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Article 53(b) EPC: A Challenge to the Novartis Theory of European Patent History†

Justine Pila*

Abstract

The authoritative (Novartis/transgenic plant systems) interpretation of the Article 53(b) EPC exclusion from European patentability of plant and animal varieties, and essentially biological processes for the creation of plants and animals, is considered, and its significance for the trend of EPO jurisprudence and legitimacy of the EC Biotechnology Patenting Directive noted. The Enlarged Board of Appeal’s justification for that interpretation in Novartis with reference to the exclusion’s legislative history is challenged, and an alternative theory of that history proposed, based on a thorough analysis of the unpublished travaux préparatoires for the Strasbourg and European Patent Conventions. In addition to elucidating the framers’ (actual and presumed) intent with respect to the Article 53(b) exclusion, that analysis offers an insight into post-war legal unification methodology and its continued impact on one of the most contentious and technical areas of intellectual property law.

1. Introduction

(a) European and Community patents

Since the 1960s, patent law in Europe has been largely harmonized. The principal instruments of that harmonization have been the Convention on the Unification of Certain Aspects of Substantive Law on Patents for Inventions (Strasbourg Convention), and the Convention on the Grant of European Patents (European Patent Convention). Signed in 1963 and 1973 respectively, those Conventions were the result of extensive work undertaken over a 22-
year period by two expert committees and two diplomatic conferences: the Council of Europe’s Committee of Experts on Patents (1951 to 1969); the EEC Patents Working Party (1961 to 1964); the Inter-Governmental Conference for the Setting Up of a European System for the Grant of Patents (Luxembourg Conference) (1969 to 1972); and the Munich Conference (1973) at which the European Patent Convention was signed.

The purpose of the Strasbourg Convention (SPC) is to establish certain foundational principles of European patentability. By Article 1, for example, Contracting States are required to grant patents ‘for any inventions which are susceptible of industrial application, which are new and which involve an inventive step’, and to deny patents for inventions not satisfying those conditions. By Article 2 they are permitted to recognise certain limited exclusions from patentability, including for plant and animal varieties, and essentially biological processes for the production of plants and animals.

Articles 1 and 2 of the SPC provide the departure point for the principles of substantive law contained in the more ambitious European Patent Convention (EPC). The purpose of that Convention is to establish ‘a system of law, common to the Contracting States, for the grant of patents for inventions’ (Article 1) and an organization, the European Patent Organization (EPO), to administer it. A patent granted under the EPC is called a European patent, but takes effect as a bundle of national patents under the laws of the Contracting States in which protection is sought. The conditions of the grant of such a European patent are contained in Articles 52 to 57, and include an exclusion from patentability in substantially the same terms as those permitted by Article 2 of the SPC, including one covering plant and animal varieties, and essentially biological processes for the production of plants and animals.

At present there is no Community or other unitary patent in Europe. There is however a strong commitment within the EC to creating one, and to achieving more generally a closer harmonization of European patent laws than is possible with a supra-national, pre-grant system such as the EPC. Still, the goal of a Community patent seems a distance away, notwithstanding considerable investment of time and resources, and significant legislative achievements as well,
including the conclusion of the Community Patent Convention of 1975, the Agreement relating to Community Patents, the Council Regulation on the Community Patent (COM (2000) 412 final), and various related instruments and proposals.¹

(b) Directive 98/44/EC on the protection of biotechnological inventions

One such related instrument is Directive 98/44/EC on the protection of biotechnological inventions.² Created in 1998 after a ten-year legislative passage mired in controversy, the original purpose of the Directive was to harmonise European laws relating to biotechnology patenting. As is the way with EC Directives, various reasons were given for that aim, including the need to promote the internal market


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by clarifying existing legal uncertainty.\(^3\) In the case of the Biotech Directive, an important source of that legal uncertainty was Article 53(b) of the EPC,\(^4\) which Article provides in full as follows:

European patents shall not be granted in respect of: … (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.\(^5\)

In the Biotech Directive, this exclusion is given a clarified form in the following text of Article 4:

1. The following shall not be patentable:
   (a) plant and animal varieties;
   (b) essentially biological processes for the production of plants or animals.
2. 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.
3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 2 supplements this text with definitions of microbiological processes, and essentially biological processes for plant or animal production.\(^6\)


\(^4\) Convention on the Grant of European Patents (1973) 13 ILM 268 (European Patent Convention, as amended) (EPC).

\(^5\) In this definition, ‘plant variety’ alone is separately defined; see Implementing Regulations to the Convention on the Grant of European Patents (EPC Implementing Regulations, as amended) Rule 23b(4) (adopting the definition of the International Convention for the Protection of New Varieties of Plants (UPOV Convention, as amended) Article I(vi)).

\(^6\) ‘Microbiological process’ means ‘any process involving or performed upon or resulting in microbiological material’, and a process is essentially biological ‘if it consists entirely of natural phenomena such as crossing or selection’ (Articles 2.1(b), 2.2).
The combined effect of these EC provisions is to entrench a view of the exclusion above as not covering the following categories of subject matter: biological processes involving non-natural phenomena; technical processes; individual plants and animals; inventions having technical feasibility for two or more varieties of plant or animal; and processes not involving, performed upon, or resulting in microbiological material. The result is that each of these categories is patentable, subject to the general requirements of law.

Since their introduction in 1998, the provisions of the Biotech Directive have been expressly affirmed by the EPO through inclusion in the EPC Regulations. Of greater significance than that inclusion, however, is their independent discovery by the EPO’s superior judicial body – the Enlarged Board of Appeal (EBA) – in the text and history of the EPC. That discovery was made in Novartis, as follows:

i. Article 53(b) EPC was derived from Article 2(b) of the Strasbourg Convention and shares that Article’s legislative purpose, viz, to prohibit the grant of European patents ‘for subject-matter for which the grant of patents was excluded under the ban on dual protection contained in the [original] UPOV Convention.’ Thus, it defines the border of two regimes – patents and plant variety rights – and only excludes from patentability subject matter that is eligible for variety rights.

ii. Plant variety rights were intended to protect biological developments less suited for protection by patent grants. In contrast, technical inventions related to plants,
including technical processes for producing plants, were intended to be kept for patent protection.\textsuperscript{12}

iii. Following from paragraphs i. and ii., the exclusion in Article 53(b) is limited to specific varieties of plant. It does not cover individual plants, inventions applicable to different varieties of plant, nor technical processes for producing plants.\textsuperscript{13}

By this reasoning, the Board has cast the EC provisions as an accurate statement of the framers’ intent with respect to Article 53(b). In so doing it has given those provisions and the Directive itself additional legal and political weight as a clarification of existing law. That effect was strengthened in 2004 by the second decision in \textit{Oncomouse}.\textsuperscript{14}

According to the TBA in that case, the principles of paragraph iii. above apply equally to the animal varieties exclusion, notwithstanding the absence in European law of \textit{sui generis} animal rights, and the consequential inapplicability of the EBA’s reasoning summarised in paragraphs i. and ii.\textsuperscript{15}

When regard is had to the principles’ content, the significance of these cases becomes apparent: they support the trend of EPO jurisprudence towards a field of patentability constrained by technical character alone.\textsuperscript{16} To the extent that the exclusion detracts from this field, it is in the limited context described above; specific varieties of animal and plant. With respect to essentially biological processes: if interpreted as the Biotech Directive states, and the reasoning in \textit{Novartis} would seem to support, their exclusion adds

\begin{itemize}
\item[12] See \textit{ibid} [3.7].
\item[13] With respect to individual plants and teachings applicable to several varieties of plant, see \textit{ibid} [3.10]; see also T$_{19}$/90 (Harvard/transgenic animals) [1990] EPOR 501 (3 October 1990) (\textit{Oncomouse I}) [4.4]. With respect to technical processes for producing plants, see \textit{ibid} [3.7], cf [6]; see also \textit{Oncomouse I} [4.9.1]; n 15 below.
\item[14] T$_{315}$/03 (Harvard/transgenic animals) [2005] EPOR 31 (6 July 2004) (\textit{Oncomouse II}).
\item[15] \textit{Oncomouse II} [11.8]. \textit{Oncomouse II} also confirmed the effect of the Biotech Directive Article 2.2 (n 6 above), and that Article’s exhaustive nature and exclusion of processes for producing animals by genetic engineering (see [13.3.5]-[13.3.6]).
\end{itemize}
nothing to Article 52(2) and the threshold requirement for a (technical) invention.\(^{17}\)

One need only consider \textit{Novartis} itself, and the decisions in \textit{Oncomouse I} and \textit{II}, in order to see the significance of this for positive European patent law, \textit{viz}, it concedes the possibility of European patents for any plant or animal invention not expressly described as a variety per se. While justifications may well exist for that view, it sits uneasily with the terms of the EPC. Indeed, this is why it was described by the TBA, in the referring decision in the \textit{Novartis} case, as depending on a reading of Article 53(b) that fails the normal rules of logic.\(^{18}\)

My purpose in the current paper is not to rehearse the arguments of policy for patenting (or otherwise) animals and plants, and essentially biological processes for producing the same. Rather, it is to consider the reasoning employed in \textit{Novartis} to resolve that issue in favour of patents, and the related legitimacy of the EU’s claim not to have amended European law by entrenching the resulting legal principles in the Biotech Directive. That reasoning relies on the framers’ intent, recorded in the unpublished \textit{travaux préparatoires} for the Strasbourg and European Patent Conventions.\(^{19}\)

\(^{17}\) The biological process exclusion is the subject of a reference to the EBA; see T\_83/05 (Broccoli/Plant Bioscience) [2007] OJ EPO 644 (22 May 2007) (Broccoli).

\(^{18}\) See T\_1054/96 – 3.3.4 (Novartis/Transgenic plant systems) [1998] OJ EPO 511 (13 October 1997) [36].

\(^{19}\) It also relies on the legitimacy of the reasoning in \textit{Novartis} from i. to iii. above, and in particular, on the legitimacy of the connection asserted in \textit{Novartis} between the view of Article 53(b) as intended to complement the UPOV regime on one hand, and as not covering plants and animals, and technical processes for the generation of plants and animals, on the other. While it is not my purpose in this article to consider this connection, it is worth noting that the corresponding exclusion in Australian law is also justified with reference to the UPOV Convention, but is expressed in the Act as covering ‘plants and animals, and the biological processes for the generation of plants and animals’ (\textit{Patents Act 1990} (Cth) s 18(3)); which expression would seem on its face to undermine the connection in issue.
Hence the method adopted in this paper, which is to review the travaux for those Conventions with a view to understanding the framers’ intent with respect to Article 53(b). The conclusions I reach can be stated as follows.

The origins of Article 53(b) EPC lie in the aim of the EEC Six to transpose Article 2(b) SPC in a manner that suited their legal agenda of creating a Common Market code: a European patent system administered by central institutions without displacing national law. Consistent with this, their aim in supporting an express exclusion of the type in Article 53(b) was to restrict the grant of European patents without affecting national grants. They also desired that the exclusion be limited, so as not to cover technical inventions. However, that desire was less important to the Six than consistency with Article 2(b) itself in the interests of future Europeanisation. Thus, when the SPC framers expanded their text, the EEC States followed their suit, relinquishing their own earlier preference for a narrowly cast patent exclusion.

Immediately before the Convention was signed, 10 years after Article 53(b) was drafted, there was genuine uncertainty among the EPC framers with respect to the exclusion’s meaning and purpose. While recourse was had in resolving that uncertainty to the intent behind Article 2(b) SPC, that intent was neither well understood nor sufficiently important to the EPC framers to merit proper historical enquiry.

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21 PWP, *Proceedings of the 1st meeting of the Patents Working Party held at Brussels from 17 to 28 April 1961*, IV/2767/61 (3 May 1961) 46 (agreeing to adapt the German text of the exclusion to the French text, with the word ‘inventions’ in particular to be deleted). See also 8-10 (recording Mr Pfanner’s distinction between the production of new vegetable or animal species ‘by biological means and … [means] involving external technical factors’, and the Chairman’s response to a Netherlands reservation concerning technical processes in agriculture, *viz*, ‘that it would be difficult to exclude inventions concerning agriculture from patentability under the European Convention because of the opposition of a single State’).
Had the EPC framers undertaken that enquiry, they would have found the origins of Article 2(b) in the decision of the framers of the Strasbourg Convention not to attempt to unify aspects of law affected by matters of public interest importance. In the context of plant and animal products, and essentially biological processes for creating those products, that decision had further support from the framers on account of their limited expertise and the unsettled state of national law. The last of these factors was likely encouraged by the work of the European UPOV group on *sui generis* plant protection. When that group produced their draft Convention the framers amended their draft exclusion to adopt the UPOV terminology, *viz*, new *varieties* [of animals and] plants. However, they also unhinged their draft exclusion from the scope of the UPOV Convention provisions – even in the UPOV context of plants – by removing the requirement that varieties be *new*.

It follows from these conclusions that the near identity in the texts of Articles 53(b) EPC and 2(b) SPC is belied by a gulf in their normative bases: the former fuelled by a desire of the EEC States to create a common patent code, and the latter by agreement of the SPC framers not to attempt to unify aspects of law affected by public interest issues. This contradicts the statement in *Novartis* above that the Articles had a corresponding aim, while also making the further point that in neither case was the framers’ intent to support the ban on double protection by creating a UPOV plant exclusion, *viz*, an exclusion that mirrored the UPOV terms while reserving for protection by patent grants technical methods and (other) inventions. Further, while not of itself conclusive, it is of note nonetheless that the UPOV ban was not agreed by its framers until late in 1961, when the principal exclusions of Article 2(b) had already been settled by the SPC framers. To the extent that the legitimacy of European law with respect to the patenting of animals and plants, and biological processes for creating the same, depends on a different view from this, it is open to challenge on historical grounds.
2. The Origins of Article 53(b) EPC

Except in one respect, Article 53(b) EPC is identically worded to Article 2(b) of the Strasbourg Convention. The exception is that whereas Article 53(b) is mandatory, Article 2(b) is permissive. In particular, where Article 53(b) requires States to exclude from patentability varieties and essentially biological processes for the production of plants or animals, Article 2(b) merely permits them to.\(^{22}\)

The near identity of Articles 53(b) EPC and 2(b) SPC was not fortuitous: the actual drafters of Article 53(b) – experts from the original EEC Six\(^{23}\) – were members of the Committee of Experts on Patents responsible for drafting Article 2(b) SPC.\(^{24}\) In addition, the EEC States and SPC framers were concerned to work in association, so that the creation of a Common Market patent would not undermine the work of the Council of Europe nor preclude wider Europeanisation.\(^{25}\)

\(^{22}\) See also Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 27.3(b).

\(^{23}\) France, the Netherlands, Belgium, Luxembourg, Italy, and the Federal Republic of Germany. While membership of the PWP also included representatives from the ECSC, Euratom, and non-EEC countries, it was an explicitly EEC project. See EXP/Brev (59) 1 (n 20 above); Committee of Ministers, Report by the Committee of Experts to the Committee of Ministers on the Meeting at The Hague from 28th November to 2nd December 1960, CM (60) 150 (2 December 1960) [8]-[19]; D. Thompson, ‘Restrictive Practices, Patents and Trade Marks in the Common Market’ (1962) 11 International and Comparative Law Quarterly 594, 595.

\(^{24}\) That overlap included the Chairmen of the PWP and Coordinating Committee, Mr Haertel (from Germany) and Mr Finniss (from France), as well as Mr Pfanner (from Germany) and Mr Roscioni (from Italy). All four were members of the enlarged Bureau of the Committee of Experts, responsible for much of the preparatory work relating to Article 2(b). Mr Finniss was the Committee’s Rapporteur-General.

\(^{25}\) See, eg, CM (60) 150 (n 23 above) [8]-[19]; see also Committee of Experts, Note by the United Kingdom Representatives, EXP/Brev (60) 2 (9 June 1960) [2]. For an overview of the Council of Europe’s patent-related activities in the 1950s and 1960s, see P. Von Holstein, ‘International Co-operation in the
The result was a year of reciprocal influence, helped by the role of Mr Finniss of France in laying the groundwork for both the exclusions. By April 1962, however, those exclusions had undergone significant change in the hands of the drafters’ respective committees. The result was divergent legal texts; one covering new plant varieties and animal species, and purely biological processes for producing the same, and the other (all) plant and animal varieties, and essentially biological processes for producing animals and plants. Faced with this divergence, the EEC States had the following choice: adhere to the text which they had drafted with the intent that it be restrictive in scope, or adopt the text of the Strasbourg framers to ensure consistent patent regimes. They chose the latter, affirming their decision the following year by incorporating the microbiological exemption despite earlier concerns regarding its terms.

The issue remains of the Articles’ difference: the permissive terms of Article 2(b) and mandatory terms of 53(b). Reading the records of the framers’ discussions, a simple explanation appears for that difference, namely, that it was needed to ensure the same result of preserving the discretion of individual States on the patenting of plant and animal life and biological processes for producing such life.

For a Convention which governed national patents, this
required an exclusion of permissive form. For a Convention which governed European patents, it required an exclusion of mandatory form. Thus, the reason for the difference in the Articles’ terms lies in the EEC States’ early agenda to achieve what the Committee had failed to achieve\(^{31}\) – a unitary European law, with ‘a juridical order from a uniform source,’ supporting the grant of European patents without requiring the relinquishment of national rights.\(^{32}\) Hence the following note in the *travaux préparatoires*:

The Co-ordinating Committee concluded that European patents should not be granted for inventions relating to new plant varieties. Obviously the national legislatures of the Contracting States remain at liberty to provide for the grant of national patents for new plant varieties.\(^{33}\)

Article 53(b) was drafted in 1961–2, more than 10 years before the Convention was signed, and eight years before its idea was conceived in the *Memorandum of the Council of the European Communities*.\(^{34}\) In that period, substantial technological changes took place, prompting a review by the EPC framers of the original reason for the draft exclusion.

The first occasion for that review was the Luxembourg Conference of 1971. There the framers instructed their Working Party to study the location of Article 53(b) in the draft Convention, and the implications of that location for the exclusion’s basis.

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\(^{31}\) See CM (60) 150 (n 23 above) [12]; EXP/Brev (60) 2 (n 25 above) [1]. As this document makes clear (at [2]), it wasn’t merely that the Committee had failed to achieve this goal, but also that it did not wish to achieve it because of the impact it would have on national sovereignty (on which see n 120 below).

\(^{32}\) See EXP/Brev (59) 1 (n 20 above).


In particular it was asked whether Article 10, sub-paragraph (b) [Article 53(b)], was compatible with the provision on the protection of plant varieties in the Strasbourg Convention. According to some delegations, the present drafting of Article 10 would attribute the character of an invention to plant or animal varieties, even though they were unpatentable; another delegation was of the opinion that such a conclusion could not be drawn from the text of Article 10.35

The implication of this passage from the EPC travaux is that some delegations believed plant and animal varieties to be excluded from the scope of the Strasbourg Convention on grounds of inherent unpatentability. It followed that treating the exclusion separate from Article 52(2) was incompatible with the logic of Article 2(b).

In considering this issue, the Working Party divided into those who believed the Article 53(b) exclusion to be a product of the threshold requirement for an invention, and those who attributed it to policy instead. Following the failure of the Party to resolve that division, it rejected a proposal to move the exclusion.

Two delegations proposed that sub-paragraph (b) of Article 10 [Article 53(b)] should be inserted in Article 9(2) [Article 52(2)]. As a matter of fact, as far as the applicant is concerned, the two sets of exclusions enter into the same category. On the other hand some delegations drew a distinction between 9(2) and 10(b) in that Article 9(2) dealt with non-inventions while 10(b) dealt with inventions which were specifically excluded. It was also considered desirous to follow the wording of the Strasbourg Convention. Finally the proposal was not accepted.36

A similar uncertainty regarding the basis of Article 53(b) (and its relationship to the exclusions of Article 52(2)) was expressed three months later by several international organizations with consultative

35 Luxembourg Conference, Minutes of the 4th Meeting of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents (Luxembourg, 20 to 28 April 1971), BR/125/71 (7 July 1971) [16].

36 Luxembourg Conference, Minutes of the 9th meeting of Working party I held from 12 to 22 October 1971, in Luxembourg, BR/135/71 (17 November 1971) [100].
status to the Convention debates. The concern of those organizations was that Article 53(b) might support an expansive reading of Article 52(2)(b) as precluding the patentability of antibiotics. How it was thought that this might occur is unclear, though it presumably involved a reading of Article 53(b) as sharing the normative basis of Article 52(2).

Some of the framers also persisted with that view, despite the conclusion of the Working Party described above. In March 1972 for example, one delegation, while noting that conclusion,

...drew attention to difficulties which, in its view, could arise from the exclusion of plant varieties in sub-paragraph (b).... Article 10 could, in fact, be interpreted as listing instances of inventions excluded from patentability, whereas items not constituting inventions within the meaning of the Paris Union Convention would be provided for in Article 9. This would be contrary to the majority opinion expressed at the conclusion of the Paris Convention concerning new plant varieties [UPOV], according to which plant varieties were not inventions.38

The organizations accordingly suggested inserting a provision in the Implementing Regulations to clarify the restrictive scope of Article 52(2)(b) as meaning only forms and states as yet unknown of patentability. (See Luxembourg Conference, Minutes of the 5th Meeting of the Inter-Governmental Conference for the Setting up of a European System for the Grant of Patents; Part II (Hearing of the non-governmental international organizations on the Second Preliminary Draft of a Convention establishing a European System for the Grant of Patents) (Luxembourg, 26 January to 1 February 1972), BR/169/72 (15 March 1972) [16].) A similar concern was expressed by some delegations to the Committee of Experts in 1962, and was a principal reason for them supporting the microbiological process exemption. (See, eg, Committee of Experts, Draft Convention on the unification of certain points of substantive law on patents for invention; Proposals by United Kingdom delegation, EXP/Brev (62) 7 (28 June 1962) [1]; Committee of Experts, Draft Convention on the unification of certain points of substantive law on patents for invention; Proposals of the Swiss Observers, EXP/Brev (62) 12 (11 July 1962) 2.) Compare the comments of the EEC States (n 106 below and accompanying text).

Luxembourg Conference, Minutes of the 5th Meeting of the Inter-Governmental Conference for the Setting up of a European System for the Grant of Patents; Parts 1 and 3 (Luxembourg, 24-25 January and 2-4 February 1972), BR/168/72 (15 March 1972) [37].
By suggesting that Article 53(b) was incompatible with the UPOV Convention, the delegation contradicted earlier advice that 'according to the Plant Variety Union there was no incompatibility between the two Conventions.'

While the question of the normative basis of Article 53(b) dominated the framers' discussions of that provision, the meaning of the Article was also an issue. In the view of the United Kingdom delegation, following the 1965 position of the Patents Liaison Group, the exclusion from patentability of 'essentially biological processes' was neither clear in scope nor justified in principle. Further, there was 'no reason why any biological processes other than for the treatment of the human body should be specifically excluded by the Convention.' It was accordingly proposed that the exclusion be restricted to plant and animal varieties alone. That proposal, however, was unanimously rejected, finding no 'support from any other delegation.'

Two conclusions emerge from this discussion. The first is that at the time of the EPC's adoption in 1973 there existed genuine

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39 BR/135/71 (n 36 above) [98].
41 Ibid [41] ('The group doubts whether a distinction can or should be drawn between processes which are “essentially biological” and those which are not, bearing in mind that any process for treating plants or animals which utilises the natural functions of living matter will be more or less “biological”, and it recommends that there should be no specific exclusion in respect of the treatment of plants or animals').
42 Ibid [99]. A similar concern was expressed by the UK delegation to the Council of Europe's Committee of Experts on Patents in 1962, and was the basis for its proposal that the Committee's report accompanying Article 2(b) SPC include 'an agreed, non-exhaustive list of subjects, which should be regarded as patentable, and of subjects which should not' (see EXP/Brev (62) 7 (n 37 above) [1]; see also Committee of Experts, Observations of the Committee of National Institutes of Patent Agents (CNIPA) on the two draft Conventions being prepared by the Committee of Experts, EXP/Brev (62) 6 (28 June 1962) 2).
43 BR/135/71 (n 36 above) [99].
uncertainty among the EPC framers regarding the basis for the exclusion in Article 53(b), including its relationship to Article 52(2). And the second is that the decision to leave Article 53(b) as and where it was, was in the interests of ensuring conformity with Strasbourg rather than any particular commitment to the exclusion itself, in the sense of any particular understanding of its purpose or scope. Of central interest regarding these conclusions is the decision of the framers in 1973 to entrench the Article 2(b) text notwithstanding uncertainty on both of those matters. One possible reason for that decision, other than adherence to the Strasbourg Convention, is suggested by Dennis Thompson’s account of the meetings that took place at the Luxembourg Conference between the EPC framers and organizations.44

One of the results of those joint meetings was the expression of the general desire for a ‘maximal’ rather than a ‘minimal’ approach. In consequence the Conference agreed that ... the exceptions to patentability should be gradually phased out...45

If made, this agreement, in combination with the then state of biotechnology, might suggest that the framers in 1973 saw limited life in Article 53(b), and thus little to fear from the uncertainty above. However, that it was made is open to doubt. For a start, there is no evidence in the Article 53(b) travaux that the framers intended its exclusions from patentability to be temporary. Further, a reading of the travaux more generally shows the framers’ commitment to a ‘maximal’ over a ‘minimal’ Convention to have been a commitment to a Convention achieving the greatest degree of harmonisation, rather than, as might be inferred from Mr Thompson’s statement, the greatest degree of substantive protection. The same is supported by the contemporaneous account of the Luxembourg Conference offered

44 The account has weight because of Mr Thompson’s direct involvement in the Conference, and because the other points of agreement he describes (regarding a uniform patent term and grounds for revocation) came to pass.
45 Thompson (n 34 above) 64-65.
by the President of the Conference, Dr Kurt Haertel,\textsuperscript{46} and explains why the provisions identified by the framers as affected by the maximal principle did not include the provisions relating to patentability \textit{per se}, but rather Article 2(2) (regarding the effect of the European patent), Article 138 (regarding the grounds for revocation

\textsuperscript{46}Kurt Haertel, ‘The Draft Convention for a European System for the Grant of Patents and for the European Patent for the Common Market’ [1970] IIC 289 at 297-298: ‘The minimum approach which gives the basis to the published Draft of the First Convention, proceeds on the assumption that the purpose of the Convention is simply to rationalize the patent granting procedure in Europe and not to require compulsory standardization of national patent laws of the Member States. In other words, this Convention should assist an applicant and industry in general in acquiring a patent in different European States easily and more simply. The extent of protection provided by that patent, however, should be determined by national law in the individual States and thereby remain as varied as it has been under the present system of individual national patents. At the last session of the Inter-Governmental Conference in January of this year, the majority of the delegations surprisingly favored the so called “maximum approach.” This concept implies that the European patent can only be declared invalid in the States for which it was granted, by reasons provided for in the European patent law, and not by those provided for in the domestic patent laws. In addition, consideration is being given to a uniform period of duration for a European patent of twenty years from the filing date, regardless of the duration of national patents according to domestic law. Whether the Convention Draft will eventually contain the minimum approach or the maximum approach, will depend upon the results of discussions with various interested international organizations. But even if the interested parties opt for the maximum approach, as this author believes they will, that solution as such will not be incorporated in the Convention. In this event, the Signatory States will have the right, at least during a period of transition, to be totally exempt from the maximum approach, or to exclude certain areas of technology, for example, that of chemical and pharmaceutical products, from the maximum approach. In order to avoid a misunderstanding, it should be emphasized that the problem of a maximum or a minimum approach is only of significance to those countries not belonging to the Common Market, since the Common Market countries are bound by a provision in the Second Convention which goes even beyond that of a maximum approach.’
of a European patent), and Article 167 (regarding the reservations permitted to the EPC standards).\textsuperscript{47}

3. The Origins of Article 2(b) SPC

According to Article 2(b) of the Strasbourg Convention:

The Contracting States shall not be bound to provide for the grant of patents in respect of:
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological processes and the products thereof.

Three principles are contained in this exclusion. The first is that States are not required to grant patents for plant or animal varieties. The second is that States are not required to grant patents for essentially biological processes for plant or animal production. And the third is that States must grant patents for microbiological processes and the products thereof. What was the reason for each of these principles, and the scope of their initial intended application? Among other things, answering these questions ought to give some insight into the following areas of specific uncertainty identified by later European reformers: The normative basis of the Article 2(b) / 53(b) exclusion and its relationship, if any, to the requirement for an invention; The meaning of ‘essentially biological processes’; and The implications of the Article 2(b)/53(b) exclusions for the following four categories of subject matter: (i) plants and animals; (ii)

\textsuperscript{47} See, eg, Luxembourg Conference, Minutes of the meeting of Working Party I, Luxembourg, 7-11 September 1970, BR/49/70 (26 October 1970) [90] (‘The provision retained by the Working Party implements the “maximum approach”, according to which, after the patent is granted, it is subject to the rules applicable to national patents in each Contracting State, in as far as the Convention does not rule otherwise (cf., also, Article 133 (new) for grounds for revocation, and also Article 188a (new) for reservations which Contracting States may make at the time of signing the Convention or of depositing this instrument of ratification or accession.’). See further ‘Conclusion of the Luxembourg Inter-Governmental Conference on the Establishment of a European Patent Organization’ [1972] IIC 369 at 371.
inventions having technical feasibility across different varieties; (iii) processes consisting of non-natural phenomena; and (iv) all microbiological processes (and ‘other’ technical processes) involving, performed upon, or resulting in a microbiological material.

(a) The principle that States are not required to grant patents for plant or animal varieties

The decision to exclude plant and animal varieties from the required scope of national patentability was one of the first that was made in 1961, when the Council of Europe’s Committee of Experts set to write the foundations for the Strasbourg Convention. The starting point for their drafting work was the 1960 Memorandum on the unification of legislation written by the Committee’s Rapporteur-General. In that Memorandum, new varieties of plant were proposed for exclusion from the framers’ agenda and thus from the Strasbourg Convention itself. The reasons for that proposal were given as follows:

It would be inexpedient to try to impose a common solution for the highly controversial question of the patentability of new plant varieties. While it is

48 See Committee of Ministers, Report by the Committee of Experts to the Committee of Ministers on the meeting at Strasbourg from 2nd to 5th May 1961, CM (61) 97 [11]: Appendix V.

49 Committee of Experts, Memorandum on the unification of legislation (Item 4 of the Agenda for the meeting of 28th November 1960) by Mr. Finniss, Rapporteur-General, EXP/Brev (60) 7 (28 November 1960) (Finniss Memorandum). The Rapporteur-General’s Memorandum was the basis for his subsequent paper of March 1961 ‘summing up the various possible solutions’ to the problem of unifying the specific aspects of law earlier identified by the Bureau (see n 69 below) with a view to helping the expanded Bureau of the Committee prepare ‘at least the foundations of a preliminary draft Convention’ (CM (60) 150 (n 23 above) 10-11). (For the paper see Bureau of the Committee of Experts, Report on the unification of certain points of patent law in the countries represented on the Committee of Experts by Mr. Finniss, Rapporteur-General, EXP/Brev B (61) 1 (1 March 1961) (Finniss Report). On the use made of it see Bureau of the Committee of Experts, Report of the meeting held in Paris on 16th and 17th March 1961, EXP/Brev B (61) 3 (24 March 1961) 3.)
correct, as the French Experts pointed out, that this question is linked with that of ‘industrial character’ – since the exclusion of ‘plant patents’ is never explicit in municipal law but rests on a strict interpretation of the word ‘industrial’ or on another consideration derived from ‘industrial character’, viz. the absence of the possibility of repeating the technical process in question – it is also true that considerations of public interest play a part here equal to that in such other fields as chemical, pharmaceutical and food products; so the reasons which led the Committee of Experts to remove the problem of the patentability of these products from their unification programme are equally valid in the case of patents for ‘plant novelty’. It is known, moreover, that the legal protection of new plant varieties is at present under study in another context, following the French Government’s initiative in calling a conference in 1957, attended by the majority of European countries, with the object of drafting a convention on the subject. The only sensible and practicable endeavour would thus seem to be towards harmonising European legislation on the patentability of ‘purely agricultural’ processes as defined above.\(^50\)

According to this passage, the fact that the patenting of new varieties of plant was affected by public interest considerations made them inappropriate for inclusion on the framers’ agenda.\(^51\) As the early debates on chemical and other products show, the reason lay in the embeddedness of those issues in the economic and political fabric of States, beyond the reach of unification and the limits of the framers’ political mandate.\(^52\) Supporting this in the agricultural field was the

\(^{50}\) Finiss Memorandum 3-4.

\(^{51}\) See also Committee of Experts, Report of the French Delegation on the Unification of European Laws in respect of Patents, EXP/Brev (57) 3 (13 May 1957) 5. On the framers’ decision to exclude chemical, pharmaceutical and food products from their harmonisation agenda, see Bureau of the Committee of Experts, Minutes of the meetings of Oct. 5th and 6th 1955, EXP/Brev B (55) PV1 Final (10 October 1955) 1-2. In the event that decision was effectively reversed by the framers’ decision not to exclude such products from their Convention, other than to the extent of Article 12(1) (allowing each Contracting Party to reserve temporarily the right among others ‘not to provide for the grant of patents in respect of food and pharmaceutical products, as such’).

\(^{52}\) See Committee of Experts, Note by the Secretariat General on the Functions and Powers of a European Patents Office, CM/WP IV (51) 8 (18 June 1951) 15-16; Committee of Experts, Report on the questions inscribed on the Agenda for the 2nd session of the Committee of Experts presented by M. G. Finiss, Rapporteur-
an uncertain state of national laws and the complexity of the particular technology involved. Indeed, when the UPOV group formed in 1957 to write a Convention on plant protection, it vindicated the view among many of the framers that they themselves lacked the competence properly to do so. When that Convention was signed in 1961, with a ban against double (patent / sui generis) protection,
the framers were vindicated in their earlier decision to exclude from the scope of the Strasbourg Convention new varieties (or species) of plants.58

Further light on the proposal of the Rapporteur-General is cast by the context in which it was made. At the end of 1960, the Committee of Experts had just reconvened after a five-year break with a commitment to completing urgently its work so as not to be sidelined by the EEC Six, who had then started drafting a rival Convention.59 Given the time that had passed since the Committee first formed, and the pessimism surrounding its likely success, this must have given the exclusion a pragmatic appeal as a way of reducing its contentious work. Hence a further reason for the Rapporteur’s suggestion that ‘[i]t would be inexpedient to try to impose a common solution for the highly controversial question of the patentability of new plant varieties.’60

The terms of this suggestion draw attention to a further matter regarding the Rapporteur’s proposal above: its focus on new varieties of plant, to the exclusion of known varieties of plant, individual animals and plant, new and known varieties of animal, and other taxonomic groupings of animal and plant. In order properly to understand that focus one must consider the framers’ earlier discussions, which reveal the following things of importance.

First, in 1960 when the proposal was put, the distinction between plants and groupings of plants had little if any significance for the framers. Indeed, since their earliest discussions in 1951, the framers had used a range of expressions to denote generically products of plants without intending to convey any difference between them. In 1951 and 1952 the most common expressions were vegetable novelties, plant products and plant novelties, reflecting a concern with exclusions of food, and a focus on resolutions

57 See UPOV Convention 1961 Article 2(1) (abolished by the 1991 UPOV Act).
58 Any requirement that patents be granted for new plant varieties would have undermined the premise of the UPOV ban, inserted to ensure consistency between the UPOV and Paris Conventions (see UPOV (n 54 above) 88).
59 See sources at n 23 above, especially CM (60) 150 at [19].
60 Finniss Memorandum 3. See also Finniss Report 2 (see n 75 below).
supporting protection.\textsuperscript{61} In 1953 their attention shifted to agricultural patenting, and the extent of its allowance in national laws. The cause of that shift was a questionnaire drafted by the Bureau in 1953 to facilitate a comparative study of laws that might eventually translate into separate Conventions.\textsuperscript{62} Within the framework set by the questionnaire’s terms, agriculture was related to the ‘limits of the law’, particularly as a law of industrial property, separate from specific (subject) exceptions.\textsuperscript{63} The result can be seen in the national replies, which treat agriculture as an issue of threshold protection dependent on conceptions of industrial invention;\textsuperscript{64} and

\textsuperscript{61} See, eg, Committee of Experts, \textit{Memorandum concerning the establishment of a European Patents Office presented to the Committee of Experts on Patents by the Experts of the Federal Republic of Germany}, CM/WP IV (51) 25 (21 November 1951) 5; CM/WP IV (51) 9 (undated) 2 (n 52 above); CM/WP IV (51) 8 (n 52 above) 16; CM/WP IV (51) PV 8 (n 53 above) 2-4; CM/WP IV (51) 18 rev, and Appendix II to CM/WP IV (51) 18 rev (n 53 above); EXP/Brev (52) PV 10 prov (n 55 above); Committee of Ministers, \textit{Report to the Committee of Ministers presented by the Committee of Exerts on Patents}, CM/12 (52) 89 (12 July 1952) 5, 9.

\textsuperscript{62} See Committee of Ministers, \textit{Eighth Meeting of the Ministers’ Deputies (Paris, 18\textsuperscript{th} December, 1952): Report to the Committee of Ministers submitted by the Bureau of the Committee of Experts on Patents}, CM/12 (52) 149 (17 November 1952) 4-5.

\textsuperscript{63} See Committee of Experts, \textit{Questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe}, EXP/Brev (53) 3 (15 January 1953). By associating agriculture with industry, the questionnaire encouraged experts to consider the issue of agricultural patenting with reference to legal conceptions of industrial property generally, and the terms of Article 1 of the Paris Convention specifically. The latter states: ‘Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.’

\textsuperscript{64} See generally EXP/Brev (53) 4-(53) 12; (53) 14-(53) 17; especially Committee of Experts, \textit{Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the French legislation}, EXP/Brev (53) 4 (10 February 1953) 4; Committee of Experts, \textit{Reply to the Questionnaire...
which distinguish, further, between products and processes as the basis for a future European law. In the Secretariat-General’s study of those replies, this treatment can be seen in the following passage:

I – Industrial character (limits of application of the law)

2. Industry and agriculture:
The word ‘industry’ understood as a defined field of economic activity, may be taken – in France – in the narrow sense (in opposition to agriculture) or in a wide sense – that of human activity oriented towards practical ends. It

drawn up by the Bureau of the Committee of Experts on Patents on behalf of the Luxembourg legislation, EXP/Brev (53) 5 (2 March 1953) 2; Committee of Experts, Reply Given on the Basis of the Swiss Legislation to the Questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe, EXP/Brev (53) 6 (12 March 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe from the point of view of legislation in the United Kingdom, EXP/Brev (53) 7 (17 March 1953) 3; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of legislation in Norway, EXP/Brev (53) 9 (7 April 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts, from the point of view of legislation in the Swedish legislation, EXP/Brev (53) 10 (13 April 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the Danish legislation, EXP/Brev (53) 11 (21 April 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts, from the point of view of the Italian legislation, EXP/Brev (53) 12 (7 May 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of legislation in Ireland, EXP/Brev (53) 14 (15 May 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the Turkish legislation, EXP/Brev (53) 15 (19 May 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the Austrian legislation, EXP/Brev (53) 16 (4 July 1953) 2; Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the Belgian legislation, EXP/Brev (53) 17 (14 August 1953) 2.

This is consistent with the framers’ analogy between plant and animal products, and chemical and other ‘controversial’ products, above; the distinction between products and processes having always been important in the context of the latter. See n 52 above, especially EXP/Brev (52) 8 rev 2; EXP/Brev (52) PV 2 (final) 4-5.
seems that in France the two meanings have even predominated in turn in judicial interpretation. Thus at first, the patentability of inventions realised ‘industrially’ – in the narrow sense – but destined for agricultural applications (like the manufacture of fertilisers) was contestable. These uncertainties are reflected in the variations found in the national practices. (a) It is however generally admitted that inventions which are agricultural in their destination although ‘industrial’ by their method of operation, are amenable to the application of the law. This is the case with those which relate to the manufacture of agricultural implements, or of fertilisers, or which apply to industries for the transformation of natural agricultural products (milling, brewing, etc). (b) The divergences appear with the purely agricultural activities having no ‘industrial’ method of operation, i.e. methods or products of breeding or cultivation. Patentability either of one or the other seems at the moment to be completely excluded in countries such as United Kingdom, Ireland, Luxembourg or Netherlands. The others – more numerous – (France, Germany, Italy, Scandinavian countries, Switzerland) recognise, with varying degrees of certainty, the patentability of processes (such as methods of treating seeds to obtain uniform germination). But patentability of the products themselves, i.e. of new vegetable (or in certain circumstances animal) species is only recognised in a few countries (Italy, France), where, furthermore the question has not been definitively settled either in theory or in practice. The exclusion of agricultural products from the field of the patentable brings up it is true other questions than that of inclusion within the domain of ‘industry’ (the possibility of sufficient description or of sustained repetition of the monopoly granted by the patent) since, considering the matter solely from this point of view, there are no more reasons for excluding the product than the process.66

The framers’ conception of plant and animal patenting (as an issue of industrial character or use) survived their decision in 1955 to postpone ‘juridical unification’,67 and focus instead on procedures of grant, including those ‘aspects of substantive law’ which would need

66 Committee of Experts, Comparative Study of Substantive Law in Force in the Countries Represented on the Committee of Experts on Patents presented by the Secretariat-General [Mr Gajac], EXP/Brev (53) 18 (7 November 1953) 4-5 (footnotes omitted).

67 See EXP/Brev B (55) PV1 Final (n 51 above).
Article 53(b) EPC: A Challenge to the Novartis Theory of European Patent History

to be unified to achieve that end. In drafting a plan for such unification, they retained the framework from 1953 by deriving the relevant aspects of law from the headings of the comparative study above. The product/process distinction persisted, as did the focus on industrial use. To the extent that other language was used, it reflected the States’ diversity of views on the appropriate scope of the agricultural exclusion, and concepts of inherent patentability itself. Thus, the Scandinavian experts referred to ‘novelt[ies] of a biological nature’ and ‘higher living species (animals and plants)’; the UK experts referred to ‘processes involving the rotation of crops and new vegetables and other farm products including varieties of livestock and, generally speaking, processes for the treatment of living animals and plants’; and the German experts referred to ‘methods of breeding plants and animals.’ Reflected in these expressions are two different conceptions of agriculture, and two different conceptions of biology itself, viz, as a purely natural (non-engineered) phenomenon, and as involving forms of higher life.

In the light of this, it would seem inappropriate to read ‘varieties’ here as a term of particular scientific art. Rather, it should be read as a common usage noun for describing the object of patent

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68 The result would be the Strasbourg Convention.
69 See Committee of Ministers, Report to the Committee of Experts on Patents to the Committee of Ministers (on the meeting at Strasbourg from the 3rd to the 7th October 1955), CM (55) 137 (7 October 1953) [20]-[21], Appendix I; noting the derivation of those headings from the 1953 questionnaire used by the Committee as the basis for their pre-SPC unification efforts (see EXP/Brev (53) 3 (n 63 above) (see n 51 above).
70 Committee of Experts, Observations of the Scandinavian Experts: Note on the question of the role and scope of descriptions and claims by the Scandinavian Experts, EXP/Brev (56) 1 (14 April 1956) 5; see n 76 below.
71 See Committee of Experts, Observations of the United Kingdom Delegation; Industrial Character, EXP/Brev (56) 3 (3 May 1956) 2 (describing the established practice in the UK of refusing patents for these subject matter).
72 See ibid; Committee of Experts, Observations and proposals of the German experts on the unification of general conditions of patentability, EXP/Brev (56) 8 (26 October 1956) 2 (describing the ‘unresolvable differences between the patent laws of the different European countries’ with respect to industrial character as limited to these subject matter).
73 See further n 89 below.
rights in respect of plant and animal products. Indeed, the nature of patent protection is such that the rights conferred with respect to such products will necessarily be anchored to taxonomical groups. Another such noun (for another such group) that was commonly used by the SPC framers – including by the Rapporteur-General himself – is ‘species.’

The second thing revealed by the framers’ discussions concerns the Rapporteur’s focus on new varieties of plant. That focus was apparent from the early 1950s, when ‘plant novelties’ were the only form of higher life for which patents had any European support. There was no question of protecting known varieties, for patents exist in the realm of the new; and the idea that patents might be granted for animals seems not to have been seriously considered.

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74 Contra Novartis [3.3.1]; Oncomouse I [4.6].
75 See, eg, Finniss Report (n 49 above) 2; Bureau of the Committee of Experts, Proposal by the Secretariat, EXP/Brev B/Misc (61) 1; EXP/Brev B (61) 3 (n 49 above) Appendix. See also EXP/Brev (53) 18 (n 66 above), reproduced above.
76 The support for plant patents among the framers was weak; in 1951 it was limited to Germany (with Italy and France expressing uncertainty on the issue), and in 1953 it was limited to Germany, Italy and France (with Sweden suggesting that while plants were in principle patentable, such was the public hostility to the idea of plant patenting that patents would not in practice be granted in that country). No other countries expressed support for plant patents until 1956, when the Scandinavian countries affirmed the possibility of plant and animal patents. In respect of 1951, see Committee of Experts, Criteria of Novelty and Patentability, CM/WP (51) 9 (undated) 23 et seq (Annex containing the comments by various countries on the subjects of novelty and patentability). In respect of 1953, see n 64 above. In respect of 1956, see EXP/Brev (56) 1 (n 70 above) 5. See also Committee of Experts, Draft Official report of the Meeting of 6th July, 1951, held at The Hague in the Octrooiraad (Second Session), CM/WP IV (51) PV7 (7 July 1951) 3. The reasons offered by States for their opposition to plant patenting throughout the 1950s ranged from the legal to the practical and/or policy-based. Just as national laws differed, so did views on how the matter would be best treated under a unified law.
by the framers.\textsuperscript{77} Thus, the main question occupying the Committee’s attention was the suitability for protection, and later for exclusion,\textsuperscript{78} of new varieties (or species) of plants. This explains the focus of Mr Finniss above, while also underlining what is in any case apparent: that his comments applied to animals as well.\textsuperscript{79} Hence the March 1961 draft of the relevant exclusion:

the Contracting States shall not be bound to provide for the grant of patents, in respect of ... new plant or animal species...\textsuperscript{80}

In May 1961 the Committee approved the terms of this draft.\textsuperscript{81} In November, however, it revisited the draft, replacing the reference to ‘new plant or animal species’ with a reference to ‘plant or animal varieties.’\textsuperscript{82} Consistent with the comments on language above, an explanatory note accompanying this change cast it as one essentially of form: ‘the allusion to “plant or animal varieties” remains much as it was’.\textsuperscript{83} While no reason was given for making the change, it was likely sparked by the UPOV Convention, which was due to be signed the following month, and which required protection for new varieties of plant by patent or other (\textit{sui generis}) protection. However, it is difficult to attribute it to the UPOV ban, for that ban was not included in the UPOV draft until the end of November 1961.\textsuperscript{84} In addition, 

\textsuperscript{77} EXP/Brev (53) 4 (n 64 above).
\textsuperscript{78} In the early 1950s the framers’ focus was on positive resolutions favouring protection, explaining their focus on plant novelties (see n 76 above). It was only after 1960 when their focus shifted to exclusions from patentability that their discussions took in animals as well.
\textsuperscript{79} See Finniss Memorandum 2-3; Finniss Report 2 (n 75 above).
\textsuperscript{80} EXP/Brev B (61) 3 (n 49 above) Appendix.
\textsuperscript{81} See CM (61) 97 (n 48 above) [14]; Appendix V.
\textsuperscript{82} Committee of Experts, \textit{Memorandum by the Secretariat on the meeting held at Strasbourg from 7\textsuperscript{th} to 10\textsuperscript{th} November 1961}, EXP/Brev (61) 8 (13 December 1961) Appendix I.
\textsuperscript{83} Ibid [6].
\textsuperscript{84} The UPOV ban was agreed at the Second Session of the International (Diplomatic) Conference for the Protection of New Varieties of Plants (21 November to 2 December 1961), after the meeting of the Committee of Experts (7 to 10 November 1961) at which the final version of the Article 2(b) varieties exclusion was agreed. While the question of dual protection
and notwithstanding comments by the framers some 30 years later,\(^{85}\) there is no evidence in the *travaux préparatoires* themselves to suggest that their intent was specifically to complement the UPOV Convention by exempting from mandatory patent protection the plants to which the Convention applied.\(^{86}\) On the contrary, the evidence suggests this was *not* their intent; that they were seeking to preserve States’ national discretion with respect to certain products and processes for the reasons of principle set out above. In settling the terms of the resulting exclusion they naturally adopted the UPOV language in the interests of ensuring coherent regimes.\(^{87}\) That they were not seeking to create an obverse provision is arguably supported by the other change that they made: deleting the requirement that a variety be ‘new’, which unhinged their exclusion

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\(^{86}\) Compare the intent of the Joint Scandinavian Patent Committees in introducing an exception for plant and animal varieties in their Draft Patent Law (see Committee of Experts, *Texts communicated to the Secretariat General by the Swedish delegation*, EXP/Brev (63) 12 (13 November 1963) 3), and of the Patents Liaison Group in recommending that plant and animal varieties be excluded UK patentability in 1965 (n 40 above [40] (‘We think that plant or animal varieties should be excluded from patentability, such exclusion being necessary as regards plants to avoid overlap with the Plant Varieties and Seeds Act, 1964’)).

\(^{87}\) The EEC Six were certainly concerned to adopt the UPOV terminology: see IV/2767/61 (21) 5-6, 8, 45-46; see also PWP, *Article 12 Exceptions to patentability*, IV/2498/1/61 (undated) 3.
from the UPOV provisions even in the context of varieties of plant.  

(b) The principle that Member States are not required to grant patents for essentially biological processes for the production of plants or animals

In his 1960 Memorandum, Mr Finniss described the contention on agricultural patenting as limited to ‘purely agricultural’ inventions: new plant and animal varieties, and ‘processes applied directly to physiological phenomena’; the latter of which he seemed to understand as ‘characterized by [the] self-perpetuation of [their plant or animal] products.’ His suggestion was that while the former raised issues of public interest importance inappropriate for resolution by the SPC framers, the latter raised an issue entirely of law on which the framers might constructively focus their efforts. That issue concerned industrial use, disagreement on which could be readily resolved by adopting the following European provisions:

(1): An invention shall be deemed susceptible of industrial application:
if it can be carried out or applied in an industrial or agricultural undertaking, or

88 This effect was acknowledged; see EXP/Brev (61) 8 (n 82 above) [6] (see text accompanying n 97 below).
89 Finniss Memorandum 2 (n 79 above); see also Finniss Report 2. The implication of the Rapporteur’s definition is that by ‘purely agricultural processes’ he understood all processes giving rise to living matter; consistent with the understanding implicit in the IAPIP’s 1962 suggestion that the microbiological exemption ought not to cover processes that ‘give rise to living matter’ (see Committee of Experts, Observations of the Italian Group of the International Association for the Protection of Industrial Property on the two draft Conventions being prepared by the Committee of Experts, EXP/Brev (62) 5 (21 June 1962) 1). The Rapporteur-General’s definition (of purely agricultural processes) is otherwise reminiscent of the German experts’ 1953 conception of ‘technology’, viz, ‘[t]echnology does not belong to the world of the intellect but to the world of the senses; it works according to physico-chemical principles’ (Committee of Experts, Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe, from the point of view of the German legislation, EXP/Brev (53) 1 (12 January 1953) 2).
90 Finniss Memorandum 2-4. They also raised an issue of feasibility (at 4).
if it is designed to serve in a particular way – industrial or agricultural ends.

(2): The words ‘industrial’ and ‘agricultural’ in paragraph 1 shall be taken in the widest sense as applying not only to industry and agriculture as such but also to the extraction of mineral resources, the working of the earth, and the utilisation of natural produce such as flowers, fruits, seeds, tobacco leaves, mineral water, wine, beer and flour.\textsuperscript{91}

In March 1961 the Bureau of the Committee rejected this proposal. Instead of a provision on industrial use underlining the patentability of agricultural inventions, it preferred to extend the species exclusion to processes ‘directly employed to obtain such species.’ The result was the following redrafted provision.

The subject of an invention shall be deemed susceptible of industrial application if it is capable of serving industrial or agricultural ends in any way whatsoever. Nevertheless, the contracting States shall not be bound to

\textsuperscript{91} \textit{Ibid} 4-5, cross-referencing to the German proposal of 1956 (see EXP/Brev (56) 8 (n 72 above) 8), derived in part from Mr Gajac’s Comparative Study of 1953 (see n 66 above) and in part from Article 1 of the Paris Convention (see n 63 above). It was described by Mr Finniss as ‘combin[ing] the ideas which have grown out of judicial decisions in all countries in the attempt to delimit “industrial character”’, but as ‘not … compatible with the conceptions currently held in such States as the United Kingdom and the Netherlands’. He defended it nonetheless in the following terms: ‘If, for that reason, it could not be accepted by those States, a ‘European definition’ of industrial character could be nothing more than a sort of record of the points of agreement between national systems of law. Once again, we may ask ourselves what practical value such a definition could possess’ (\textit{Finniss Memorandum} 5). See also \textit{Finniss Report} 3-4 (reproducing the proposed provisions in full, and adding ‘[t]his wording, however, is too general in character and should be supplemented by a provision allowing national legislation to determine the protection extended to new plant varieties or new animal species as such’, making clear his intention to preserve the effect of the 1951 resolution with respect to both plants and animals (see Appendix II to CM/WP IV (51) 18 rev (n 53 above)).
provide for the grant of patents, in respect of new plant or animal species or of processes directly employed to obtain such species.\footnote{92}{EXP/Brev B (61) 3 (n 49 above) 3, 6.}

In May 1961 the plenary Committee considered this draft, aided by the findings of the EPC framers, explained by the Chairman of their Working Party; the Committee’s Rapporteur-General himself.\footnote{93}{See CM (61) 97 (n 48 above) [14].} While substantially narrower than the Rapporteur’s own proposal, some members of the Committee remained concerned. According to the \textit{travaux}:

The Italian Experts were doubtful as to the expediency of including it. The proposed clause would treat as patentable any invention, whatever its intended field of use (agriculture, fishing, industry, etc.), if its exploitation necessarily involved an industrial operation. The text proposed by Mr. Wallace (United Kingdom) was adopted unanimously. The last phrase of the second paragraph (‘purely biological, horticultural or agricultural processes’) was added to meet the observations of certain experts.\footnote{94}{\textit{Ibid} [16].}

The result was the following agreed provision:

The words ‘susceptible of industrial application’ shall be understood in the widest sense. Nevertheless, the Contracting States shall not be bound to provide for the grant of patents, in respect of new plant or animal species or of purely biological, horticultural or agricultural (agronomic) processes.\footnote{95}{\textit{Ibid} Appendix V, Preliminary draft Convention on the unification of certain points of substantive law on patents for inventions (Article 2). See also Committee of Experts, \textit{Texts provisionally adopted}, EXP/Brev/Misc (61) 8 (3 May 1961) (Article 2).}

The changes in this text had a two-fold effect. First, they required that the limits of patentability be understood in the widest sense, but not expressly to cover agricultural inventions. And second, they decoupled the species and process exclusions so that the latter might be more expansively cast to cover any process of relevant type, regardless of the object which it produced.

This was not, however, the end of the matter, for in November
1961 the Committee reviewed the draft above and agreed to change its final clause from ‘purely biological, horticultural or agricultural (agronomic) processes’ to ‘essentially biological processes for the production of plants or animals.’ A note explained this change as follows:

Considerable changes were made in the second paragraph of Article 2 (definition of industrial character), which leaves States free to exclude certain classes of biological invention from patentability. While the allusion to ‘plant or animal varieties’ remains much as it was, the reference to ‘processes’ is quite differently worded in several respects and thus requires some explanation. First of all, the new text no longer mentions ‘horticultural or agricultural (agronomic)’ processes. Contracting States, however, still have the right to refuse patents for inventions of this kind. But a very important innovation, which represents a noteworthy concession on the part of some delegations (Netherlands, United Kingdom), is that this right of exclusion now appears only in Article 6, among the ‘reservations’, and thus acquires a merely temporary character in the new text. The processes for ‘the production of plants or animals’ referred to in the new text include those which may produce known varieties as well as those which may produce new ones, it being understood that only new varieties can eventually qualify for protection in themselves. Selection or hybridization of existing varieties may be mentioned as examples of such processes (in the vegetable kingdom). The new text specifies that the processes which may be ineligible for patents are essentially (and no longer purely) biological. It was evident that the exclusion should be extended to cover processes which were fundamentally of this type even if, as a secondary feature, ‘technical’ devices are involved (use of a particular type of instrument in a grafting process, or of a special greenhouse in growing a plant), it being understood

96 The origins of this change lie in a proposal of the Committee’s Working Party; see Committee of Experts, Proposal by the Working Group, EXP/Brev/Misc (61) 13 (8 November 1961); Committee of Experts, Draft Convention on the unification of certain points of substantive law on patents for invention; Proposals of the Drafting Committee, EXP/Brev/Misc (61) 14 (9 November 1961) 2, 4-5 (Articles 2 and 6).
that such technical devices may perfectly well be patented themselves, but not the biological process in which they are used. \(^{97}\)

Three important conclusions can be drawn from this note. The first is that the restriction of the exclusion to \textit{biological processes for the creation of certain (plant or animal) products} was a compromise reached by two groups of States: those supporting the exclusion of May 1961, and those supporting a more limited version of the same, akin to the exclusion proposed in March. \(^{98}\) The second is that the extension of the exclusion to \textit{essentially} biological processes was a result of the framers’ uniform acceptance that to limit it to \textit{purely} biological processes – \textit{viz}, processes applied directly to physiological phenomena, and producing self-perpetuating (plant or animal) products \(^{99}\) – would limit it to purely non-technical processes, which would make it unduly narrow in scope. And the third is that the reference to production of \textit{plants or animals} – rather than production of plant or animal \textit{varieties} – was not understood as having a substantive effect. \(^{100}\) This last point confirms the analysis of language above; noting that while the protection conferred by plant and animal patents will necessarily be anchored to taxonomical groups, the protection conferred by biological process patents will be anchored to conceptions of ‘process’ alone.

(c) The principle that States are required to grant patents for microbiological processes and the products thereof

The reason for the exemption of microbiological processes and the products thereof from the Article 2(b) exclusion seems clear from the \textit{travaux}: they did not raise matters of public interest importance, and were generally regarded as appropriate for patents. Indeed, when

\(^{97}\) EXP/Brev (61) 8 (n 82 above) [6] (emphasis in original). See also Committee of Ministers, \textit{Report of the Committee of Experts to the Committee of Ministers on the meeting held at Strasbourg from 10\textsuperscript{th} to 13\textsuperscript{th} July 1962}, CM (62) 160 (8 August 1962) [7].

\(^{98}\) This is not to suggest it was the product of actual negotiation (see n 96 above).

\(^{99}\) See n 79 above.

\(^{100}\) Hence the references throughout the passage to plant and animal ‘varieties'
the various professional organizations with consultative status to the framers’ debates proposed the exemption for inclusion in the text, even the United Kingdom agreed.\textsuperscript{101} On the issue of the exemption’s intended scope, and the meaning of ‘microbiological process’ itself, the records offer limited guidance. The CNIPA suggested that the exemption should cover ‘processes for treating plants with externally applied means’;\textsuperscript{102} the UK delegation suggested it should cover ‘improved processes for producing yeasts and bacteria and chemical processes involving bacterial action’;\textsuperscript{103} and the Swiss observers focused on processes used in the manufacture of new antibiotics.\textsuperscript{104} Only the Italian Group of the IAPIP, and the EEC Patents Working Party, considered what the exclusion ought not to cover, and expressed concern over its possible scope. The IAPIP thought it ought not to cover processes giving rise to living matter,\textsuperscript{105} and at least some in the EEC Working Party were concerned that it might distort the meaning of the principal two exclusions themselves:

\textsuperscript{101} See Committee of Experts, Observations of the International Association for the Protection of Industrial Property on the two draft Conventions being prepared by the Committee of Experts, EXP/Brev (62) 1 (24 May 1962) 3; Committee of Experts, Observations of the Italian Group of the International Association for the Protection of Industrial Property on the two draft Conventions being prepared by the Committee of Experts, EXP/Brev (62) 5 (21 June 1962) 1 (n 89 above); EXP/Brev (62) 6 (n 42 above) 2; EXP/Brev (62) 7 (n 37 above) 1; Committee of Experts, Comments of the International Federation of Patent Agents on the two draft Conventions being prepared by the Committee of Experts, EXP/Brev (62) 8 (29 June 1962) 1-2; Committee of Experts, Observations of the Swedish Delegation on the two draft Conventions being prepared by the Committee of Experts, EXP/Brev (62) 9 (28 June 1962) 4; EXP/Brev (62) 12 (n 37 above) 2; Committee of Experts, Comments of the Austrian Group of the International Association for the Protection of Industrial Property (IAPIP) on the two draft Conventions being drawn up by the Committee of Experts, EXP/Brev (62) 14 (25 July 1962) 2.

\textsuperscript{102} EXP/Brev (62) 6 (n 42 above).

\textsuperscript{103} EXP/Brev (62) 7 (n 37 above).

\textsuperscript{104} EXP/Brev (62) 12 (n 37 above).

\textsuperscript{105} EXP/Brev (62) 5 (n 89 above).
Mr. van Bentham reported that, in the Netherlands, the text of the Strasbourg [SPC] Draft had been submitted to the interested circles who had asked to have inserted therein a provision such as that in the European Convention. It seemed preferable to leave the question of micro-organisms raised by sub-paragraph (b) to the courts without laying down any express rules. The Chairman … also thought that the question of micro-organisms should be left to the courts since there was a risk of any express rule distorting the sense of the provision by introducing an a contrario argument.106

Overall, it seems that those who expressed a view on the matter did not understand the exemption to cover animals, plants, or essentially biological processes, which were caught by the terms of the principal exclusions.

3. The Boards’ Approach to Article 53(b): Discovering the Intent of the EPC Framers

(a) The Actual Intent of the EPC Framers

The conclusions reached in the analysis above contradict the view of the relevant exclusions expounded by the Board in Novartis as follows:

[T]he purpose of Article 53(b) EPC corresponds to the purpose of Article 2(b) SPC: European patents should not be granted for subject-matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention 1961.107

This view on its face is hard to accept because of the terms of the Articles themselves, which refer to more than new varieties of plant.108 Given this, it is important to consider the reasoning of the

106 6551/IV/62 Section 7 (n 29 above) 7-8; see n 30 above.
107 Novartis [3.6].
108 Of particular note is the exclusion’s reference to animal varieties. The explanation offered by Armitage and Davis for that reference in 1994 (Armitage & Davis, n 85 above at 14) was as follows: ‘The extension to animal ‘varieties’ was a logical consequence for two reasons. First, it would have been highly anomalous to refuse protection for a certain category of
Board, in order fully to understand its view. That reasoning is contained in the following passage.

[I]nventions ineligible for protection under the plant breeders’ rights system were intended to be patentable under the EPC provided they fulfilled the other requirements of patentability. The idea that the exclusion in the EPC should correspond to the availability of protection in UPOV was expressed in the early stages of the preparatory work on the EPC. In the remarks on Article 12 of the Haertel Draft 1961 proposing the exclusion of inventions relating to processes of breeding of plant or animal varieties, it was said that it remained to be considered whether the patentability of technical processes for breeding new plants (e.g. by radiation) had to be taken expressly into the Draft or whether this was self evident from general principles. Previously, in the ‘Haertel Study’ of July 7, 1960 (p. 13 et seq.), the parallel work on the preparation of the UPOV Convention was mentioned in connection with possible exceptions to patentability. This corresponds to remarks made by Pfanner on Article 2(b) SPC after the majority of Member States of the Council of Europe had decided to protect plant varieties by plant breeders’ rights and not by patents (...G.R.U.R. In. 1962, 545, at p. 548). Moreover, in the EEC ‘Patents’ Working Party the distinction between biological and technical breeding processes was also discussed (Report on the 5th meeting...). After consultation with interested parties, it was decided to add a clarification to Article 10b of the May 1962 Draft according to which the exclusion did not apply to microbiological processes and the products thereof (Report on the 19th meeting...). This historical background shows at least an intention to protect by the plant breeders’ rights system biological developments for which the patent system was less suited (Pfanner, supra) and to keep technical inventions related to plants within the patent system. There is nothing in the travaux préparatoires to suggest that Article 53(b) EPC plants while according it to the corresponding category of a higher life form viz. animals. Secondly, it was thought prudent to allow for the possibility of the creation of a system of protection of animal breeds along the lines of the known plant variety protection (although none was in the offing at the time and in fact nothing has developed since).’ The first of these reasons is inconsistent with the theory of Article 53(b) as having been introduced by the framers to define the boundary between patent and plant variety rights.
could or even should exclude subject-matter for which no protection under a plant breeders’ rights system was available.  

Five items are cited in this passage to support the EBA’s view above, and the conclusion in law to which it led, viz, that the exclusion in Article 53(b) EPC corresponds to the available UPOV protection, and is accordingly confined to non-technical developments, at least in the context of products of plants: i. The comments on Article 12 of the 1961 Haertel Draft regarding the exclusion of inventions not being technical processes; ii. The 1960 Haertel Study mentioning the parallel work on the UPOV Convention; iii. The comments by Mr Pfanner of the EEC Patents Working Party published in the 1962 volume of GRUR International; iv. The distinction drawn by Mr Pfanner at a meeting of the Party between biological and technical breeding processes; and v. The decision to exempt from the Article 53(b) exclusion microbiological processes and the products thereof. In addition to these items, the Board refers in the passage above to the absence of evidence for a different conclusion, viz, evidence ‘to suggest that Article 53(b) EPC could or even should exclude subject-matter for which no protection under a plant breeders’ rights system was available.’

Several points can be made in response to this reasoning. First, the Board fails to mention that i. to iv. relate to a draft of Article 53(b) that was later rejected by the EEC States in preference for the wording of Article 2(b); which wording was expressly understood by

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109 Ibid [3.7].
110 The comments referred to are those that were published with the first preliminary draft of the EPC exclusion in March 1961: IV/2071/61 Section 14 (n 33 above).
111 K. Haertel, Studie: Über die grundsätzlichen Probleme der Schaffung eines europäischen Patents, das neben die nationalen Patente tritt (Bonn, 7 July 1960).
112 See K. Pfanner, ‘Vereinheitlichung des materiellen Patentrechts im Rahmen des Europarats’ [1962] GRUR International 545; and see n 24 above.
113 See n 21 above (noting that this distinction was drawn by Mr Pfanner at the first meeting of the PWP and not its fifth meeting as stated by the EBA).
114 See n 30 above.
its framers to cover processes using technical means.\textsuperscript{115} Second, the exemption described in paragraph v. was adopted because of its inclusion in Strasbourg, and only then after concerns by some of the framers that it might ‘distort[] the sense of’ the exclusions themselves.\textsuperscript{116} This leaves the assertion regarding the absence of evidence to support an alternative reading of Article 53(b).\textsuperscript{117} That assertion fails to account for the evidence above, that from April 1962 the EEC States (and later EPC framers), had no greater aspiration with respect to that text than that it mirror the corresponding Article 2(b). Indeed, from the Luxembourg Conference in 1971, the framers seem not to have understood the meaning of that text; they were unable to agree the exclusion’s basis, nor to answer the question of the UK delegation, \textit{why exclude biological processes at all?}\textsuperscript{118} This leaves the intent of the SPC framers, which was to exclude from the scope of the Strasbourg Convention all higher forms of plant and animal life, and essentially biological processes for creating such life, regardless of whether they involved technical means or were entitled to other (\textit{sui generis}) protection. The reason was the public interest nature of the issues raised by their patenting, and the inexpediency of attempting to resolve those issues by a process of Europeanisation. Of central importance with respect to that reason is that it did not presume any particular conception of plants, animals or biological processes.

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\item \textsuperscript{115} While this understanding was expressed by the SPC framers – and in particular, the Secretariat-General (Mr Gajac) and Mr Nathansohn (see EXP/Brev (61) 8 (n 82 above) 24) – the association between the Committee of Experts and EEC Working Party memberships in December 1961 when the understanding was documented makes the distinction somewhat artificial.
\item \textsuperscript{116} See 6551/IV/62 Section 7 (n 29 above) 7-8 (text accompanying n 106 above).
\item \textsuperscript{117} An alleged absence of evidence has also been relied on by the EPO in support of its interpretation of the animal varieties exclusion in terms supporting the Novartis theory of Article 53(b) as motivated by the UPOV Convention (see Oncomouse I [4.7]).
\item \textsuperscript{118} See n 42 above and accompanying text.
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(b) The presumed intent of the EPC framers

According to the EPO Boards of Appeal, discovering the intent of the EPC framers is only half the task of European courts seeking to interpret Article 53(b). Such courts must also consider their presumed intent in light of the changes that have since occurred.\textsuperscript{119} This ought to be, however, a simple task, notwithstanding the extent of the changes involved, for the framers’ approach to Article 53(b) was driven more by their theory of harmonization than their view of the patent issues at hand. Given this, there is no reason to think that had circumstances been different they would have altered their approach with respect to those issues.

What, though, of the SPC framers? Their approach was similarly influenced by their view of their task, but a different view, and of a different task. Rather than creating a European patent, their aim was to harmonize aspects of law, meaning more than codifying common positions, but nothing that would detract from the sovereignty of States on matters with public interest dimensions.\textsuperscript{120}

Given this understanding, it seems likely that the Strasbourg framers of the 1960s, imbued with knowledge of today’s technology, would have maintained their commitment to an expansive exclusion covering all higher forms of plant and animal life, and essentially biological processes for producing such life. The reason is obvious: the public interest issues which their patenting raise are more

\textsuperscript{119} Oncomouse I [4.7].

\textsuperscript{120} The question what if any sacrifice of national sovereignty a harmonised European law would require (and result in) is a matter on which States expressed different views. Compare, eg, Consultative Assembly of the Council of Europe, First Ordinary Session, 16\textsuperscript{th} sitting, 6 September 1949: Creation of a European Patents Office: Report proposed by M. Longchambon on behalf of the Committee on Economic Questions, Appendix I, 180; Committee of Experts, Munich Meeting of the Heads of the European Examining Patent Offices: Summary of Proceedings, EXP/Brev (57) 4 (20 June 1957) [V]; with Finniss Memorandum 3; Committee of Experts, Preliminary draft Convention on the unification of certain points of substantive law on patents for invention: Statement presented by the Danish, Norwegian and Swedish Experts, EXP/Brev (61) 5 (3 November 1961) 2; and EXP/Brev (56) 3 (n 71 above) 3; EXP/Brev (63) 7 (n 52 above) 3; CM (63) 101 (n 52 above) 16 (see n 52 above).
complex and contentious than ever before.\textsuperscript{121}

4. Conclusion

As the EPO has recognised, the meaning of Article 53(b) EPC must be determined with reference to its terms construed in the light of their statutory context as well as the provision’s ‘object and purpose.’\textsuperscript{122} In Novartis, considerable reliance was placed on the legislative history of the Article, in an attempt to determine the last of these factors. It was the EBA’s analysis of that history that was the basis for its conclusion that the referring Board had erred in answering the following question:

Does a claim which relates to plants but wherein specific plant varieties are not individually claimed \textit{ipso facto} avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?\textsuperscript{123}

According to the referring Board, an affirmative answer to this question would defy the normal rules of logic.\textsuperscript{124} According to the Enlarged Board, that view failed to account for the Article’s purpose in defining the border between the two regimes of patents and plant variety rights.\textsuperscript{125}

In the analysis above this view has been challenged, and an argument made that the EBA’s suggestion that Articles 2(b) and 53(b) were motivated by the UPOV ban on double protection, and must therefore be read as supporting a limited exclusion covering only such subjects as are (otherwise) protected, is flawed. My suggestion is that the foundation of contemporary European jurisprudence on

\textsuperscript{121} The controversy is apparent from the history of the passage of the Biotech Directive, and the fact that of all the clauses in the TRIPS Agreement, Article 27.3b is the only one that was subject to early review.

\textsuperscript{122} Novartis [3.3.3].

\textsuperscript{123} Ibid [Summary of Facts and Submissions, numbered question 2].

\textsuperscript{124} Ibid [Summary of Facts and Submissions]; [3.10].

\textsuperscript{125} Ibid [3.10]. Note also n 19 above.
Articles 53(b) EPC is consequently unstable, along with the legitimacy of Article 4 of the Biotech Directive as a codification of the European framers’ intent. The EBA’s statement that ‘[t]here is nothing in the travaux préparatoires to suggest that Article 53(b) EPC could or even should exclude subject-matter for which no protection under a plant breeders rights system was available’,126 is disputed.

The implications for positive law are clear, namely, that if the EBA is to persist with its reading of Article 53(b) EPC, it ought to find a different justification not grounded in the terms of the UPOV Convention. If that justification is to continue to draw on the framers’ intent, it must be their intent with respect to the EPC overall – provided that intent can be properly established and supports the reading which the EBA supports – and not specifically Article 53(b). Conversely, if the EPO were to continue to consider the Strasbourg Convention and the purpose of Article 2(b) SPC,127 it would be difficult to maintain its current support for a field of European patentability limited only by concepts of (technical) invention and unaffected by matters of public interest importance. The reason is the unitary nature of the EPC system, which, by committing States to such a field, denies the legitimacy of divergent positions which it was the explicit intent of the SPC framers to protect through the exclusions of Article 2(b).

126  Ibid [3.7].
127  Contemporary decision makers enquiring into the original intention behind Article 53(b) have been led almost immediately to Article 2(b) SPC. See, eg, Oncomouse I [4.4]–[4.7]; ibid [3.4].