

Prof. Dr Sigrid Sterckx

Gent University

Dept of Philosophy & Moral Science

Blandijnberg 2

B-9000 Gent

Belgium

13 September 2008

**BY FACSIMILE**


(+49 89 2399 3014)

Dear Sirs

**Enlarged Board of Appeal Cases G2/07 and G1/08**

I am transmitting herewith an amicus brief in relation to the above case currently pending before the Enlarged Board.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Sigrid Sterckx', written over a horizontal line.

Sigrid Sterckx

# The non-patentability of 'essentially biological processes'

Prof. Dr Sigrid Sterckx<sup>1</sup>

## 1. Introduction

A patent allows the patent owner to stop others from using the patented product or process or the direct product of a patented process. Patents are useful to help an inventor to secure the investment necessary to take an idea through to a product on the market and as a result should not be dismissed out of hand as an unnecessary and undesirable barrier to free trade. However, patents grant monopolies and should be viewed as a necessary evil, to be constrained to operate only to the extent that is required to obtain the social benefits that patents are intended to achieve.

As this paper will try to explain, the principle of the non-patentability of essentially biological processes, which is laid down in the European Patent Convention (EPC, 1973),<sup>2</sup> is currently under threat and this may have far-reaching consequences for agriculture and hence for food security. Hence the questions as to what is an "essentially biological process", why essentially biological processes ought to be excluded from patentability, and how this exclusion must be interpreted, are very pertinent, not only for lawyers but also for ethicists, farmers and the public at large.

The EPC, which governs the issue of patents for most European countries, states in Article 53(b) that:

European patents shall not be granted in respect of [...] plant [...] varieties or essentially biological processes for the production of plants [...]<sup>3</sup>

Here we must stress that "microbiological" processes, as opposed to "essentially biological" ones, are *not* excluded from patentability by Article 53(b) EPC, and are not the subject of this paper.

This Article is qualified by an implementing regulation, Rule 26(5) EPC, which states that:

---

<sup>1</sup> Professor of Ethics at the Vrije Universiteit Brussel and Universiteit Gent, Belgium and Senior Research Fellow, Fund for Scientific Research Flanders, Belgium. This paper has been submitted as an *amicus curiae* brief to the Enlarged Board of Appeal of the European Patent Office in relation to cases G2/07 and G1/08, on the author's own behalf and not at the request of or on behalf of any other party.

<sup>2</sup> European Patent Office (2007), *Convention on the Grant of European Patents* (European Patent Convention), European Patent Office, Munich [hereinafter EPO 2007a].

<sup>3</sup> EPO 2007a: 81-82.

A process for the production of plants [...] is essentially biological if it consists entirely of natural phenomena such as crossing or selection.<sup>4</sup>

Here it must be noted that Rule 26(5) EPC *exemplifies* what is excluded and does not give an exhaustive list of what is excluded, it states that “X is excluded if it consists entirely of Y” rather than that “X is excluded *only* if it consist entirely of Y”.

According to Article 164(2) EPC, if a Rule changes the effect of an Article then the Article must overrule the Rule. This is important since the abovementioned Rule, as well as a few other Rules, were implemented in 1999 —following the adoption of Directive 98/44/EC<sup>5</sup> on the legal protection of biotechnological inventions by the European Union, the member states of which overlap considerably with the states which are party to the EPC— while the Article dates back to 1973 or even earlier. However, given its *exemplificative* rather than *exhaustive* nature, it is difficult to see that Rule 26(5) EPC is in conflict with Article 53(b) EPC.

Article 53(b) EPC derives from Article 2(b) of the *Convention on the Unification of Certain Points of Substantive Law on Patents for Invention* (the Strasbourg Convention)<sup>6</sup> which sought to avoid double intellectual property protection for new plant varieties in view of the earlier *sui generis* protection afforded to plant breeders by the *International Convention for the Protection of New Varieties of Plants* (UPOV)<sup>7</sup>. Article 2(b) of the Strasbourg Convention reads as follows:

The Contracting States shall not be bound to provide for the grant of patents in respect of [...] plant [...] varieties or essentially biological processes for the production of plants [...]

## **2. Referral of the *Plant Bioscience* and *State of Israel* cases to the EPO Enlarged Board of Appeal**

The question as to what is an “essentially biological process” has recently arisen in two appeals before the European Patent Office (EPO) — T83/05 *Broccoli/Plant Bioscience*<sup>8</sup> and T1242/06 *Tomatoes/State of Israel*<sup>9</sup>. These cases relate to

---

<sup>4</sup> EPO 2007a: 256.

<sup>5</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *Official Journal of the European Communities*, 30 July 1998, L213, pp. 13-21. Rule 26(5) EPC reflects Article 2(2) of this EU Directive.

<sup>6</sup> Council of Europe (1963), *Convention on the Unification of Certain Points of Substantive Law on Patents for Invention*, European Treaty Series No. 47, available at <<http://conventions.coe.int/Treaty/en/Treaties/Word/047.doc>>

<sup>7</sup> UPOV (1991), *International Convention for the Protection of New Varieties of Plants of December 2, 1961*, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, available at <http://www.upov.int/en/publications/conventions/1991/act1991.htm>

<sup>8</sup> EPO (2007b), Interlocutory Decision T83/05 *Plant Bioscience*, 22 May 2007, European Patent Office, Munich [hereinafter EPO 2007b].

'inventions'<sup>10</sup> made by Richard Mithen, Kathy Faulkner and Gary Williamson<sup>11</sup> and by Arthur Schaffer<sup>12</sup> respectively.

### 2.1. *Broccoli/Plant Bioscience*<sup>13</sup>

In April 1998, Richard Mithen and Kathy Faulkner filed a provisional US patent application (USSN60/081169) for a method of producing broccoli having elevated levels of certain glucosinolates (compounds found to have beneficial properties) as well as for certain types of broccoli plants and heads. An international patent application designating the EPO<sup>14</sup> and claiming priority from the US application was by filed *Plant Bioscience Ltd*, a British company, in April 1999 and was later published as WO99/52345.

The EPO issued an International Preliminary Examination Report on this international application raising only essentially formal objections at least to the first twelve claims. The European phase of the international application was entered in October 2000 and the EPO issued a first examination report in March 2001 repeating the objections raised in the international preliminary examination report. *The question of Article 53(b) EPC was not raised.*

*Plant Bioscience* responded and thereafter the application was accepted and a patent was granted as EP-B-1069819 in July 2002. Shortly before the end of the 9-month opposition period, oppositions to the patent were filed by *Syngenta Participations AG*, a Swiss company, and by *Groupe Limagrain Holding*, a French company. *Syngenta* and *Limagrain* are both major players in agribusiness. The opponents alleged insufficiency, lack of entitlement to priority, lack of novelty, lack of inventive step, added matter, and that claims 1 to 3 were directed to "essentially biological processes" and should therefore be revoked under Article 53(b) EPC.

---

<sup>9</sup> EPO (2008a), Interlocutory Decision T1242/06 State of Israel, 4 April 2008, European Patent Office, Munich [hereinafter EPO 2008a].

<sup>10</sup> Various questions can be raised regarding the extent to which these patent applications meet the patentability requirement of inventive step, but we cannot go into this here.

<sup>11</sup> Mithen R., Faulkner K. & Williamson G. (1999), *Method for selective increase of the anticarcinogenic glucosinolates in Brassica sp.*, International Patent Application Publication Number WO99/52345, World Intellectual Property Organization, Geneva.

<sup>12</sup> Schaffer A. (2001), *Method for breeding tomatoes having reduced water content and product of the method*, International Patent Application Publication Number WO01/13708, World Intellectual Property Organization, Geneva.

<sup>13</sup> The documents on the *Plant Bioscience* and *State of Israel* cases can be accessed at <http://www.epoline.org/portal/public/registerplus/> by entering the publication numbers EP1069819 and EP1211926 respectively.

<sup>14</sup> An international patent application designates one or more countries or regions, meaning that it can later be transformed into national or regional patent applications in those designated countries and regions.

A hearing was held on 17 June 2004 at which the Opposition Division *rejected the Article 53(b) EPC objection* and maintained the patent. A written decision to this effect issued in November 2004 in which the Opposition Division commented on the Article 53(b) EPC objection.

This decision was appealed by *Syngenta* and *Limagrain* in January 2005 and the appeal procedure was given the case number T83/05. The *Article 53(b) EPC objection was maintained* and on 4 April 2006 a request was made for the Technical Board of Appeal to refer questions relating to Article 53(b) EPC to the Enlarged Board of Appeal, a body essentially equivalent to the US Supreme Court or the UK House of Lords as the final arbiter of what a provision in the EPC should mean.

An appeal hearing took place in May 2006 and an interlocutory decision was issued, referring two questions to the Enlarged Board of Appeal (cf. *infra*). The case before the Enlarged Board of Appeal was given the number G2/07 and the Enlarged Board of Appeal asked interested parties, the President of the EPO, *Plant Bioscience, Syngenta* and *Limagrain* to submit comments. At the time of writing, many *amicus curiae* briefs have been filed, as well as comments from the President of the EPO and the parties to T83/05.

## 2.2. Tomatoes/ State of Israel

In August 1999, the *State of Israel - Ministry of Agriculture* filed an Israeli patent application relating to a method of breeding tomato plants that produce tomatoes having reduced fruit water content, as well as to certain tomato plants and tomato fruits. In July 2000 an international patent application was filed claiming priority from the Israeli application. This international patent application was published as WO01/13708.

An International Preliminary Examination Report was issued by the EPO, raising no substantive objections to the claims. The European phase was entered in March 2002 and the application was *accepted without any substantive objections being raised*. The patent issued as EP-B-1211926 in November 2003.

Shortly before the end of the opposition period, the patent was opposed by *Unilever NV*, a major Dutch company. *Unilever* raised objections of insufficiency, lack of novelty, lack of inventive step, and an Article 53(b) EPC objection. At a hearing on 13 June 2006, *the Opposition Division rejected the State of Israel's main request as failing the requirements of Article 53(b) EPC, but decided to maintain the patent with an amended claim set*. The Opposition Division's written decision was issued in May 2006.

This decision was appealed by both the *State of Israel* and *Unilever*. Interestingly, in its appeal, *Unilever* did *not* mention Article 53(b) EPC. The appeal was given the case number T1242/06 and in November 2006 the Technical Board of Appeal drew the

parties' attention to the *Plant Bioscience* case. In its summons to the parties to attend a hearing in September 2007, the Board indicated that only the referral of questions relating to Article 53(b) EPC to the Enlarged Board of Appeal would be considered.

The hearing took place and in its decision of 8 April 2008 the Technical Board of Appeal referred two questions to the Enlarged Board of Appeal (cf. *infra*). The case was assigned the number G1/08 and the Enlarged Board of Appeal invited the parties and the President of the EPO to submit comments. Comments have been submitted by the *State of Israel*, and the President of the EPO referred to the comments she had already submitted in the *Plant Bioscience* case.

The Enlarged Board of Appeal has decided to consolidate the two cases, i.e. to consider the two at the same time and to issue a single decision covering both. It can be expected that the Enlarged Board of Appeal will set a date for a hearing in the coming months.

### 2.3. The main process claims

In the *Plant Bioscience* case, the first of these claims, as considered at the hearing of the Technical Board of Appeal of the EPO, read as follows:

*A method for the production of Brassica oleracea with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises: a) crossing wild Brassica oleracea species selected from the group consisting of Brassica villosa and Brassica drepanensis with broccoli double haploid breeding lines; b) selecting hybrids with levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines; c) backcrossing and selecting plants with the genetic combination encoding the expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both; and d) selecting a broccoli line with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates [sic], or both, capable of causing a strong induction of phase II enzymes, wherein molecular markers are used in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes.*<sup>15</sup>

Roughly translated, this means routine plant breeding to introduce a desired feature, and selecting offspring having the desired feature by the use of a standard procedure, which may or may not be technical, as simple inspection for phenotype (appearance) may be enough, as admitted by *Plant Bioscience*.

---

<sup>15</sup> EPO 2007b: 1-2 (emphasis added).

In the *State of Israel* case, the first claim considered at the Technical Board of Appeal hearing read as follows:

*A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of: crossing at least one Lycopersicon esculentum plant with a Lycopersicon spp. to produce hybrid seed; collecting the first generation of hybrid seeds; growing plants from the first generation of hybrid seeds; pollinating the plants of the most recent hybrid generation; collecting the seeds produced by the most recent hybrid generation; growing plants from the seed of the most recent hybrid generation; allowing fruit to remain on the vine past the point of normal ripening; and screening for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.*<sup>16</sup>

Again, translated roughly, this means routine plant breeding to introduce a desired feature, but this time selecting offspring having the desired feature by late harvesting followed by physical inspection.

Article 84 EPC requires patent claims to have clear meanings, yet both of these quoted claims contain appallingly unclear terms, such as “elevated levels”, “strong induction”, “reduced water content”, and “past the point of normal ripening” and both appear to go no further than routine plant breeding to produce new varieties with desired characteristics.

#### 2.4. The questions referred to the EPO's highest arbiter

As mentioned earlier, the EPO appeal judges have referred the matter to the Enlarged Board of Appeal of the EPO. The two referrals, G2/07 and G1/08, have been consolidated and pose the following questions:

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants *escape the exclusion* of Article 53(b) EPC *merely because it contains*, as a further step or as part of any of the steps of crossing and selection, an *additional feature of a technical nature*?<sup>17</sup>

2. If question 1 is answered in the negative, what are the *relevant criteria* for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?<sup>18</sup>

[3]. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b)

---

<sup>16</sup> EPO 2008a: 1-2 (emphasis added).

<sup>17</sup> EPO 2007b: paragraph 48 (emphasis added).

<sup>18</sup> Ibid.

EPC *only* if these steps reflect and correspond to *phenomena which could occur in nature without human intervention?*<sup>19</sup>

[4]. *If question [3]... is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?*<sup>20</sup>

### **3. Analysis of the questions referred to the Enlarged Board of Appeal**

#### **3.1. The monopolies sought**

In both the *Plant Bioscience* and the *State of Israel* cases, the core of the 'invention' is a crossing and selection process, the type of process, knowingly or unknowingly, carried out by humans for millennia. In the case of *Plant Bioscience*, the process involves selecting broccoli produced by crossing on the basis of genetic markers in the progeny, while in the case of the *State of Israel* the process involves selecting tomatoes produced by crossing on the basis of measured physical properties of the progeny fruit.

That said, however, in both cases *the monopolies sought extend beyond the process of crossing and selection and the selected direct progeny to encompass the progeny of the progeny and so on*, e.g. whole plants and parts of plants (such as seed, fruit, etc.) produced by the normal biological process of growing a seed to produce a plant without any further 'technical' intervention.

In this regard it should be noted that Article 64(2) EPC provides that:

If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by the process.<sup>21</sup>

For present purposes, the *direct* products of the methods as claimed are the selected broccoli plants and the screened tomatoes, and not the offspring in perpetuity of the seeds from such plants/fruits. We will come back to this.

Moreover, both patents include not only process claims but also *product* claims. We will comment on some of the problems posed by these claims below.

#### **3.2. The legislative history and justification of the exclusionary provision**

How should Article 53(b) EPC be applied in relation to attempts to seek patent coverage for essentially biological processes or for products which are the *direct*

---

<sup>19</sup> EPO 2008a: paragraph 20 (renumbered and emphasis added).

<sup>20</sup> *Ibid.* (renumbered and emphasis added).

<sup>21</sup> EPO 2007a: 90.

products of an essentially biological process? As an international treaty, the provisions of the EPC must be interpreted in the light of their history, i.e. the *travaux préparatoires*, the discussions which led to their adoption. In the case of Article 53(b) EPC, this includes the *travaux préparatoires* for the Strasbourg Convention and there we find the following relevant comment in the *Comments on the First Preliminary Draft Convention relating to a European patent law of 14 March 1961*:

Even if protection of new plant varieties and processes for producing new plants is excluded under European patent law, European patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g. processes for producing new plants by irradiation of the plants themselves or the seeds with isotopes.<sup>22</sup>

Back when the Strasbourg Convention was negotiated, and indeed when the EPC was negotiated in 1973, the only way to produce a new plant was the essentially biological process of natural plant growth - it would be grown from seed or a cutting. Human intervention to facilitate growth was possible, e.g. by watering, fertilizing, weeding or treatment with insecticide, and human intervention to derive a new plant variety by crossing or irradiation, and selecting was likewise possible. However, the resultant plant still grew and its progeny seeds were formed by virtue of the natural phenomenon of plant growth.

As mentioned above, where development of something new requires investment of time or money, there may be some justification for the grant of an intellectual property (IP) right to secure that investment. As with other investment-intensive technologies, our society has made IP rights available to plant breeders. A plant breeder may secure IP rights through registration of a new plant variety by way of UPOV<sup>23</sup> —and obtain a so-called *plant breeder's right*— or, in view of the above quote from the *travaux préparatoires*, through *patent* protection of a process of a *technical* nature.

UPOV, which was first brought into law in 1961 and was present in the foreground of the negotiations leading to the adoption of Article 2(b) of the Strasbourg Convention and of Article 53(b) EPC, provided a specialised, *sui generis*, form of plant variety protection taking into account the need to ensure that IP rights were granted for what was new and stable. *The legislators of the Strasbourg Convention and the EPC thus knowingly consigned plant protection to UPOV rather than to patents.* In doing so, they must also be considered to have acted *in the understanding that UPOV's sui*

---

<sup>22</sup> Council of Europe (1961), *Comments on the First Preliminary Draft Convention relating to a European patent law of 14 March 1961*, Document IV/2071/61-E, referred to in T83/05 (EPO 2007b: paragraph 39).

<sup>23</sup> UPOV (1991), *International Convention for the Protection of New Varieties of Plants of December 2, 1961*, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, available at <http://www.upov.int/en/publications/conventions/1991/act1991.htm>

*generis system provided checks and balances to protect the public interest, which hence did not need to be introduced in relation to patents in the EPC.*

These checks and balances are closely connected with the vital social goals of protecting and promoting food security, which necessitate allowing certain long-established agricultural practices to continue unhampered.

UPOV acknowledges that the generation of still further new plant varieties is desirable, and that the farmer should be allowed to continue the traditional farming practices of reserving part of her harvested seed for planting to produce a new crop. Where a new variety of a basic food plant is introduced which has a significantly higher yield, the farmer has little alternative but to buy seed of the new variety as otherwise her return on her crop will inevitably drop below the level required for her farm to remain profitable. As a one-off investment, purchasing the new seed is an acceptable operating cost. However, *should the new seed have to be bought every season, then the normal patterns and economics of farming change for the worse, as the example of India has shown:*

In 1998, the World Bank's structural adjustment policies forced India to open up its seed sector to global corporations like Cargill, Monsanto, and Syngenta. The global corporations changed the input economy overnight. Farm saved seeds were replaced by corporate seeds which needed fertilizers and pesticides and could not be saved.

As seed saving is prevented by patents as well as by the engineering of seeds with non-renewable traits, seed has to be bought for every planting season by poor peasants. A free resource available on farms became a commodity which farmers were forced to buy every year. This increases poverty and leads to indebtedness.

As debts increase and become unpayable, farmers are compelled to sell kidneys or even commit suicide. More than 25,000 peasants in India have taken their lives since 1997 when the practice of seed saving was transformed under globalisation pressures [...]<sup>24</sup>

Thus, from 1961 UPOV has enshrined a "breeder's right" to use the seed of a new plant variety to generate yet further new varieties, and from 1978 a "farmer's privilege" to retain part of a crop for replanting. The fact that the farmer's privilege was not present in UPOV from its beginning perhaps reflects the fact that it was seen as implicit in 1961. The fact that the farmer's privilege was made explicit in 1978 possibly reflects the facts that the seed industry was beginning to fall into the hands of a small number of major players and that a biotechnological revolution in plant breeding was just beginning to become visible on the horizon.

---

<sup>24</sup> Shiva V. (2004), *The suicide economy of corporate globalisation*, Countercurrents, available at <<http://www.countercurrents.org/glo-shiva050404.htm>>

In consigning IP protection for plants to UPOV, the EPC legislators were perhaps confident that they had done all that was necessary to guard society's interests by passing Article 53(b) EPC: old plant varieties would be excluded by the patentability requirement of novelty; new plant varieties would be excluded by Article 53(b) EPC; and in view of the natural process of growing plants being essentially biological, that process and its direct products would have been excluded by Article 53(b) EPC as well.

If there is no patent protection for the seeds of new plant varieties, then seed vendors can seek to ensure fresh seed purchases by farmers by contract or by the use of suicide genes (i.e. where the seeds as sold grow to plants but the seeds of such plants do not themselves grow). The latter has generated such revulsion amongst the public that it has been shelved.<sup>25</sup> As to the strategy of using contracts, this is routinely practised.<sup>26</sup> Industrial vendors of seed for commercial crops such as corn or rape frequently sell their seed under contracts which allow the farmer to use the seed to grow a crop but not thereafter to grow further seed from the progeny seed.

### 3.3. *Plant Bioscience and State of Israel violate Article 53(b) EPC and the intention of the legislators*

With the *Plant Bioscience* and *State of Israel* cases before the Enlarged Board of Appeal, we now see the seed vendors seeking to circumvent the exclusion of Article 53(b) EPC and to obtain patent coverage for new plant varieties — i.e. patents with claims that would be infringed by the actions of a farmer of growing plants, selling the resultant seeds, fruits or flowers, or retaining seeds for resowing. As mentioned earlier, the IP coverage granted by patents does *not* provide the checks and balances that are provided by the breeder's right and the farmer's privilege in UPOV.

In the context of an analysis of the potential implications should the Enlarged Board of Appeal's decision serve to maintain the *Plant Bioscience* and *State of Israel* patents, it is important to look at the extent to which both the process and the product claims could act as a barrier to the 'normal' activities of the farmer or plant breeder that the legislator was seeking to protect by enacting Article 53(b) EPC.

Consider first the *process claims*. A claim to a process is infringed *inter alia* by dealings with the *direct* product of the process. Of key importance here is Article 64(2) EPC which states that:

---

<sup>25</sup> BBC (1999), *Terminator gene halt a 'major U-turn'*, available at:  
<<http://news.bbc.co.uk/1/hi/sci/tech/465222.stm>>

<sup>26</sup> See e.g. *Monsanto Canada Inc. v. Schmeiser*, Supreme Court of Canada, Judgement of 21 May 2004, 2004 SCC 34.

If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by the process.<sup>27</sup>

As a result, *the exclusion of Article 53(b) EPC must be read to mean that no patent claim can be granted that covers a plant, fruit or seed that is the direct product of an essentially biological process.* If read otherwise, the exclusion from patentability of essentially biological processes becomes meaningless. We will come back to this.

Thus, where a process for plant production is invented which involves a technical step which may be followed by natural growth processes, the process can only validly be claimed in such a way that the *direct* product of the claimed process is the *direct* product of the *technical* step and *not* the product of any subsequent "essentially biological process".

Turning now to the question as to what extent the *product* claims can act against the legislator's intention as a barrier, the resultant plant product likewise should only be validly claimed as the *direct* product of the technical step rather than as a "plant or seed having characteristic X", as the latter claim would also cover progeny produced by the essentially biological process of normal plant growth.

In decision T83/05 –the EPO Board of Appeal decision in the *Plant Bioscience* case– three options for interpretation of Article 53(b) EPC were suggested:

The first of these approaches was analogous to that used under Article [53(c)] EPC relating to methods of treatment by surgery or therapy and led to the result that the inclusion in a claimed process of a step of essentially biological nature would not be allowable. The second approach was the one adopted in decision T 320/87 [...] The third approach was to require, in order to escape the prohibition of Article 53(b) EPC, at least one clearly identified "non-biological" process step but allow any number of additional "essentially biological steps" which would be carried into allowability by the "non-biological" process step.<sup>28</sup>

The same Board described the second approach mentioned above as follows:

that the applicability of the exclusion had to be judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved [...] the necessity of human intervention in itself was not regarded as a sufficient criterion for the process not being "essentially biological". Human interference might only mean that the process was not a "purely biological" process, without contributing anything beyond a trivial level.<sup>29</sup>

---

<sup>27</sup> EPO 2007a: 90.

<sup>28</sup> EPO 2007b: paragraph 46 (Article renumbered).

<sup>29</sup> EPO 2007b: paragraph 43. In this context see also the statement by the EPO Board of Appeal in the PGS/Greenpeace case, that the following subject-matter should *not* be considered as an 'essentially biological process': "a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the

Each of these approaches involves problems. The *first* one would be unnecessarily draconian. It might seem odd to argue that this approach is *not* too draconian when medical treatment processes are at issue whereas it *is* overly draconian in the case of biological processes. However, there is a relevant difference between these two contexts. In order to explain this, we need to briefly consider how processes may be claimed in a patent application and how process claims may be infringed.

A process claim may be *infringed* for example by: someone who performs the process; someone who collaborates with others to perform the process; someone who produces or deals with the direct product of the process; and someone who knowingly supplies a non-standard starting material.

A process may be *claimed* either as a single step or as a series of steps, each of which is itself a process.

If a process is claimed as a *single step* and such a step is excluded by the EPC, then there is no doubt – it cannot be patented.

Next, consider a *two-step* process, the *second step* of which is a *medical treatment*. The intention of the legislator with Article 53(c) EPC was to allow physicians and veterinarians to do the best for their patients. Here, if such claims are permitted, the physicians and veterinarians would infringe as they produce the *direct* 'product' of the process (the treated patient). Therefore, a claim to a two-step process, the second step of which is a medical treatment, must be *excluded*. We hold that *the same is true for an essentially biological process*, so that the farmer is free to do what she normally does.

Now consider the case where the *medical treatment* step is the *first step of a two-step process*. The physician or veterinarian might infringe if she collaborates with the performer of the second step (e.g. where that is to give a treated patient a glass of water and send him to bed or to monitor an animal's blood pressure for 24 hours after invasive surgery). As a result, if this medical-treatment-followed-by-non-medical-treatment process were patentable, the physician or veterinarian would have to assess the risk of patent infringement before performing her primary duty of providing care. Such a situation would be undesirable and hence it is most effective also to *exclude* from patentability this type of process.

*This does not hold, however, for the plant breeder or farmer*, where there is not the life or death urgency of a decision to treat or not and so it is not desirable that they be allowed to collaborate in patent infringement. Thus, for medical treatment processes, no claim can be allowed which includes a medical treatment step, while for biological

---

final result". EPO (1995), Decision T356/93 Plant Genetic Systems, *Official Journal of the European Patent Office* 1995, 357, § 28 of the decision.

processes claims need *only* be rejected if the *final step*, or the *only step*, of the process is an essentially biological process.

The *third* approach to interpreting Article 53(b) EPC mentioned by the Board of Appeal in the *Plant Bioscience* case is as unacceptable as the first approach, as it would allow clever claim drafting to emasculate the Article 53(b) exclusion. In fruit and vegetable production, it is commonplace to pick, trim, clean and package the crop. These are not essentially biological steps. Thus, if a process is claimed by reciting steps such as these, as occurring subsequent to an essentially biological process, then, if accepted, the farmer carrying out that *unpatentable* essentially biological process would inevitably infringe since she must also perform those commonplace steps.

*To allow the simple inclusion of a non-biological process step to render a process claim acceptable under Article 53(b) EPC is to completely emasculate Article 53(b) EPC.* No doubt, this would be considered a desirable state of affairs by some. In the EPO case file regarding the *State of Israel* case, it can be noted that the *State of Israel* has argued in its submissions to the Enlarged Board of Appeal that since "plant breeding methods are basically technical teachings, one may wonder what subject-matter is still supposed to fall under the exclusion clause" of Article 53(b) EPC!<sup>30</sup> However, as will be discussed below, it is not open to the administrators of the EPO or even to EPO Appeal Board members to set aside an exclusion purposely put in place by the legislators and not amended in 35 years or more.

The *second* approach to interpreting Article 53(b) EPC mentioned by the Technical Board of Appeal in the *Plant Bioscience* case might seem reasonable at first sight, but it must also be rejected. First, although the purpose of the 'decisive human intervention' criterion clearly is to distinguish between technical and non-technical processes for the production of plants and animals, this criterion remains far too vague and subjective. A second, and more important, reason for rejecting the second approach is that it would not achieve the goal of the legislator to allow farmers and breeders to carry out their traditional work as long as they themselves do not perform the novel technical step.

The exclusion of Article 53(b) EPC is an exclusion of *type*. It should be clear to the patent office Examiner whether or not claimed subject matter falls within the excluded type without having to delve into the importance or impact of the new technical feature. Where the Examiner's assessment involves subjective judgement, the opportunity is opened to the patent applicant to seek to overwhelm the Examiner with evidence as to the success or importance of an invention. Such subjective judgement has its proper place in determining whether the subject matter is inventive

---

<sup>30</sup> Submission to the Enlarged Board of Appeal dated 22 August 2008, paragraph 2.6.3.

rather than whether or not it is excluded, an objective determination which must be made beforehand.

3.4. Interpreting Article 53(b) EPC consistently with Rule 26(5) EPC, Article 64(2) EPC and EPO case law relating to methods of medical treatment

However, Article 53(b) EPC can and should be interpreted in a way which does *not* pose any of the abovementioned problems. If we focus on the legislator's intent to refuse patents that prevent farmers or plant breeders from carrying out essentially biological processes, i.e. patents containing product or process claims which could be infringed by the performance of only an essentially biological process, we can see that Rule 26(5) EPC, Article 53(b) EPC and Article 64(2) EPC are both consistent and coherent *only* if the *direct* product of the claimed process cannot itself be the product of natural phenomena, such as routine plant growth, and if the *direct* product of a process which is essentially biological cannot be covered by a claim.

It should be emphasised that this interpretation does *not* conflict with Rule 26(5) EPC —which states that a process "is essentially biological if it consists entirely of natural phenomena such as crossing or selection"— for, as mentioned above, this Rule in fact serves to *exemplify* what is excluded rather than to give an exhaustive definition of all that is excluded. This has been pointed out among others by *Limagrain* in their submissions to the Technical Board of Appeal in the *Plant Bioscience* case.

Thus, within this interpretation, *Rule 26(5) EPC is entirely consistent with Article 53(b) EPC* and should not be viewed as having been introduced *ultra vires*.

Moreover, this interpretation of Article 53(b) EPC is consistent with the view expressed by the President of the EPO in the recent Oral Proceedings in June 2008 in relation to case *G2/06 Human embryonic stem cells/WARF*,<sup>31</sup> where the President argued that the precise wording chosen for the claims of a patent application was not determinative as to what the "invention" to be considered should be, i.e. that the linguistic skills of clever patent attorneys should not be sufficient to circumvent the legislator's intention in adopting exclusions from patentability.

*The abovementioned interpretation is also consistent with the EPO's case law relating to medical treatments.* Under Article 53(c) EPC, European patents shall not be granted in respect of:

methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body [...]<sup>32</sup>

---

<sup>31</sup> Documents relating to case G2/06 may be found at the EPO website at <http://www.epoline.org/portal/public/registerplus/> by entering the publication number EP1069819.

<sup>32</sup> EPO 2007a: 81-82.

Where an application claims an invention which involves a therapeutic, surgical or diagnostic step, the EPO will refuse it.<sup>33</sup> However, where the invention may be performed (and the patent could be infringed) without that step, i.e. where the claims cover only steps up to, or only steps after, the excluded step, then patent cover is permitted.

While Article 53(b) EPC denies patentability to essentially biological processes, Article 53(c) EPC likewise denies patentability to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. The *direct* product of such methods of surgery or therapy is the treated human or animal. The decision by the legislator to exclude from patentability certain processes would be completely circumvented were the Enlarged Board of Appeal to allow patents for the *direct* product of the excluded process since the person performing the excluded process would inevitably be producing the patented product and thus would be infringing the patent, as mentioned earlier.

If we take the case of an invention which resides in exposing a mammalian animal to surgery to fuse three vertebrae together and thereby minimise the pain of a slipped disc, the direct product (which we can assume for argument's sake to be novel and inventive) of veterinary surgery on a sheep would be, say, "A non-human mammalian animal having three adjacent fused vertebrae". If such a claim were to be permitted, then we are left with the ridiculous position that no veterinarian could perform the procedure on a sheep, as she would infringe this product claim by producing the claimed product, and that a farmer would likewise infringe by keeping or selling the patented product (the treated sheep). Here it should be noted that current EPO Technical Board of Appeal case law does permit claims of this format,<sup>34</sup> despite the provisions of Article 53(b) EPC relating to the exclusion from patentability of animal "varieties".

### 3.5. Some of the product claims are reach-through claims

We must also point out that some of the product claims of the *Plant Bioscience* and *State of Israel* patents are essentially so-called reach-through claims and ought to be rejected. To illustrate, let us enter the not-so-fantasy "patentworld" in which a patentee is entitled to a court injunction forbidding use of a patented product (or of course of the direct product of a patented process). Let us consider two cases, one where the invention is a flat-ended spike for securing bits of wood together and the

---

<sup>33</sup> See Opinion G1/04 by the EPO Enlarged Board of Appeal: EPO (2006), Opinion G1/04, European Patent Office, Munich.

<sup>34</sup> See EPO (1990), *Decision T 19/90 Harvard*, Official Journal of the European Patent Office, 1990, 476, and EPO (2004), *Decision T315/03 Harvard*, Official Journal of the European Patent Office, 2005, 246.

other where the "invention" is a rape seed selected to produce none of the mustard-tasting compounds present in natural rape seed. Let us take a first claim to "Munich airport containing a building itself containing two planks nailed together with a flat-ended spike". Where a plank in Munich airport is nailed to another plank by a nail having a disc-like head and a ribbed shank, would the Munich courts injunct all patent attorneys flying into Munich to attend EPO hearings? We think not. Now consider a claim to "Rape seed not containing mustard-flavoured compounds". Should a farmer, planting the seventh generation of rape seeds which, while mustard-taste free, have also successively been bred free of C>20 fatty acids and bred free of saturated fatty acids, be injuncted? Again, we think not. The answer lies in the *determinative* nature of the characterising feature of the "invention". Where the alleged infringement is far removed in time or development, many, many other features are determinative as to its existence, rather than *solely* the characterising feature of the patent claim.

Indeed, patent offices in general have shown great reluctance to grant what are known as "reach through" claims -- claims which reach through to cover products which are several stages downstream of the stage in which the technical invention lies. Such claims are desired for example by inventors of drug discovery processes - for example if an inventor finds that by screening a library of drug compounds for a certain set of activities, a shortlist of candidate drugs can be identified, she may wish to obtain a patent covering any drug compound identified by her procedure and any pharmaceutical composition containing any such drug. The *direct* product of the screening procedure itself however is *information* rather than a pharmaceutical product. In the present cases, it can be argued that *certain product claims of Plant Bioscience and of the State of Israel are likewise reach-through claims* since they cover not just the plants, fruits or seeds which are what remains after the act of selection using the allegedly technical features, but also their progeny *ad infinitum*.

In the *Plant Bioscience* case, the claim set considered by the Technical Board of Appeal included the following product claims:

A broccoli plant having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, wherein the broccoli plant is a hybrid plant following crossing of broccoli double haploid breeding lines with wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* and the levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, are between 10 and 100µmoles per gram of dry weight of said plant.

A broccoli inflorescence having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, wherein the broccoli inflorescence is obtained from a hybrid plant following crossing of broccoli double haploid breeding lines with wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* and the levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl

glucosinolates, or both, are between 10 and 100µmoles per gram of dry weight of the inflorescence.<sup>35</sup>

While these claims recite a crossing step, they also read onto broccoli plants and heads *well beyond* those selected according to the claimed process.

In the *State of Israel* case, the claim set considered by the Technical Board of Appeal included the following product claims:

A tomato fruit of the species *Lycopersicon esculentum* which is naturally dehydrated, wherein natural dehydration is defined as wrinkling of the skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said natural dehydration being generally unaccompanied by microbial spoilage.

A tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin, dehydration of the fruit and wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage.

A tomato plant having the tomato fruit of claim 15 or 16 [i.e. the two claims just above quoted] on the vine.<sup>36</sup>

These claims would appear to cover almost any *L. esculentum* (tomato) fruit that has wrinkled but not yet begun to decay. In addition to the fact that these are reach-through claims, one suspects that, to put it mildly, there might be problems with the novelty of these claims.

### 3.6. The language of the exclusion

Before concluding, we must turn again to the language of the exclusion of Articles 52 and 53 EPC. Article 52 EPC lists certain things which are deemed not to be patentable inventions *as such*, i.e. that claims to these things must be rejected but that the exclusion may be interpreted narrowly, as has been the habit of the EPO. Article 53 however does *not* exclude essentially biological processes *as such*, i.e. the third interpretation mentioned in T83/05, but instead inventions which *relate to* essentially biological processes. This language requires an interpretation which fulfils the intention of the legislators to allow farmers and plant breeders to carry out their traditional practices, of performing essentially biological processes, without fear of being found to infringe patents.

## 4. Conclusion

---

<sup>35</sup> EPO 2007b: 3-4.

<sup>36</sup> EPO 2008a: 2-3.

To conclude, *the answer to the questions put to the Enlarged Board of Appeal* should be that a claim to a process for the production of a plant should be allowed if, and only if, the characterising technical step is the *final* step of the claimed process, and that plants or reproductively-capable plant components (e.g. seeds) should only be patented as the *direct* product of such a process.

The member states of the EPC and the drafters of Strasbourg Convention settled at the level of foundational principle the protection for plants when they agreed to the exclusion enshrined in Article 53(b) EPC. If the Enlarged Board of Appeal of the EPO would support a line of interpretation in which a technical effect at any point in the chain of steps of a biological process is enough to remove it from the operation of Article 53(b) EPC then *this foundational principle would be given away*. Bodies charged with the interpretation of treaties may not introduce new substantive rights and obligations that were not there before in the treaty. Only member states can do that.<sup>37</sup> The history of the EPC, the Strasbourg Convention and UPOV mean that Article 53(b) EPC must be interpreted in a way that gives it *substantive effect* rather than being reduced to a formal decoration.

It can be expected that the Enlarged Board of Appeal will set a date for a hearing in the coming months. Further developments in the *Plant Bioscience* and *State of Israel* cases are awaited with great interest.

---

<sup>37</sup> Article 3(2) of the Dispute Resolution Understanding of the World Trade Organization (WTO), e.g., makes this expressly clear for WTO members, however it is a generally recognized basic principle. We are grateful to Professor Peter Drahos for pointing this out.