Directive was discussed. In this chapter the discussion focuses on how the dual protection ban's cessation may affect the understanding of the term *animal variety*.

At first glance, the cessation of the dual protection ban seems not to affect the interpretation of *animal variety* in EPC and the Directive because the UPOV Convention concerns the protection of *plant varieties* not *animal varieties*. If the understanding of *plant variety* in EPC and the Directive is not affected by the cessation of the dual protection ban in UPOV-91, there is no reason for the interpretation of *animal variety* to be affected. However, if the change in the UPOV Convention affects the understanding of *plant variety* in EPC and the Directive in the sense that the term is interpreted more narrowly or perhaps *plant varieties* are no longer excluded from patentability at all, this may have consequences for the interpretation of *animal variety* in EPC and the directive. From a teleological point of view, the interpretation of *animal variety* has to be related to the intention of the variety exception. Bearing in mind that the variety exception was created due to the patent systems' relationship to plant breeder's rights protection, it can be argued that a more comprehensive exclusion of animal subject matter than plant subject matter would not be in accordance with a teleological interpretation of the variety exception. The contextual aspect requires the interpretation of *animal variety* to be seen in connection with the variety exception as a whole. This means that the interpretation of the term *plant variety* has to be taken into account when understanding *animal variety*. In principle, the two terms may very well be interpreted differently. Taking into consideration, however, the close connection between the terms and the relation to the reason for excepting *plant and animal varieties*, it can be said that *animal variety* should not be interpreted at least not more extensively than *plant variety*. Consequently, if the interpretation of the term *plant variety* is affected by the cessation of the UPOV dual protection ban, it can be argued that the understanding of *animal variety* should be affected accordingly.



## 6 The TRIPs Agreement's impact on the interpretation of EPC and the Directive

The question to be examined here is how the understanding of the term *plant varieties* in Article 27 (3) (b) TRIPs affects the understanding of *plant variety* in EPC and the EC Directive. Before assessing the consequences of using TRIPs as a source of law, the relevance of the Agreement as a means of interpretation for EPC and the Directive has to be examined. Thereinafter, the TRIPs understanding of the term is discussed before assessing the consequences for the interpretation of *plant variety* in EPC and the Directive.

### 6.1 TRIPs as a means of interpretation for EPC

The question in this chapter is whether the *plant varieties* in Article 27 (3) (b) TRIPs can be used in the interpretation of *plant variety* in EPC. This is not a question of direct application of TRIPs, which according to EPO case law EPC does not open for.<sup>285</sup> The question is merely whether TRIPs can be taken into consideration when interpreting EPC. The point of departure is that a state is only obligated by the obligations it has taken on.<sup>286</sup> This means that the main rule of international law is that one treaty does not create obligation when interpreting another treaty. In Article 31, third paragraph, *litra c* an exception to this starting point is presented. It emphasises that a treaty can be interpreted in the light of another treaty when the interpretation aid is a 'relevant rule of

---

<sup>285</sup> International Business Machines Corporation/Asynchronous resynchronization of a commit procedure, T 1173/97 point 2.2 of the Reasons.

<sup>286</sup> Article 34 of the Vienna Convention.

international law' which is applicable 'between the parties'. The TRIPs Agreement is taken into consideration when interpreting EPC in T 1173/97.<sup>287</sup> The Technical Board of Appeal emphasised that TRIPs did not have direct effect, but was taken into consideration since it is aimed at setting common standards for patent rights.<sup>288</sup> This argumentation has later been repeated in the joined cases J 9/98 and J 10/98.<sup>289</sup> Furthermore, the terms *plant variety* and *plant varieties* in EPC and TRIPs are similar, both on the field of intellectual property rights. Thus, the *plant varieties* in Article 27 (3) (b) TRIPs is 'a relevant rule of international law' in relation to the understanding of *plant variety* in EPC. All parties to EPC are also WTO members.<sup>290</sup> This entails that the term *plant varieties* in Article 27 (3) (b) TRIPs is applicable 'between the parties'. Consequently, EPC is interpreted in the light of TRIPs on this point of law.

## 6.2 TRIPs as an interpretation aid when interpreting the EC Patent Directive

The question here is whether the term *plant varieties* in Article 27 (3) (b) TRIPs can have an influence on the understanding of *plant variety* in the EC Patent Directive. The question of direct effect of the TRIPs Agreement in EC law is not discussed since it is not necessary for the assessment in this thesis.<sup>291</sup> The European Community as such is a

---

<sup>287</sup> T 1173/97 point 2.3 of the Reasons.

<sup>288</sup> Ibid..

<sup>289</sup> AstraZeneca/Priority from India, J 9/98 and J 10/98 point 5.1 of the Reasons.

<sup>290</sup> See [www.epo.org/epo/members.htm](http://www.epo.org/epo/members.htm) cf.

[www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm). Accessed on 10 November 2003.

<sup>291</sup> EC law does not, as a point of departure, open for direct effect of WTO law. See Snyder 2003 p. 326.

member of WTO.<sup>292</sup> The point of departure in EC law is that international agreements concluded by EC are integral parts of EC law.<sup>293</sup> This means that they can be used in the interpretation of EC law. The question is whether this also is the case for WTO law. WTO law has served as a model for the anti-dumping legislation in EC.<sup>294</sup> WTO law is therefore used as an aid for interpreting EC secondary legislation on this field.<sup>295</sup> On the field of intellectual property rights, however, EC legislation has not been affected by WTO law to that extent.<sup>296</sup> Nevertheless, Advocate General Jacobs used TRIPs as an interpretation aid in the *Silhouette* case and the *Procter & Gamble* case.<sup>297</sup> The European Court of Justice did not refer to TRIPs, but came to the same result on the merits. This can indicate that the European Court of Justice is reluctant to interpret EC secondary legislation on the field of intellectual property rights in the light of the TRIPs Agreement. However, it can also mean that they agreed with Advocate General Jacobs in principle, but not need to address the issue due to the merits of the cases. On this background, the understanding of *plant variety* in the EC Patent Directive is interpreted in the light of *plant varieties* in Article 27 (3) (b) TRIPs.

---

<sup>292</sup> See [www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm). Accessed on 10 November 2003.

<sup>293</sup> C-181/73, *Haegeman*, (1974) ECR 449 and *Racke*, ECR I-3655. See also *Bourgeois* 2000 p. 92 with further references and *Kapteyn and Themaat* 1998 p. 278.

<sup>294</sup> *Snyder* 2003 p. 320.

<sup>295</sup> See for example joined Cases T-33 & 34/98, *Petrotub SA and Republica SA v. Council*, (1999) ECR II-3837. See also *Snyder* 2003 p. 321.

<sup>296</sup> *Snyder* 2003 p. 322.

<sup>297</sup> C-355/96, *Silhouette International Schmied GmbH & Co KG v. Hartlauer Handelslsgesellschaft mbH*, (1998) ECR I-4799 and C 383/99, *Procter & Gamble v. Office for Harmonisation in the Internal Market (Trade Marks & Designs)*, (2001) ECR I-6251.

### 6.3 The interpretation of Article 27 (3) (b) TRIPs –*Plant variety*

The question to be discussed here is, as suggested in the previous paragraph, how the term *plant varieties* in Article 27 (3) (b) TRIPs is to be understood.

In the last sentence of Article 27 (3) (b) it is stated that the provision is to be reviewed four years after the entry into force of the WTO Agreement.<sup>298</sup> The WTO Agreement entered into force in 1995. This entails that the provision was opened for review in 1999. The review is yet to be concluded. An assessment of the possible outcome and consequences of the review would lead non-legal discussions which cannot be investigated by means of legal methodology and thus beyond the scope of this thesis. The review is therefore not further discussed.

#### 6.3.1 Wording

The second part of Article 27 (3) (b) concerns the protection of *plant varieties*. According to the wording of the provision, *plant varieties* have to be protected efficiently by patent law, a *sui generis* system or a combination of the two. A further explanation of the term *plant variety* is not given in TRIPs. A clear understanding of the term is therefore not evident from assessment of the wording of the provision and a contextual interpretation in relation to other parts of the agreement.

---

<sup>298</sup> Article 27 (3) (b) TRIPs.

### 6.3.2 Influence from the UPOV-91 Convention

Placing the provision in a broader context, it may be possible to assess *plant variety* in relation to existing definitions and understandings of the term in other intellectual property right regimes. This opens for two questions. First, if one specific external definition from another treaty may be applied in the understanding of *plant varieties* in TRIPs on the basis of an interpretation of TRIPs. Second, if an external understanding is to be applied on the basis of customary law. Thus, though related, this is not a question of if there are one or more ‘effective’ *sui generis* systems for the protection of *plant varieties*, but rather a question of how the term *plant variety* in TRIPs is to be understood.<sup>299</sup>

In the following it is assessed whether the UPOV-91 understanding of *plant variety* may be used in the interpretation of the term *plant varieties* in the TRIPs Agreement.<sup>300</sup> Thus, this is related to the first question namely if another treaty can be used in the interpretation of TRIPs. It is not given that UPOV is the only system of plant variety protection which is ‘effective’ according to the TRIPs Agreement, and thus in a position where it may have an impact, but since UPOV is the worlds leading *sui generis* system for protection of *plant varieties* its potential impact on the understanding of *plant variety* in TRIPs is discussed.<sup>301</sup>

As seen in Chapter 5.2, the principle of sovereignty of state is mirrored in the Vienna Convention. According to Article 34 of the Vienna Convention a treaty cannot create

---

<sup>299</sup> Article 27 (3) (b) TRIPs.

<sup>300</sup> Cf. the first question.

<sup>301</sup> Matthews 2002 p. 59 and Correa 1998 p. 197.

neither obligations nor rights for states which are not party to the treaty at hand.<sup>302</sup>

Since the TRIPs Agreement and UPOV-91 are independent treaties not directly related to each other this indicates that, as a point of departure, the understanding of *plant variety* in the UPOV-91 Convention cannot be applied to the interpretation of *plant varieties* in the TRIPs Agreement. The subsequent question is if the exception to this starting point is applicable.

In Article 31, third paragraph, litra c it is stated that:

‘There shall be taken into account, together with the context...any relevant rules of international law applicable in the relation between the parties.’<sup>303</sup>

In relation to Article 31, third paragraph, litra c of the Vienna Convention, the question is if the requirement which demands that the rule has to be a ‘relevant rule of international law’ in relation to the TRIPs Agreement. Some of the states which are not members of UPOV oppose to the UPOV understanding of *plant variety*. Correa, for example, suggests that that not only plant breeder’s rights, but also farmers rights to the less industrialised *farmers varieties* should be included in the term *plant varieties* in the TRIPs Agreement.<sup>304</sup> Such interpretation is not consistent with the UPOV understanding of the terms.<sup>305</sup> Moreover, EPC and the EC Patent Directive delimits their protection towards *plant varieties* as defined in UPOV-91.<sup>306</sup> This is related to the strong

---

<sup>302</sup> Article 34 of the Vienna Convention.

<sup>303</sup> Article 31, third paragraph, litra c of the Vienna Convention.

<sup>304</sup> Correa 1998 p. 197.

<sup>305</sup> Article 1 (vi) of the UPOV-91 Convention.

<sup>306</sup> See Chapter 4.2.

teleological connection between EPO and EC patent protection and plant breeder's rights protected through the UPOV Convention.<sup>307</sup> Members of WTO on the other hand are, through the TRIPs Agreement, obligated to afford adequate intellectual property protection for *plant varieties*.<sup>308</sup> Thus, TRIPs does not relate to the UPOV Convention to the same extent as EPC and the Directive. This indicates that the UPOV-91 understanding of *plant variety* is not 'a relevant rule of international law' in relation to the interpretation of *plant varieties* in TRIPs.

The next question is whether the criterion applicable 'between the parties' is fulfilled. 23 of the WTO members are also parties to the UPOV-91 Convention. In these states' plant variety legislation *plant variety* holds the UPOV meaning.<sup>309</sup> 122 other WTO members are not parties to the UPOV-91 Convention.<sup>310</sup> These have objected to the legal content of the 1991 version of UPOV and have therefore not ratified the convention. An understanding of *plant varieties* in accordance with the UPOV-91 definition would entail that states not parties to UPOV-91 are, through TRIPs, tied to the very definition they rejected. Since there are states which are members of the WTO but not parties to UPOV-91, the criterion 'between the parties' is not fulfilled.

To conclude, the discussion above indicates that according to Article 34 and 31, third paragraph, *litra c* of the Vienna Convention the UPOV-91 understanding of *plant variety* cannot be used in the interpretation of *plant varieties* in Article 27 (3) (b) TRIPs.

---

<sup>307</sup> See Chapter 4.2.9.

<sup>308</sup> Article 27 (3) (b) TRIPs.

<sup>309</sup> The numbers based on the latest available membership lists from WTO (14 April 2003) and UPOV (31 July 2003).

<sup>310</sup> *Ibid.*.

The circumstances concerning the limited concurrence of contracting states to the TRIPs Agreement and the UPOV Convention lead to the second question. Namely, as mentioned above, if an external understanding of *plant varieties*, in particular the UPOV-91 definition, is to be applied on the basis of customary law.<sup>311</sup> According to customary law, codified in Article 38 (1) (b) ICJ, international customary law is created on the basis of ‘general practice’ which is ‘accepted as law’.<sup>312</sup> This means that the practice has to be followed by all states which are to be bound by the custom and that they see the practice necessary to fulfil their legal obligations according to public international law (*opinio juris*). Furthermore, Article 38 of the Vienna Convention stresses that a rule can become binding to a third party if that state’s practice is in line with the rule and it fulfils the requirements customary law. Applied to the situation at hand, this suggests that all WTO members have to practice and accept the UPOV-91 plant variety definition as a legal obligation when interpreting the concept of *plant varieties* under TRIPs. Taking into account that 122 members of the WTO are not parties to the 1991 version of UPOV, many of whom have not ratified this version partly due to the plant variety definition, it seems that a custom on this point of law is non-existing.

Moreover, another feature in WTO law which makes the creation of customary law in this matter less plausible is that application of customary law in WTO is rare because the system is treaty and not custom based.<sup>313</sup> According to the Dispute Settlement Body international customary law does not override explicit provisions of the WTO

---

<sup>311</sup> Article 1 (vi) of the UPOV-91 Convention.

<sup>312</sup> Article 38 (1) (b) ICJ.

<sup>313</sup> Palmetier and Mavroidis 1998 p. 407.



Agreements.<sup>314</sup> Even though there is no direct conflict between the wording of Article 27 (3) (b) TRIPs and a prospective UPOV-91 based plant variety custom simply because the wording does not define *plant varieties* in TRIPs, the findings of the Dispute Settlement Body indicates a reserved attitude towards use of international customary law.

The conclusion is that there is not, on the basis of international customary law, grounds for understanding *plant varieties* in the Article 27 (3) (b) TRIPs to be identical to the definition presented in the UPOV-91 Convention. Moreover, an understanding of *plant varieties* based on customary law does not currently exist under WTO law.

### 6.3.3 The understanding of the term *plant* in relation to *plant variety*

*Plant* is used as a term in the TRIPs Agreement to determine subject matter which according to the agreement can be excluded from patentability.<sup>315</sup> It is stated that:

‘Members may also exclude from patentability:...plants....’<sup>316</sup>

---

<sup>314</sup> EC –Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States, WTO Doc. WT/DS26/R/USA, paragraph 8.157 (August 18, 1997), Complaint by Canada, WTO Doc. WT/DS48/R/CAN, paragraph 8.160 (August 18, 1997) and WTO Doc. AB-1997-4, WT/DS26/AB/R, WT/DS48/AB/R paragraph 123 (January 16, 1998).

<sup>315</sup> Article 27 (3) (b) TRIPs.

<sup>316</sup> Ibid..

Hence, according to the wording the members of WTO can choose to not grant patents to claims expressing plants. In this relation, the question is if the term *plant* is different from *plant variety* and thus can provide a contribution to a negative definition of *plant variety*. *Plant* can be understood as a certain taxonomical category or it can be interpreted broader that is to mean plants as such or in other words categories of plants on all taxonomical levels. Since the term *plant variety*, which according to a textual interpretation is narrower than *plant*, is used in the same article, an ordinary understanding of the wording and a contextual interpretation suggests the term *plant* is considered to encompass all taxonomical levels. Consequently, this can entail that *plant variety* can be delimited towards other taxonomical categories such as species or families.

#### 6.3.4 The demarcation between *micro-organism* and *plant variety*

The term *micro-organism* is used in Article 27 (3) (b) TRIPs. It is stated that:

‘Members may also exclude from patentability:...plant...other than micro-organisms....’<sup>317</sup>

This entails that *micro-organisms* cannot be excluded from patentability. If the understanding of the term *micro-organism* can be determined it can contribute to the TRIPs understanding of *plant variety*. The question is therefore how *micro-organism* is interpreted in the TRIPs Agreement. The term is, however, not defined in the agreement. Statements in the revision process of Article 27 (3) (b) supports that view.

---

<sup>317</sup> Article 27 (3) (b) TRIPs.

The United States, Japan and Switzerland are for example of the opinion that the definition of *micro-organism* in the Oxford Dictionary is sufficient to distinguish plants and animals from *micro-organisms*.<sup>318</sup> According to the dictionary quoted by these states a *micro-organism* is:

‘an organism not visible to the naked eye, e.g., bacterium or virus.’<sup>319</sup>

This may indicate that also plant cells, proteins and genes are encompassed by the term. In Contrast, Brazil is in favour of a more scientific understanding.<sup>320</sup> Such divergences in the interpretation of the bordering term make it difficult to deduce a negative definition of *plant varieties* from the term *micro-organism*. This suggests that a definition of *plant varieties* cannot be based as definition of the neighbouring term *micro-organism*.

### 6.3.5 Consequences for the interpretation of *plant variety* in EPC and the Directive

The question here is what impact the understanding of *plant varieties* in TRIPs has on the understanding of *plant variety* in EPC and the Directive. Based on the available

---

<sup>318</sup> Communication From Switzerland to the TRIPs Council, 15 June 2001, Document IP/C/W/284 p. 3.

<sup>319</sup> Communication From Switzerland to the TRIPs Council, 15 June 2001, Document IP/C/W/284 p. 3, note 4.

<sup>320</sup> Communication from Brazil to the TRIPs Council, 24 November 2000, Document IP/C/W/228 p. 2.

sources of law, assessed above in Chapters 6.3.1-6.3.4, it is difficult to have a clear understanding of the term *plant varieties* in Article 27 (3) (b) TRIPs. This means that EC, which is a member of WTO, is left with a margin of appreciation on this point of law. Since the term is ambiguous, the term *plant varieties* in the TRIPs Agreement has little practical effect on the interpretation of *plant variety* in EPC and the Directive.

## 7 Implications

In this thesis the legal delimitation of the terms *plant variety* and *animal variety* has been discussed. The assessments have shown that the understandings of *plant variety* in EPC and the Directive are reflections of the UPOV-91 understanding of the term. And thus creates the basis for a division of work between plant breeder's rights and the patent regimes. At the time of conclusion of the variety exception it was not technically possible to modify plants or animals in such manner that the result would fulfil the patent requirements.<sup>321</sup> With the introduction of modern biotechnology, in particular gene technology, this situation has changed.<sup>322</sup> The thesis shows that plants and animals on taxonomical levels superordinate to *variety* are patentable. This practice of the variety exception opens for broad patents on plant and animal subject matter other than *plant* and *animal variety*. The exclusive right afforded through the grant of a patent shall cover the purpose of the invention.<sup>323</sup> If the exclusive right afforded goes beyond

---

<sup>321</sup> Hellstadius 2001 p. 34 and Hellstadius 2002 p. 67.

<sup>322</sup> Westerlund 2001 p. 447.

<sup>323</sup> Bently and Sherman 2001 p. 502.

the invention, the patent is too wide. The problem with too broad patents is that they may deter other inventors from patenting inventions covered by the patent, but which lies beyond the purpose of the patented invention. This situation may result in that some products and processes are not invented, hence hindering innovation. With regard to plant and animal subject matter with for example one introduced gene, inventing around an existing patent is particularly difficult since there rarely are other genes, than the one type encompassed by the patent, coding for a particular characteristic. This means that broad patents are a particularly comprehensive challenge when dealing with plant and animal subject matter. The current interpretation of the variety exception opens for a situation where broad, though not necessarily too broad, patents may prosper. Thus, this shows the connection between patentability and the scope of the patent claims.<sup>324</sup> The challenge of limiting the scopes of patents on this field is, due to the current practice of the variety exception, left to the European Patent Office and national patent offices. This shows that an exception which, due to the technology available at the time of conclusion, appeared to be a total prohibition of patenting of plants and animals today has evolved making the field of plant and animal subject matter an area where broad patents has become a challenge.

---

<sup>324</sup> See Chapter 1.1.

## 8 Literature

Andersen and Koktvedgaard 1990 –Mads Bryde Andersen and Mogens Koktvedgaard, *Bioteknologi og patentret*, Copenhagen: Københavns Universitet Det retsvidenskabelige Institut A, 1990.

Aust 2000 –Anthony Aust, *Modern Treaty Law and Practice*, Cambridge: Cambridge University Press, 2000.

Arnesen 1992 –Finn Arnesen, *Introduksjon til rettskildelæren i EF*, Second edition, Oslo: Universitetsforlaget, 1992.

Ballreich 1995 –Hans Ballreich, *Treaties, Effect on Third States*, in Encyclopedia of Public International Law, Volume IV, pp. 945-949, editor R. Bernhardt, Amsterdam: North-Holland, 1995.

Bently and Sherman 2001 –Lionel Bently and Brad Sherman, *Intellectual Property Law*, Oxford: Oxford University Press, 2001.

Bernhardt 1995 –Rudolf Bernhardt, *Customary International Law*, in Encyclopedia of Public International Law, Volume I, pp. 898-905, editor R. Bernhardt, Amsterdam: North-Holland, 1995.

Bernhardt 1995 II –Rudolf Bernhardt, *Interpretation of International Law*, in Encyclopedia of Public International Law, Volume II, pp. 1416-1426, editor R. Bernhardt, Amsterdam: North-Holland, 1995.

Blakeney 1996 –Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement*, London: Sweet and Maxwell, 1996.

- Blakeney 2002 –Michael Blakeney, *Legal Aspects of Biotechnology*, in the Conference Material from the International Conference on Biolaw 2002, Bangkok, pp. 9-36.
- Bogdandy and Makatsch 2001 –Armin von Bogdandy and Tilman Makatsch, *Collision, Co-existence or Co-operation? Prospects for the Relationship between WTO Law and European Union Law*, in *The EU and the WTO: Legal and Constitutional Issues*, pp.131-150, Oxford and Portland: Hart Publishing, 2001.
- Borgli and Arnesen 1993 –Anneke Biesheuvel Borgli and Finn Arnesen, *Institusjoner og rettskildelære i EF og EØS –en introduksjon*, Oslo: Universitetsforlaget, 1993.
- Bourgeois 2000 –Jacques H. J. Bourgeois, *The European Court of Justice and the WTO*, in *The EU, the WTO and NAFTA*, pp. 71-123, editor J. H. H. Weiler, Oxford: Oxford University Press, 2000.
- Brownlie 1998 –Ian Brownlie, *Principles of Public International Law*, Fifth edition, Oxford: Oxford University Press, 1998.
- Burca and Scott 2001 –Grainne de Burca and Joanne Scott, *The Impact of the WTO on EU Decision-making*, in *The EU and the WTO: Legal and Constitutional Issues*, pp.1-30, Oxford and Portland: Hart Publishing, 2001.
- Commission Green Paper 2002 –The Commission of *Promoting innovation through patents*, Green Paper on the Community patent and the patent system in Europe presented by the Commission, 11 April 2002.
- Campell, Reede and Lawrence 1999 –Niel A. Campell, Jane B. Reede and Lawrence G. Mitchell, *Biology*, fifth edition, California: Benjamin/Cummings, 1999.
- Correa 1998 –Carlos M. Correa, *Patent Rights*, in *Intellectual Property and International Trade: The TRIPS Agreement*, pp. 189-222, editors Carlos M. Correa and Abdulqawi A. Yusuf, London, The Hague and Boston: Kluwer Law International, 1998.

- Dillon 2002 –Sara Dillon, *International Trade and Economic Law and the European Union*, Oxford and Portland: Hart Publishing, 2002.
- Ellis and Tridimas 1995 –Evelyn Ellis and Takis Tridimas, *Public Law of the European Community: Text, Materials and Commentary*, London: Sweet and Maxwell, 1995.
- Fauchald 2001 –Ole Kristian Fauchald, *Patenter og allmenningens tragedie*, in *Lov og Rett* 2001, pp. 399-412.
- Grubb 1999 –Philip W. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, Oxford: Oxford University Press, 1999.
- Heller and Eisenberg 1998 –Micael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, in *Science*, Vol. 280, 1 May 1998, pp. 698-701.
- Hellstadius 2001 –Åsa Hellstadius, *Patent eller växtförädlarrätt? –Immaterialrättsligt skydd för växter med avseende på undantaget för "växtsorter" i europeiskpatenträtt och praxis inom EPO*, nr. 109, Stockholm: Institut För Immaterialrätt och Marknadsrätt vid Stockholms Universitet, 2001.
- Hellstadius 2002 –Åsa Hellstadius, *Gene Technology and the Law*, nr. 116, Stockholm: Institut För Immaterialrätt och Marknadsrätt vid Stockholms Universitet, 2002.
- Hornby 1974 –A S Hornby, *Oxford Advanced Learner's Dictionary of Current English*, Oxford: Oxford University Press.
- Flammer 1999 –Richard Flammer, *Biotechnologische Erfindungen im Patentrecht*, Vienna: Verlag Österreich, 1999.
- Gilat 1995 –David Gilat, *Experimental Use and Patents*, IIC Studies, vol. 16, Weinheim and New York: VCH, 1995.
- Goldbach and Vogelsang 1997 –Klara Goldbach, Heike Vogelsang-Wenke and Franz-Josef Zimmer, *Protection of Biotechnological Matter under European and German Law*, Weinheim and New York: VCH, 1997.



- Judd... (et al.) 2002 –Walter Judd, Christopher Campbell, Elizabeth Kellogg, Peter Stevens and Michael Donoghue, *Plant Systematics a phylogenetic approach*, Sunderland: Sinauer Associates, 2002.
- Jördens 2002 –Rolf Jördens, *Legal and technical developments leading to this symposium: UPOV's perspective*, in WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeder's Rights in the Promotion of Biotechnological Developments, Geneva, October 25 2002, WIPO-UPOV/SYM/02/2.
- Kapteyn and Themaat 1998 –P.J.G Kapteyn and P. VerLoren van Themaat, *Introduction to the Law of the European Communities*, Third edition, London, The Hague and Boston: Kluwer Law International, 1998.
- Lauwaars 2000 –Richard H. Lauwaars, *Interpretations of International Agreements by National Courts: An EC View*, in *New Directions in International Economic Law*, pp. 509-522, editors Marco Bronckers and Reinhard Quick, The Hague, London, Boston: Kluwer Law International, 2000.
- Lesser 2000 –William Lesser, *An Economic Approach to Identifying an 'Effective sui generis System' for Plant Variety Protection Under TRIPs*, in *Agriculture and Intellectual Property Rights*, pp. 53-76, editors V. Santaniello et al., Wallingford and New York: CABI Publishing, 2000.
- Llewelyn 2000 –Margaret Llewelyn, *The Patentability of Biological Material: Continuing Contradiction and confusion*, in *European Intellectual Property Review*, pp. 191-197, London: Sweet & Maxwell, 2000.
- Llewelyn 2002 –Margaret Llewelyn, *Intellectual Property and Biotechnology: A European Perspective*, in the *Conference Material from the International Conference on Biolaw 2002*, pp. 73-106, Bangkok 2002.
- Marin 2002 –Patricia Lucia Cantuaria Marin, *Providing Protection for Plant Genetic Resources*, The Hague: Kluwer Law International, 2002.

- Martin and Hine 2000 –Elizabeth Martin and Robert S. Hine (editors), *Oxford Dictionary of Biology*, fourth edition, Oxford: Oxford University Press, 2000.
- Matthews 2002 –Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPs Agreement*, London and New York: Routledge, 2002.
- Mayr 1982 –Ernst Mayr, *The Growth of Biological Thought, Diversity, Evolution and Inheritance*, Cambridge, MA and London: The Belknap Press of Harvard University Press, 1982.
- Moore 1997 –Adam D. Moore (editor), *Intellectual Property*, Lanham, Boulder, New York and Oxford: Rowman & Littlefield Publishers, 1997.
- Nordic Gene Resource Council 2002 –Nordic Gene Resource Council (Secretary: Morten Walløe Tvedt), *A Nordic Approach to Access and Rights to Genetic Resources*, 2002.
- Nuffield Council on Bioethics 2002 –*The ethics of patenting DNA*, London: The Nuffield Foundation, 2002.
- Oppenheim 1992 –L.F.L Oppenheim, *Oppenheim's International Law*, Ninth Edition, Volume I, Peace, Introduction and Parts 1-4, editors Robert Jennings and Arthur Watts, London: Longman, 1992.
- Overwalle 1996 –Geertrui van Overwalle, *Octrooieerbaarheid van Patentenbiotechnologische Uitvindingen*, Brussel: Bruylant, 1996.
- Paterson 1992 –Gerald Paterson, *The European Patent System*, London: Sweet and Maxwell, 1992.
- Palmeter and Mavroidis 1998 –David Palmeter and Petros C. Mavroidis, *The WTO Legal System: Sources of Law*, in *The American Journal of International Law*, Volume 92, Issue 3, pp. 398-413, Washington DC: American Society of International Law, 1998.

- Peers 2001 –Steve Peers, *Fundamental Rights or Political Whim? WTO and the European Court of Justice*, in *The EU and the WTO: Legal and Constitutional Issues*, pp.111-130, Oxford and Portland: Hart Publishing, 2001.
- Pervan and Arash 2001 –Linda Pervan and Babak Arash, *Patenträtten och växtförädlarrätten*, in *Immaterialrättsliga överlappningar*, pp. 102-122, nr. 108, editors Johanna Kallifatides and Marianne Levin, Stockholm: Institut För Immaterialrätt och Marknadsrätt vid Stockholms Universitet, 2001.
- Petrusson 1999 –Ulf Petrusson, *Patent och industriell omvandling*, Stockholm: Norstedts Juridik, 1999.
- Robinson 1996 –Raoul A. Robinson, *Return to Resistance, Breeding Crops to Reduce Pesticide Dependence*, Davis, CA and Ottawa: agAccess and International Development Research Centre, 1996.
- Rosendal 1999 –G. Kristin Rosendal, *Implementing Environmental Agreements in Developing Countries: The Creation and Impact of the Convention on Biological Diversity*, Oslo: Department of Political Science, University of Oslo and Unipub forlag, Akademika, 1999.
- Rosenlund 1993 –Lars B.Rosenlund, *Immaterialrättsligt skydd för växter*, nr. 70, Stockholm: Institut För Immaterialrätt och Marknadsrätt vid Stockholms Universitet, 1993.
- Ruud and Ulfstein 1998 –Morten Ruud and Geir Ulfstein, *Innføring i folkerett*, Oslo: Tano Aschehoug, 1998.
- Sandvik 1994 –Jostein Sandvik, *Om patent på mikrobiologiske fremgangsmåter og produkter av slike fremgangsmåter*, thesis for the Cand.jur. degree at the University of Oslo in 1994. Available at the Library, the Faculty of Law, University of Oslo.
- Singer 1995 –Romuald Singer and Margarete Singer, *The European Patent Convention*, revised by Raph Lunzer, London: Sweet and Maxwell, 1995.

- Snyder 2003 –Francis Snyder, *The Gatekeepers: The European Courts and WTO Law*, in *Common Market Law Review*, Vol. 40, pp. 313-367, London: Kluwer Law International, 2003.
- Stenvik 1999 –Are Stenvik, *Patentrett*, Oslo: Cappelen Akademisk Forlag, 1999.
- Stenvik 1999 II –Are Stenvik, *Genteknologi og patenter*, in *Lov og Rett* 1999, pp. 257-258.
- Stenvik 2001 –Are Stenvik, *Patenters beskyttelsesomfang*, Oslo: Cappelen Akademisk Forlag, 2001.
- Trebilcock and Howse 1999 –Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, second edition, London and New York: Routledge, 1999.
- Tvedt 2001 –Morten Walløe Tvedt, *Access to Genetic Resources –The Convention on Biological Diversity Article 15 and the Costa Rican Biodiversity Act*, Oslo: SUM, 2001.
- Weatherill and Beaumont 1999 –Stephen Weatherill and Paul Beaumont, *EU Law*, third edition, London: Penguin Books, 1999.
- Westberg 1993 –Else Westberg,, *Bioteknologisk patentpraxis i Sverige och europeiska patentorganisationen*, nr. 68, Stockholm: Institutet För Immaterialrätt och Marknadsrätt vid Stockholms Universitet, 1993.
- Westerlund 2001 –Li Westerlund, *Biotech Patents*, Stockholm: Juridiska fakulteten vid Stockholms universitet, 2001.
- Wetzel and Rauschnig 1978 –Ralf Günter Wetzel and Dietrich Rauschnig (editors), *The Vienna Convention on the Law of treaties –Travaux Preparatoires*, Frankfurt: Alfred Metzner Verlag, 1978.
- Wilson 1993 –Edward O. Wilson, *The Diversity of Life*, Harmondsworth: The Penguin Press, 1993.

## **9 Table of Cases**

### ***The European Patent Organisation***

SIGMA/Classifying areas, T 162/82

Ciba-Geigy/Propagating Material Application, T 49/83 (1979-85) C EPOR 758

Lubrizol/Hybrid plant, T 320/87 (1990) EPOR 173

Harvard/Onco-mouse, T 19/90 (1990) EPOR 501

Howard Florey/Relaxin, T 74/91 (1995) EPOR 541

Plant Genetic Systems/Glutamine synthetase inhibitors, T 356/93 (1995) EPOR 357

Inadmissible referral, G 3/95 (1995) EPOR 505

International Business Machines Corporation/Asynchronous resynchronization of a  
commit procedure, T 1173/97

Novartis/Transgenic plant, T 1054/96 (1999) EPOR 123

Novartis/Transgenic plant, G 1/98 (2000) EPOR 303

AstraZeneca/Priority from India, J 9/98 and J 10/98

### ***The European Community***

C-10/61, Commission v. Italy, (1962) ECR 1

C-181/73, Haegeman, (1974) ECR 449

C-270/80, Polydor Ltd & RSO Records Inc v. Harlequin Record Shops Ltd & Simons  
Records Ltd, (1982) ECR 329

C-355/96, Silhouette International Schmied GmbH & Co KG v. Hartlauer  
Handelsgesellschaft mbH, (1998) ECR I-4799

C-377/98R, The Netherlands v. Council of the European Union and European  
Parliament

Racke, (1998) ECR I-3655

Joined Cases T-33 & 34/98, *Petrotub SA and Republica SA v. Council*, (1999) ECR II-3837

C 383/99, *Procter & Gamble v. Office for Harmonisation in the Internal Market (Trade Marks & Designs)*, (2001) ECR I-6251

### ***The World Trade Organisation***

United States –Standards for Reformulated and Conventional Gasoline, WTO Doc. AB-1996-1, WT/DS2/AB/R, at 17 (May 20, 1996), 35 ILM 603 (1996)

EC –Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States, WTO Doc. WT/DS26/R/USA, (August 18, 1997)

EC –Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada, WTO Doc. WT/DS48/R/CAN, (August 18, 1997)

EC –Measures Concerning Meat and Meat Products (Hormones), WTO Doc. AB-1997-4, WT/DS26/AB/R, WT/DS48/AB/R, (January 16, 1998)

## **10 Table of Legal Documents**

### ***The European Patent Organisation***

Convention on the Grant of European Patents –EPC (The European Patent Convention), 5 October 1973

The Convention on the Unification of Certain Points of Substantive Law on Patents for Invention –The Strasbourg Patent Convention, SPC, 27 November 1963

Implementing Regulations to the Convention on the Grant of European Patents –The  
EPC Implementing Regulations, 6 June 1999

The Rules of Procedure of the Boards of Appeal –RPBA

The Official Journal of EPO, OJ EPO 8-9/1999, pp.545-587

### ***The European Community***

The Rome Treaty –Consolidated Version of the Treaty Establishing the European  
Community, 25 March 1957

Directive of the European Parliament and of the Council of 6 July 1998 on the legal  
protection of biotechnological inventions – 98/44/EC (The EC Patent Directive)

Regulation of the Council of 27 July 1994 on Community plant variety rights –EC  
Regulation NO 2100/94

Community Patent Convention– CPC, 1975

### ***The International Union for the Protection of New Varieties of Plants***

International Convention for the Protection of New Varieties of Plants, Act of 1961 –  
UPOV 61

International Convention for the Protection of New Varieties of Plants, Act of 1978 –  
UPOV 78

International Convention for the Protection of New Varieties of Plants, Act of 1991 –  
UPOV 91

The Records of the Diplomatic Conference for the Revision of the International  
Convention for the Protection of New Varieties of Plants, Geneva, 1991

***The World Trade Organisation***

The Marrakesh Agreement Establishing the WTO –The WTO Agreement

Annex 1c to the Marrakesh Agreement Establishing the WTO, The Agreement on Trade-Related Aspects of Intellectual Property Rights –TRIPs

Communication from Switzerland to the TRIPs Council, 15 June 2001, Document IP/C/W/284

Communication from Brazil to the TRIPs Council, 24 November 2000, Document IP/C/W/228

***Other Convention and documents***

The Statutes of the International Court of Justice, 26 June 1945

The Vienna Convention on the Law of Treaties– The Vienna Convention, 23 May 1969

Convention on Biological Diversity– CBD, 5 June 1992

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, COP Decision VI/24

The International Treaty on Plant Genetic Resources for Food and Agriculture –IT-PGRFA, 3 November 2001



A

B

C