Exclusions from Patentability

How Far Has the European Patent Office Eroded Boundaries?

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To Peter Messerli
Chairman of the Enlarged Board of Appeal of the European Patent Office, 1996–2011

Aside from the globalisation and harmonisation of patent law, the patent universe has been growing in another manner: the scope of what is regarded as patentable subject-matter has quietly expanded. This expansion has occurred in two ways. First, the scope of patentable subject-matter has been given an inclusive interpretation. Secondly, the restrictions on patentability have been narrowly interpreted … Patent offices can, through their decisions, include more things in the scope of patentability or narrow the operation of restrictions on patentability. Moreover, if they are supranational entities, as in the case of the EPO, they can exercise a profound harmonising influence on national systems. English courts, for example, have pointed out that it is of the 'utmost importance' that the exclusions in section 1 of the UK Patents Act 1977 should have the same interpretation as the EPO gives to the exclusions contained in Article 52 of the EPC. The EPO has been singularly successful in giving a narrow reading to the limits on invention and patentability contained in Articles 52 and 53 of the EPC. In interpreting the historical text that surrounds the creation of the EPC, … the EPO has suggested that the widest possible conception of patentability was a predominant conception. This conclusion has led to another … exceptions to patentability have to be narrowly construed … The effect of the assumption is to make the restrictions on patentability function weakly, if at all … A crucial aspect to the expansion of [the concept of patentability] has been the development of juridical arguments and theories that have enabled [patent applicants] to overcome existing bars. One of the interesting things is that, while these arguments are often analytically weak, they have been readily accepted by the patent community in the name of adapting the patent system to changing circumstances of technology and innovation. There is nothing wrong in adapting systems of law to changing circumstances. The crucial thing is that such adaptations must be governed by the public purposes that are embedded in patent law and the broader public ethic rather than private purposes. In the case of the adaptation of the patent system it is not at all clear that this has been the case.

(Drahos 1999: 442–3, footnotes omitted)

2 The historical development and current scope of the European Patent Convention

> [B]ack in 1960 … we first met in Brussels … as representatives of [the six EEC] … countries … [W]e had been shaped by our experiences in World War II and we approached with enthusiasm and determination the task of promoting European Integration, thus helping to create a situation in which war between our countries could never again be either possible or conceivable. The group included my four German friends: Kurt Haertel,[1] Albrecht Krieger,[2] Romuald Singer,[3] and Klaus Pfanner[4] … These four friends did more than merely work with me towards a common goal. As a Dutchman who had spent some difficult years as a student in the Dutch resistance against the occupying troops, I had emerged from the war with a hostile attitude to the Germans. My friends were able to show me a different Germany, and different, democratic and spiritually open-minded Germans who had outgrown nationalism.
>
> (van Benthem[5] 1993)

2.1 Introduction

The European Patent Convention (EPC)[6] is a multinational treaty, in operation since July 1978, which established a system under which patent applications could be filed, examined for patentability under a common standard, granted by a single body, the European Patent Office (EPO), and then brought into force as patents equivalent to those granted by the national patent offices in the Contracting States[7]

[1] Dr Kurt Haertel (°1910–⁺2001), to our minds the father of the EPC.
[2] Dr Albrecht Krieger, later chairman of the Administrative Council of the EPO.
[3] Dr Romuald Singer, later the first chairman of the EBoA.
[4] Dr Klaus Pfanner, later the Deputy Director General of WIPO (World Intellectual Property Organization).
[5] Dr Johannes Bob van Benthem, the first president of the EPO.
[6] References to the EPC throughout this book are to the current version, EPC 2000, rather than the original version, EPC 1973, unless the Article or Rule in question is otherwise identified.
[7] As of 6 December 2011: *Albania*, Austria, Belgium, Bulgaria, *Croatia*, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, *Iceland*,

and the Extension States,[8] a set of countries that now encompasses most of Europe and all of the European Union (EU) countries. The EPC's common standard for patentability has, de facto, become the 'European' common standard.

As with most patent laws, the EPC contains provisions that exclude certain subject-matter from patentability. Exclusions from patentability can be expected to derive from an understanding that an invention may be one to which the state does not wish to grant its imprimatur, for example the morality-based exclusions. They can also be expected to derive from an understanding that certain things are part of our common heritage, free to all, monopolisable by no one. Further, it can be expected that certain activities should not be constrained by fear of patent infringement, or indeed cannot practically be constrained (e.g. mental acts). Finally, some activities are protected by other laws, for example properly belonging to the field of the creative arts, that is artistic activities rather than industrial ones. These are perceived as being more correctly protected by copyright rather than patents since their originality lies in their form rather than in the underlying concepts.

2.2 The international harmonisation of patent law

While patent law is now extraordinarily uniform globally, this has not always been the case. At different stages in the relatively recent past, many countries have been without patent laws (e.g. The Netherlands and Switzerland – see Schiff 1971), have had patent laws from which many categories of inventions (for example medical treatments, pharmaceuticals, foodstuffs and life forms) have been excluded from patentability (e.g. the USA, UK and Germany, among many others), or which have favoured local inventors (e.g. the USA and UK).

The Convention on the Grant of European Patents (European Patent Convention), the EPC, with which we are concerned here, represents only *one* facet of the international harmonisation of patent laws that has been under way since the late nineteenth century. The stages of patent law harmonisation may be summarised as follows:

– the adoption of local or national patent laws, generally accepted as having begun in Venice in 1474 (Prager 1944, Mandich 1948);

Ireland, Italy, Latvia, *Liechtenstein*, Lithuania, Luxembourg, *Former Yugoslav Republic of Macedonia*, Malta, *Monaco*, the Netherlands, *Norway*, Poland, Portugal, Romania, *San Marino*, *Serbia*, Slovakia, Slovenia, Spain, Sweden, *Switzerland*, *Turkey* and the United Kingdom. Countries in italics are not European Union Member States.

[8] As of 6 December 2011: Bosnia and Herzegovina, and Montenegro.

- the adoption in 1883 of an international agreement as to certain basic reciprocities, the Paris Convention for the Protection of Industrial Property 1883 (PC 1883);
- the efforts by the Council of Europe (CoE) to harmonise first formalities relating to patent applications and then substantive requirements for patentability, in the latter case leading to the adoption in 1963 of the Strasbourg Patent Convention (SPC 1963);
- the negotiations beginning in 1957 which led in 1961 to the adoption of the Convention Internationale pour la Protection des Obtentions Végétales (International Convention for the Protection of New Varieties of Plants) (UPOV 1961);
- a temporary attempt in 1961 by the CoE to produce a Convention allowing for a single examination and the grant of a 'European Patent', perhaps the true precursor of the EPC, namely the Draft European Convention for facilitating the filing of applications for patents in respect of the same invention in several States and the examination thereof, which, for want of a better name, we will refer to as the Council of Europe Patent Convention (CEPC 1961);
- the stalled attempt in 1965 by the European Economic Community (EEC – then a group of six European nations – the Federal Republic of Germany (West Germany), France, Italy, The Netherlands, Belgium, and Luxembourg) to set up a system for the granting of European Patents, the Convention relating to European Patent Law (CEPL 1965);
- the creation in 1970, following the suggestion of the USA, of an international system for patent applications, the Patent Cooperation Treaty (PCT 1970);
- the creation in 1973 of a common system for the examination and grant of patents in Europe, that is the European Patent Convention (EPC 1973);
- the stalled attempt to create a patent system for the EU, which led to the signing in 1975 of the Community Patent Convention (CPC 1975);
- the negotiation, from 1986 to 1994, of global minimum requirements for patentability in the Uruguay round of the negotiations on the Global Agreement on Tariffs and Trade, resulting in the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS 1994);
- the debates, starting in 1988, which led in 1998 to the modification of the EU's requirements for patentability of biotechnology as set out in Directive 98/44/EU (the European Biotech Directive – EBD 1998)

and to the introduction in September 1999 into the Implementing Regulations of the EPC of corresponding Rules; and
– the modification in 2000 of the EPC, inter alia to achieve greater compliance with TRIPS, the amended law having entered into force in 2007 (EPC 2000).

This harmonisation process is not complete, not even at the EU level – as of June 2012 the CPC is not in force after thirty-seven years. Global harmonisation continues and revision of TRIPS continues to be discussed.

The first stage of *global* harmonisation was the Paris Convention of 1883 (Penrose 1951, Bodenhausen 1969), which gave rise to the priority right and to national treatment,[9] but included no provisions as to what would constitute patent infringement or what was patentable.

For harmonisation regarding what is patentable, we must look elsewhere and identify where, when, how and why the exclusions from patentability currently present in the EPC appeared. The legislative history of the exclusions from patentability in Europe can be seen to relate to three sets of exclusions:

– those of Art. 53(a) and (b) EPC, which were essentially agreed in the drafting of the SPC;
– those of Art. 52(2) and (3) EPC, which began life in the drafting of the CEPL, were transferred to the drafting of the EPC and were modified to some extent by the adoption of PCT Rule 39.1; and
– that of Art. 53(c) EPC, which began with the CEPL, was first placed with the precursor of the Art. 52(2) EPC exclusions to avoid conflict with the SPC, was transferred to Art. 52(4) EPC 1973 under the legal fiction of non-susceptibility to industrial application, and in the revision to produce EPC 2000 was transferred to Art. 53(c) EPC.

The development of these exclusions was not straightforward and has involved an interplay between the development of several different international intellectual property laws and treaties as well as political and economic developments spanning more than half a century.

[9] That is the right to claim the filing date of the first patent application covering an invention in corresponding patent applications filed in other countries party to the Paris Convention, and the right to have one's patent application in a Paris Convention country examined in the same way as an application filed by a national of the country would be.

2.3 The early history

Before the Second World War, the German chemical industry had an almost overwhelmingly dominant position globally, backed up by its national and foreign patents (Jeffreys 2008, Dutfield 2009). During that war, as with the First World War, German-owned patents were of course seized by Allied governments as enemy property (Wadlow 2010). In April 1945 American forces also seized the papers of the German Patent Office, which had been hidden, for safe-keeping, in a mine near Heringen in Hessen (Haddon 2008, Walker 1946). Those papers, tons in all, were eventually transferred to the US Department of Commerce. The German Patent Office did not start receiving patent applications again until 1948, and when the first post-war patent was issued, it was numbered 800001 to reflect the missing files.

Following proposals by, among others, Winston Churchill, the CoE was set up in 1949. In August 1949 the Committee of Ministers of the CoE placed the creation of a European Patent Office on their agenda, and in November 1949 they instructed their Secretary-General to collect all useful material regarding the creation of a European Patent Office, to prepare a report on the best way of handling it, and if necessary to call on the services of experts appointed by their governments (Document Res (49) 27-E). A Committee of Experts was formed in 1950 and presciently reported in 1952 that the recommendation could not be carried out immediately. The Committee of Experts was instructed to proceed (Document Res (52) 51-E).

In January 1953 the Committee of Experts sent a questionnaire to Member States asking what was excluded from patentability in those countries, in particular in relation to: '(1) Substances, especially chemical substances[;] (2) Foodstuffs, including tobacco and other luxuries[;] (3) Medicines and medical appliances [; and] (4) Further exceptions, including inventions contrary to law and morality' (Document EXP/Brev (53) 3: 2).

The Committee of Experts drafted two Conventions, the first dealing with patent application formalities (signed in December 1953) and the second dealing with classification (signed in December 1954). Then they turned to unification of substantive laws. A first draft of a European convention on patents had in fact been prepared by Dr Eduard Reimer in 1953 (see Document EXP/Brev (53) 19, and Wadlow 2008: 369–70), but, as Wadlow comments, the proposals: 'were too far ahead of their time to be adopted.' A study on substantive points of patentability was presented for the Committee of Experts by Roger Gajac in November 1955. This 'Gajac study' sought to set out the common features of

possible exclusions from patentability, and needs to be quoted at length (authors' translation from French), for it provides the foundation, as well as a rationale, for most of the exclusions set out in Art. 52 and Art. 53 EPC:

1. Invention and discovery:

As a general rule, a patent can only protect an invention (a creation) and not a discovery, that is the mere becoming aware of a pre-existing reality. A natural product or a natural phenomenon could no more be the object of patent protection than the revelation of a law of nature, even though a patentable technical indication may be based on a discovery, and the scientific expression of an empirically known causality may, for example, provide an industrial activity with a precise and constant character and therefore yield a patentable application, if it takes the form of a concrete technical instruction addressed at industry.

2. Industry and agriculture:

The word 'industry', understood as a defined field of economic activity, can be interpreted – in France – in a narrow sense (as opposed to agriculture) or in a broad sense, as all human activity that is oriented towards practical goals. It appears that, even in France, both meanings in turn have prevailed in judicial interpretation …

These uncertainties are reflected in the diversity of national practices.

(a) It is nevertheless admitted without restriction that agricultural inventions, in view of their purpose or the origin of the products they relate to, although industrial through their implementation, fall under the scope of application of the law. The same holds for inventions relating to the manufacturing of tools.

(b) The divergences arise with regard to purely agricultural activities, without 'industrial' implementation, that is methods for or products of cultivation or breeding. The patentability of both currently seems totally excluded in countries such as the United Kingdom, Ireland, Luxemburg or The Netherlands. The other countries – the majority – (France, Germany, Italy, the Scandinavian countries, Switzerland) acknowledge, more or less firmly, the patentability of methods (such as methods for treating seeds enabling a uniform germination). However, the patentability of the products themselves, that is the new types[10] of plants (or possibly animals) is admitted in only a few countries (Germany, France, Italy), where the question moreover is not definitively resolved, either in legal doctrine or in practice. The exclusion from patentability of agricultural products, it is true, has to do with other criteria than the criterion of belonging to the domain of 'industry' (the possibility of a sufficient description or a repetition, the scope of the monopoly guaranteed by the patent) since, from this

[10] In the original 'espèces', which according to the Collins–Robert French–English Dictionary (Atkins *et al.* 1987: 272) translates as: 'species; … sort, kind, type.'

strict point of view, there is no more reason to exclude the product than the process.

3. Systems, methods and so on:

If the patentability of inventions relating to agricultural techniques remains subject to divergent responses, this is not the case for inventions in the field, not of 'industrial' techniques, but of financial, accounting, commercial, publicity, educational, military, tourist, medical, and so on techniques. All national practices agree on excluding monetary, insurance, accounting, calculation, education, publicity, and so on systems, as well as rules of games or methods of medical treatment, from the scope of application of the law.

On the other hand, the manufacturing of products or appliances, of which the non-industrial techniques make use, obviously falls within the boundaries of industry. In this respect, the field of industrial techniques is broader for 'products' than for methods, since a product, even applicable to other techniques, is necessarily industrial through its manufacture, whereas a method can only have an industrial character if it makes use of natural resources and not merely of the faculties of the human mind. That is how, unlike 'abstract' curative methods, medical products or instruments would be patentable everywhere without consideration of public interest or societal ethics.

4. Scientific principles and theories:

All the countries' practices are also in agreement that purely scientific doctrines, principles or theories are excluded from the scope of the application of the law, whereas their industrial applications are not …

5. Creations of form:

It is obviously a general rule that creations of form fall outside patent protection and fall within the scope of the special protection of designs and industrial models. Likewise, ways of typographical presentation of printed material would only fall under the remit of the laws relating to artistic property …

Ordre public, morality:

In all countries' practices (if not in their laws – the Belgian law remains silent in this respect), one finds a prohibition on patenting inventions that are contrary to 'ordre public' or morality …

The applications of this rule, which are always extremely rare, seem to address similar considerations. The refusal or invalidation of a patent may stem from either the fundamentally illicit nature of the invention (the application of which would in itself be criminal), or from it being prohibited by specific legal or regulatory provisions. The possibility of a partially licit application is always sufficient to ensure patentability. Sometimes it is required, in such a case, that the illicit application be subject to a formal disclaimer. (Document EXP/Brev (53) 18 rev: 4–7 and 22, references omitted)

In October 1956 Eduard Reimer,[11] on behalf of the German experts, put forward a more concrete proposal (the 'Reimer proposal') as to what should not be eligible for patents:

No invention shall be patentable when it is simply a question of:

(a) scientific principles and theories,
(b) instructions to the human brain, such as accounting systems and rules of games,
(c) the creation of aesthetic forms,
(d) the bringing to light of a pre-existing fact (discovery). (Document EXP/Brev (56) 8: 8)

This was said to list, on the basis of the Gajac study, 'cases where the question of patentable invention does not arise' (Document EXP/Brev (56) 8: 3). The experts considered that the Gajac study was 'of a restrictive nature' and that it could be supplemented. The Reimer proposal also suggested that European patents should be granted in respect of inventions that were 'capable of industrial application', deeming that this term should: '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, action exercised on the *development* of plants and animals and the *utilization* of natural produce such as flowers, fruits, seeds, tobacco leaves, mineral water, wine, beer and flour' (Document EXP/Brev (56) 8: 8, emphasis added). It will be seen that these extended examples relate to processes rather than to products as such, that is they give no suggestion that plants, animals or natural materials should themselves be patentable. Indeed, in the body of the text it was stated that the German experts considered that: 'there are no unresolvable differences between the patent laws of the different European countries – with the possible exception of the question of extending patentability to cover *methods of breeding* plants and animals' (Document EXP/Brev (56) 8: 2, emphasis added).

In March 1957 the Treaty of Rome was signed, coming into force in January 1958 and creating the EEC, the forerunner of the current EU, uniting six European countries (France, the Federal Republic of Germany, Belgium, Luxembourg, The Netherlands and Italy). One may suspect that getting the EEC up and running distracted attention from the project for a European Patent Office and a common European patent law. Indeed, between October 1955 and June 1960 things had not progressed enough in the patent field to hold a full meeting of the

[11] President of the German Patent Office. Unfortunately, Dr Reimer's involvement in the European patent law project was cut short by his death in 1957.

CoE Committee of Experts. Nonetheless, a meeting of the Bureau of the Committee of Experts in May 1960 asked the Committee's rapporteurs to complete their reports.

2.4 Plant variety protection – the negotiations leading to UPOV 1961

Although the issue of some form of intellectual property protection for plant breeders was discussed at the AIPPI (Association Internationale pour la Protection de la Propriété Intellectuelle) Congress in Vienna in 1952, there was no agreement as to the form such protection might take. Plant breeders had hoped for protection by way of a patent or equivalent right. At the request of the plant breeders' association ASSINSEL (Association internationale des sélectionneurs professionnels) following their June 1956 congress, in February 1957 the French government invited the governments of twelve other European countries to a diplomatic conference to discuss the possibility of drafting an international convention to provide protection to new breeds of plant. The term actually used was '*nouvelles obtentions végétales*' (Document UPOV (57) 1: 14). The accompanying *aide-mémoire*, intended to serve as the starting position for the discussions, also used the terms new plant variety (*nouvelle variété de plante*), plant novelty (*nouveauté végétale*) and race (*race*) (Document UPOV (57) 3: 16). The first Diplomatic Conference took place in May 1957 and was attended by delegates from Austria, Belgium, Denmark, France, Italy, The Netherlands, Norway, Spain, Sweden, Switzerland and the Federal Republic of Germany. The German delegation included Dr Klaus Pfanner and the French delegation included Guillaume Finniss, the director of the French Patent Office and a member of the CoE's Committee of Experts on Patents. Three organisations were also represented: BIRPI (Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle (United International Bureau for the Protection of Intellectual Property) – the predecessor of WIPO (the World Intellectual Property Organization)); OEEC (the Organisation for European Economic Co-operation – the predecessor of the OECD (the Organization for Economic Co-operation and Development)); and UNFAO (the United Nations Food and Agriculture Organisation).

In his introductory address at the conference, Mr Darras, representing the French Secretary of State for Industry and Commerce, commented that some countries excluded food materials from patentability and that others had special legal instruments for protecting plants. More interestingly, he mentioned that: 'It must be understood

that plants, unlike industrial products, can reproduce themselves and that this ability raises serious problems, on the one hand in proving infringement, and on the other in regulating the use of her harvest by the purchaser of the propagating material, for example seeds, tubers, and so on' (Document UPOV (57) 5: 22, authors' translation from French). The different government delegations explained whether and how new types of plant could be protected in their countries. In Germany patent protection was possible. In Austria no one had applied for a patent on a plant since 1940, and any such application would be rejected. The Belgian Patent Office had granted about twenty patents for plants, but Belgian patent applications underwent no substantive examination and so 'it was difficult to comment on their value'. Similarly such patents were granted in France but without 'any guarantee as to their value'. In Italy patents had been granted for plants, while in Switzerland the Federal Courts had revoked patents granted for plants (Document UPOV (57) 6: 23–4, authors' translation from French).

The delegations agreed to use the broad term plant novelties (*nouveautés végétales*) to cover the subject-matter for which protection might be sought and described the requirements the plant 'variety' (*variété*) would have to meet – distinctiveness, sufficient homogeneity, and stability from generation to generation on reproduction or whatever form of multiplication. The variety could thus be, for example, a pure line, a clone or possibly an F1 hybrid.

The *breeders' right* was agreed at this first conference, that is the clause providing that other plant breeders could use a protected variety as the starting material for generating new varieties. This immediately put the new form of protection outside the field of patents and the distinction between patents and plant variety protection was explicitly acknowledged (Document UPOV (57) 6: 25–6).

The delegates agreed to appoint a Committee of Experts to draft the UPOV Convention. They met for the first time in April 1958 and appointed Jean Bustarret (later the director of the renowned French Institut National de la Recherche Agronomique) as president. The experts were drawn from Austria, Belgium, Germany (including Klaus Pfanner), Spain, Norway, Denmark, Italy, Sweden, Switzerland, The Netherlands, France, the UK, BIRPI and UNFAO.

Our emphasis on the wording used for the subject-matter of plant variety protection is to demonstrate that the term 'plant variety' did not have a precise meaning but meant no more than 'type of plant' or 'kind of plant'. The Committee of Experts indeed felt that the term 'variety' was unsatisfactory and that the word 'cultivar' should be used instead

(Document UPOV (58) 1: 33). Nonetheless, in the Annex to the minutes of the Committee's meeting, the term plant novelty (*nouveauté végétale*) was used and explained as 'a new variety or cultivar' (*variété ou cultivar nouveau*) (Document UPOV (58) 1: 34).

The Committee of Experts met again in September 1958 with the French delegation including Roger Gajac of the CoE Committee of Experts on patents. The experts could not agree on a satisfactory response as to what categories of plants should be protected. However, they agreed that, in principle, protection could extend to all members of the plant kingdom. It was agreed that the Drafting Committee should meet at the turn of the year. Rough drafts of the types of Article the Convention should contain were appended to the minutes of the meeting. In these Annexes, the terms 'plant novelty' and 'new variety' were used (Document UPOV (58) 2: 38–9).

The Drafting Committee met in January and April 1959 and produced a first preliminary draft (*avant-projet*) of the UPOV Convention (Document UPOV (59) 1). Art. 1(1) referred to the proposed subject-matter as 'plant novelty' (*nouveauté végétale*). Art. 4(1) qualified this to refer to 'plant novelty – new species, variety or cultivar' (*nouveauté végétale – espèce, variété ou cultivar nouveau*). Art. 4(1)(a) required that the novelty must result from a labour of genetic improvement and not merely from the use of a pre-existing plant material. Art. 4(1) also set out the properties required for a variety to be protectable, namely distinguishing characteristics capable of being described (optionally being physiological rather than morphological characteristics), sufficient homogeneity, and stability following successive reproductions or multiplications. Art. 13(1) confirmed that the Convention applied to all kinds and species of plant (*genres et espèces de végétaux*), subject to any relevant exclusions being made. Art. 3 provided the breeders' right mentioned above.

With this draft before them, the Committee of Experts had its third meeting in June/July 1959. The German delegation included Dr Kurt Haertel as well as Klaus Pfanner. The Committee agreed that the (genetic) improvement required by Art. 4(1)(a) of the draft corresponded to 'breeding' or *Züchtung* (Document UPOV (59) 2).

In January 1960 the Group of Legal Experts, including Pfanner, Bustarret, Finniss and Gajac, met to discuss the relationship between the proposed UPOV Convention and the existing Paris Convention. At this meeting the question of a ban on double protection was discussed. The legal experts finally agreed that 'for a same species or group of species, there can be only one form of protection', that is, depending on the choice of the contracting state, a plant variety falling within a particular

species could not be protected both as a plant variety and by a patent (Document UPOV (60) 1: 51, authors' translation from French).

The Drafting Committee met again in January 1960 and produced a revised preliminary draft of the UPOV Convention (Document UPOV (60) 2). Following this, Art. 1(1) contained an even longer list of the synonyms for 'plant variety' ('plant novelty – new species, variety, cultivar, line, clone'), Art. 3(2) had a clause confirming that 'variety' was used in this and subsequent Articles 'to designate a defined plant type', and yet the text continued to refer to plant novelties. No exclusion of double protection was yet present.

In February 1960 the Committee of Experts had their fourth and last meeting. They identified certain questions relating to the relationship between plant breeders' rights and patents that needed to be addressed:

> [W]ill it be possible for certain countries to protect plant novelties via patents … [and] can one allow the co-existence of a patent with the new plant breeders' right? … The Legal Experts have arrived at the following conclusions … Against the objections of some amongst them, they have not rejected the possibility of countries which absolutely desire to do so to continue to protect plants via patents while adhering at the same time to the new Convention … The majority of the experts were of the opinion that for a particular species only one form of protection should be available. (Document UPOV (60) 3: 57, authors' translation from French)

The Committee of Experts also decided that the Drafting Committee should define the word 'variety' in Art. 1.

A final revised draft (the '*projet*') was produced in April 1960 (Document UPOV (60) 4). Art. 1(1) referred to a new plant variety (*variété végétale nouvelle*). In Art. 1(2) it was stated that: 'the word variety in the sense of the present Convention applies to any cultivar, clone, line, stock, hybrid susceptible of being cultivated and meeting the conditions of Article 6(1)(c) and (d)' (Document UPOV (60) 4: 61, authors' translation from French). Art. 4(1) confirmed that the Convention was applicable to all botanical kinds and species of plant (*genres et espèces botaniques de végétaux*). The draft was still silent as to double protection.

In September 1960 the president of the Committee gave his final report (Document UPOV (60) 5). The Committee, considering that the new Convention should leave Member States free to adopt the mode of protection they considered most suitable, had refrained from adopting any provision that would *forbid* the Member States that wished to protect new plants via patents from doing so. The majority of the experts, however, had made it clear that, for varieties of any single

botanical species, only one mode of protection should be available in each Member State. The desire to see a ban on double protection had thus been clearly stated during the UPOV negotiations well before the first drafts of the SPC and CEPL were produced for discussion.

The different governments made observations (Document UPOV (61) 1) on the draft and in July 1961 the French government invited them to the second and final Diplomatic Conference, which was to take place from 21 November to 2 December 1961. The Diplomatic Conference was attended by Germany, France, Austria, Denmark, Belgium, The Netherlands, the UK, Italy, Finland, Spain, Sweden and Switzerland, as well as by delegates from the EEC, OECD, UNFAO, BIRPI, AIPPI, ASSINSEL, FIS (the Federation Internationale du Commerce des Semences) and CIOPORA (the Communauté Internationale des Obtenteurs de Plantes Ornamentales de Réproduction Asexuée). After the first plenary session, work proceeded in committee and the minutes of the committees show that the General Committee put four questions to the Legal Committee, which may be rendered as: (1) can the UPOV Convention coexist with the Paris Convention; (2) can the UPOV Convention coexist with other national intellectual property laws, in particular patent laws; (3) where more than one system for intellectual property protection can coexist, can the plant breeder acquire protection under more than one such system or must she select just one to benefit from; and (4) what relationship is the UPOV Convention to have with BIRPI (Document UPOV (61) 9: 119).

The Legal Committee was not of one mind on the first question, with Italy being notably out of line. The majority decision, however, was that the UPOV Convention could coexist with the Paris Convention. The UK delegation felt that it was necessary to establish a separate Convention (UPOV), and the Dutch delegation agreed, 'considering it impossible to protect plant novelties under the legislation relating to patents of invention' (Document UPOV (61) 9: 119, authors' translation from French). The Legal Committee's answer to the second and third questions deserves to be quoted in full:

> According to the French delegation, countries that wish to allow two laws to coexist must be permitted to do so when the scope is not the same. This opinion is, in its mind, *even more important as the domain of patent law has a tendency to spread*. The representative of BIRPI believed that if this coexistence were permitted and if the choice were to be left to the plant breeder, the two laws would conflict. In conclusion, the Committee considered that it was necessary to allow the national legislatures the choice of the system of protection, *but that for one and the same species there could be no cumulative protection*. (Document UPOV (61) 9: 119, authors' translation from French, emphasis added)

At the final plenary session of the Diplomatic Conference on 2 December 1961, the text proposed by the General Committee was adopted with minor modifications and signed. The ban on double protection and the definition of plant variety appeared in Art. 2 UPOV 1961 as follows:

(1) Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species.
(2) For the purposes of this Convention, the word 'variety' applies to any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies the provisions of subparagraphs (1)*(c)* and *(d)* of Article 6.

When UPOV was amended in 1978 (UPOV-1978), the definition of variety was deleted. When it was amended again in 1991 (UPOV-1991), a new definition was introduced, the prohibition on double protection was removed, and a farmer's privilege was added – providing that Member States might restrict the breeder's rights in order to permit farmers to use, for propagating purposes and on their own holdings, the product of the harvest that they had obtained by planting the protected variety on their own holdings.

2.5 The parallel drafting of the SPC and the CEPL (with UPOV 1961 in the background)

The preparation of a preliminary draft SPC was agreed by the CoE Committee of Experts at its meeting in November–December 1960. At that meeting the Committee was advised that a working party of the heads of various examining patent offices had met several times in the previous five years to draft a convention to facilitate the making of patent applications in different countries for the same invention. In January 1961 that working party adopted a resolution expressing the wish that the convention on which they had been working, the CEPC, be concluded within the framework of the CoE and that the working party should become a sub-committee of the Committee of Experts (Document EXP/Brev (61) 2 rev: 2).

At their November 1960 meeting the Co-ordinating Committee of the Patents Working Party (PWP) of the EEC had 'concluded that the concept of patentability in the European patent law must be as wide as possible' and 'that European patents should not be granted for inventions relating to new plant varieties' (Document IV/2071/61-E, Section 14: 5–6). Should individual countries wish to grant patents for

new plant varieties, that could of course be done via national law but not via the Convention relating to European Patent Law (CEPL). In December 1960 the preparation of a draft of the CEPL was agreed by this Co-ordinating Committee. From this stage until the signature of the SPC in November 1963, the work on the SPC and the CEPL would proceed side by side with several individuals being deeply involved in both.

For the CoE's Committee of Experts' November–December 1960 meeting, a report on the unification of the legislation had been prepared by Guillaume Finniss of the French Patent Office (and of the UPOV Committee of Experts). The Finniss report proposed the exclusion of new varieties of plants:

> It would be inexpedient to try to impose a common solution for the highly controversial question of the patentability of new plant varieties … 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 … with the object of drafting a convention on the subject. (Document EXP/Brev (60) 7 (1960))

At the November 1960 meeting Finniss also explained in detail the problems of achieving harmonisation in respect of purely agricultural inventions (Document EXP/Brev (60) 7, quoted in Pila 2009: 448 and referred to in Moufang 1991: 13).

A draft of the SPC was produced in March 1961 containing, in Arts. 1 and 2, the precursors to the 'morality' and 'agriculture' exclusions of Art. 53(a) and (b) EPC:

> Inventions, the exploitation of which would be contrary to the public interest (ordre public ou bonnes moeurs), shall not be patentable …
>
> 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 processes directly employed to obtain such species]. (Document EXP/Brev B (61) 3: 6)

A first preliminary draft of the CEPL and comments on that draft were presented in March 1961 before the first meeting of the EEC's Patents Working Party (PWP) in April 1961. Art. 12 [Art. 53 EPC][12] read:

> European patents shall not be granted in respect of:
>
> 1. Inventions the exploitation of which [either in the territory of all Contracting States or in the territory of individual Contracting States] would be contrary to morality or 'ordre public'.

[12] Where appropriate, the number of the corresponding Article of the EPC will be included in square brackets.

2. Inventions relating to the production of or a process for producing a new plant variety or a new animal species. This provision shall not apply to processes of a technical nature.
3. [Inventions which must be kept secret for reasons relating to the defence of one of the Contracting States.][13] (Document IV/2071/61-E Section 13: 3)

The accompanying comments confirmed that the tentative draft of Art. 11 [Art. 52 EPC] was based on the 'Reimer proposal', and copies of the Reimer proposal, the Gajac study and a report by Dr Kurt Haertel (the chairman of the PWP) dated July 1960 (Document Haertel, the 'Haertel Study') were considered. Referring to the Haertel Study, it was noted that mention of technical progress might be problematical but that it was: 'apparent from the comments in … the Reimer Proposal that it is unnecessary to incorporate the concept of "technical progress" in a European patent law since it is self-evident that an invention contributes to technical knowledge and must therefore constitute technical progress' (Document IV/2071/61-E, Section 14: 4).

Regarding the proposed exclusion of 'new plant variety or a new animal species', it was commented that:

> Even if protection of new plant varieties and processes for producing new plants is excluded under European patent law, European patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g. processes for producing new plants by irradiation of the plants themselves or the seed with isotopes. (Document IV/2071/61-E, Section 14: 5–6)

It was confirmed that these comments applied also to new animal species.

On the definition of industrial applicability, the warning was sounded that: 'it should be noted that the concept of "industrial application" is apparently interpreted differently in the individual countries of the Common Market and that, in particular, purely agricultural processes are not regarded as patentable in all countries' (Document IV/2071/61-E, Section 14: 7).

The EEC's PWP, under the chairmanship of Haertel, met for the first time in April 1961 and also considered the draft SPC produced in the previous month. At this first meeting the Reimer Proposal was considered by Haertel not to give a clear and precise definition. The PWP agreed not to include any exceptions, that is not to include more than the equivalent of Art. 52(1) EPC in Art. 11. They also agreed not to include a definition of technical progress. On Art. 12 [Art. 53 EPC

[13] The square brackets in draft laws under discussion imply that the bracketed text is tentative. Paragraph 3 was later deleted.

1973], the Co-ordinating Committee had given instructions that only inventions contrary to morality or 'ordre public' should be excluded. However, Haertel proposed that 'inventions relating to new plant or animal varieties be excluded as well'. After some discussion the PWP agreed to set 'ordre public' aside and consider: whether it was necessary to provide such exceptions; what the definition of morality should be; whether there was a European definition of morality; whether national definitions of morality should be applied; and whether something should be treated as unpatentable if it was contrary to morality in only one state (Document IV/2767/61-E: 6).

The following day, the PWP agreed that inventions that were contrary to morality should be unpatentable. Nonetheless:

> The Working Party recognised that there was no European definition of morality. The German delegation and the Chairman preferred to refer to national concepts. But the majority felt that if such a stance were taken, it would give too great a prominence to national concepts in the European Convention. The Working Party unanimously thought that interpretation of the concept of morality should be a matter for the European institutions. It was therefore enough to mention the concept of morality in Article 12, paragraph 1, without giving further details.
>
> The Chairman made two reservations. First he pointed out that the European Office was liable to interpret the concept of morality in a manner at variance with a national concept, a point on which the States were particularly sensitive. Secondly, the Chairman felt that when examining the problem of revocation, the problem of revocation of a European patent in one State on the grounds that the patent was contrary to morality there would have to be examined in greater depth … As regards 'ordre public', the Working Party investigated in what States that concept existed and how it was interpreted. It found that in the Netherlands the concept was particularly wide and the exclusion applied to an invention which merely contravened a single law. In all other States, apart from Germany, the 'ordre public' requirement existed but had no practical significance … Two solutions were put forward:
>
> (1) making no mention of 'ordre public' in the European Convention, or
> (2) mentioning 'ordre public' but qualifying it with a rider that the mere fact that an invention was contrary to a national law was not sufficient for 'ordre public' to be invoked. (Document IV/2767/61-E: 7–8)

The exclusion of '[i]nventions relating to the production of or a process for producing a new plant variety or a new animal species' was approved unanimously. However, the exclusion of 'processes of a technical nature for producing new vegetable or animal species' was delayed to allow further discussion. One delegate, Klaus Pfanner, 'stated however that a distinction had to be drawn between production by biological means and production involving external technical factors' (Document

IV/2767/61-E: 8). As discussed above, Pfanner had been a representative for Germany during the UPOV negotiations.

As a result of this first meeting of the PWP, the wording of Art. 12 [Art. 53 EPC 1973] was revised to:

> European patents shall not be granted in respect of:
> 1. *1st variant:*
> inventions the exploitation of which would be contrary to morality;
> *2nd variant:*
> inventions the exploitation of which would be contrary: (a) to morality, (b) [to the fundamental principles of] 'ordre public': the mere fact that a legal provision prohibits the exploitation of an invention shall not be decisive for the application of this Article.
> 2. new plant varieties or new animal species and purely biological processes for producing them. (Document IV/2498/1/61-E: 3)

The CoE Committee of Experts then met in May 1961, considered the draft SPC text proposed in March 1961 and the comments of the EEC's PWP from April 1961, and agreed some changes to the 'morality' and 'agriculture' exclusion clauses, which then came to read:

> There shall be no obligation to grant patents for inventions, the exploitation of which would be contrary to 'ordre public' or morality …
>
> 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. (Document EXP/Brev (61) 2 rev: 26)

Regarding the words 'ordre public', the CoE Committee of Experts commented that: 'For the English text, [it had] decided to insert the French words "ordre public", those words to be taken in a narrow sense' (Document EXP/Brev (61) 2 rev: 10). More interestingly, it was stated in relation to Art. 1 of the draft SPC, which provided that 'patents shall be granted for any new inventions susceptible of industrial application', that the notion of 'invention' itself served to exclude certain subject-matter: 'It was understood that scientific laws and theories, instructions to the human brain (such as accounting systems or rules of games), creations of form and the mere disclosure of a pre-existing fact (discovery) do not fall under the notion of "invention"' (Document EXP/Brev (61) 2 rev: 10).

Art. 2 of the draft SPC from March 1961 was revised: 'The last phrase of the second paragraph ("purely biological, horticultural or agricultural processes") [being] added to meet the observations of certain experts' (Document EXP/Brev (61) 2 rev: 10–11).

In November 1961 the sub-committee of the CoE Committee of Experts proposed a draft of the CEPC (Document EXP/Brev II (61) 5).

However, later that month at the meeting of the Committee of Experts itself, Haertel:

> speaking as Chairman of the Common Market Working Party rather than as a German expert, said that the Convention under consideration by that Working Party [i.e. the CEPL] would be open to accession by other States [i.e. it would not be restricted to members of the EEC]; it had the same objectives as the draft [CEPC] before the Committee of Experts, but was much more comprehensive. (Document EXP/Brev (61) 8: 12)

Some of the experts wanted to press ahead with the CEPC; others felt that in view of the CEPL it was better to postpone any consideration of the CEPC. The latter group won out and the CEPC disappears from our story.

At this same November 1961 meeting the wording of Arts. 1 and 2 of the draft SPC was again revised. As concerns the exclusions from patentability, the 'morality' clause in Art. 1 was essentially unchanged. However, despite the suggestion from the Scandinavian delegations that the second part of Art. 2, or at least the final part referring to biological processes, be deleted (Document EXP/Brev (61) 5, referred to by Moufang 1991: 16), the 'agriculture' clause of Art. 2 was instead amended to become Art. 2(2) and to read: 'Nevertheless, the Contracting States shall not be bound to provide for the grant of patents in respect of plant or animal varieties or of essentially biological processes for the production of plants or animals' (Document EXP/Brev (61) 8: 16).

Thus, while commenting that the 'allusion to "plant or animal varieties" remains much as it was' (Document EXP/Brev (61) 8: 4), the Committee had nonetheless settled on this term 'plant or animal varieties', presumably to avoid confusion by reflecting the language of the UPOV Convention settled that month. However, as Crespi (1992: 169–70) points out, even those working on plant breeders' rights 'especially in the context of UPOV, have not found it necessary in the past to fix upon a rigid definition of the term'.

On the question of 'processes for the production of plants or animals', the narrow term 'purely' was replaced by the broader term 'essentially', with the Committee commenting that:

> 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 hybridisation 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 were involved (use of a particular type of instrument in a grafting process, or of a special greenhouse in growing a plant), it being understood that such technical devices may perfectly well be patented themselves, but not the biological process in which they are used. (Document EXP/Brev (61) 8: 5, emphasis in original)

This clearly demonstrates that the exclusion of 'essentially biological processes' in Art. 53(b) EPC relates to processes for the production of known types of plants and animals as well as of new types, and was confirmed in the CoE Council of Ministers report in August 1962 in essentially the same terms (Document CM (62) 160: 4).

In Spring 1962 AIPPI submitted comments on the draft SPC, asking for clarification on the question of the patentability of microbiological processes (Document EXP/Brev (62) 1, referred to in Moufang 1991: 17). This was supported by the British, Swedish and Swiss delegations.

At the fifth meeting of the EEC's PWP in April 1962, the PWP decided to endeavour, for Arts. 11 and 12, to follow closely the wording of the draft Arts. 1 and 2 SPC. For Art. 12(2) it was decided to adopt the wording of draft Art. 2(2) SPC. However, following a proposal from the French delegation, a reference to publication was inserted into Art. 12(2) [Art. 53(a) EPC] (Document 3076/IV/62, Section 4: 137). This amendment was later challenged unsuccessfully by the Swiss delegation, but was removed some thirty-eight years later in the revision of the EPC that produced EPC 2000.

The draft CEPL was in a form ready for publication in May 1962. Art. 12 [Art. 53 EPC 1973] had become Art. 10 and had been brought into line with the draft of Art. 2 SPC to read:

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to morality *or* to the fundamental principles of 'ordre public', *provided that this Article shall not apply merely because the exploitation of the invention is prohibited*;
(b) plant or animal varieties or *essentially* biological processes for the production of *plants or animals*. (Document 4488/IV/62-E, emphasis in original)

Meanwhile, Art. 9 [Art. 52(1) EPC] contained no list of exclusions and read: 'European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step' (Document 4488/IV/62-E).

At the sixth meeting of the EEC's PWP in June 1962, the question of putting an exemption for microorganisms into the exclusion of

Art. 10(b) (i.e. Art. 53(b) EPC) was discussed, but was not acted on (Document 6551/IV/62-E: 7–8).

The CoE Committee of Experts met in July 1962, considering what was, with minor unsubstantial differences, the final text of the exclusion of Art. 2 SPC. Following AIPPI's comments, Art. 2(b) included an exemption for microbiological processes and their products, and, bringing the text into line with the draft CEPL, Art. 2(a) now referred to 'publication' as well as 'exploitation':

> The Contracting States shall not be bound to provide for the grant of patents in respect of
>
> (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, the mere prohibition of the exploitation of the invention not making it so contrary.
> (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 or the products thereof. (Document CM (62) 160: 11)

At the tenth meeting of the EEC's PWP in September 1963, the majority agreed to leave Art. 9 [Art. 52(1) EPC] specifying just the requirements of novelty, inventive step and industrial application: 'Mr *Pfanner* made the point that it would be inappropriate to change this article which had influenced the formulation of the Strasbourg draft at a time when the latter draft was soon to be signed.' The wording was to be brought into line with the SPC draft and a proposal to introduce the microorganism exemption into Art. 10(b) [Art. 53(b) EPC] was agreed (Document 9081/IV/63-E-Final, Section 11: 64–5, emphasis in original).

The SPC was considered by the meeting of the Ministers' Deputies in October 1963 and signed in November 1963.

Work on the CEPL continued. At the fourteenth meeting of the EEC's PWP in June 1964, the chairman noted that: '[the German and Dutch] delegations had been asked to draw up a note clarifying Article 9 of the Convention with a list of what would not be considered inventions. It would specify, in particular, that methods of medical treatment were excluded from patentability.' Although not directly pertinent to exclusions from patentability, an exclusion from infringement was discussed and:

> the Working Party decided to provide that prescriptions prepared by a pharmacist on a doctor's instructions would not constitute infringement if the pharmacist's preparation was the same as a medicament protected by a patent. … The Working Party thought that such a provision could be included in the

Convention. It felt that while its practical scope was quite small, its psychological impact was considerable. Such a provision recognised the principle of freedom to exercise the medical profession. (Document 6498/IV/64-E, Section 3: 13)

The question of providing patent protection for 'second indications', that is inventions relating to the second or further medical use of a material already known to have a medical use, was discussed with no outcome (Document 6498/IV/64-E-Final, Section 3: 14–15).

In October 1964, for the fifteenth meeting of the PWP, the German and Dutch delegations had submitted their proposal (Document 9663/IV/64) for a list of subject-matter that should not be considered eligible for patenting. This was essentially an extended version of the Reimer proposal. The PWP had to consider whether to insert the listing into Art. 9 [Art. 52 EPC] or Art. 10 [Art. 53 EPC]. The listing included methods of therapy and it was considered that although their inclusion would have the same effect irrespective of which Article was used as the vehicle, Art. 9 should be used since Art. 10 corresponded exactly to Art. 2 SPC. The inclusion of diagnostic methods was also agreed (Document 11821/IV/64-E, Section 8: 3–4).

In January 1965 the final revised draft of the CEPL was produced with Art. 9 and Art. 10 [Art. 52 and 53 EPC 1973] as follows:

Article 9

(1) European patents shall be granted for inventions which are new, which involve an inventive step and which are susceptible of industrial application.
(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
  (a) scientific knowledge and theories as such;
  (b) mere discovery of substances occurring in nature;
  (c) purely aesthetic creations;
  (d) financial or accounting systems, rules for playing games or other systems, insofar as they are of a purely abstract nature;
  (e) methods of therapy, including diagnostic methods.

Article 10

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by laws or regulations in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof. (Document 2335/IV/65-E)

There the question of a unified European law on the grant of patents rested until 1969.

2.6 The 1960s pause and the arrival of the PCT

The UK had applied to join the EEC in 1961 and was rebuffed by France in 1963. Negotiations continued, but France's President Charles de Gaulle again indicated that he would veto the UK's entry in November 1967. De Gaulle resigned in April 1969. A limitation on the national ability to define what was or was not patentable, when a major European competitor was not so limited, would clearly have been contrary to the national interests of Germany and France (especially given Germany's history of manipulating patent law to its advantage – see Dutfield 2009), and it is accordingly of little surprise that further progress on harmonisation in the European Community stalled.

With development of a unified European patent law on hold, the forum for international harmonisation shifted in 1966 to BIRPI.[14] The US delegation made a proposal to the International (Paris) Union for the Protection of Industrial Property and in September 1966 the Executive Committee of that Union recommended BIRPI (now WIPO) to study possible solutions for reducing duplication of effort by applicants and national patent offices. A draft Patent Cooperation Treaty was produced in May 1967 (Document PCT/I/3) and a revised draft was produced in July 1968 (Document PCT/III/5).

The PCT was and is a system whereby a single patent application may potentially become a national or regional patent application in any of the Contracting States. The first substantive step in the handling of a PCT application is an 'International Search' conducted by one of many national or regional patent offices. At the time the PCT was signed, and indeed at the time it came into force, the relevant patent offices did not all have experience in searching inventions in all technological fields.

Thus, importantly, draft Rule 39.1 PCT set out the subject-matter that the international searching authorities would not have to search. This 1969 draft, which was adopted with little change, listed most of the exclusions from Arts. 9 and 10 CEPL, but also included 'mere presentations of information' and 'computer programs to the extent that the International Searching Authority is not equipped to search prior art concerning such programs' (Document PCT/DC/5).

[14] In 1893 the secretariats of the Paris Union and the Bern Union were joined in BIRPI. In April 1970 WIPO incorporated BIRPI and its functions.

2.7 The process restarts

From May 1969 to June 1972 a series of Intergovernmental Conferences (IGCs) were arranged by European countries to work towards a common system for the grant of patents (the 'Luxembourg Conferences'). At the first IGC a memorandum was submitted confirming that the six Member States of the EEC had studied the possibility of setting up such a system and concluded that two conventions were required, one open to all European countries and the other covering the EEC, that is the EPC and the CPC (Document BR/2/69). The CEPL, the SPC and the 1968 draft of the PCT were considered.

The drafting of the substantive parts of the EPC was to be the work of Working Party I (WP-I), which held its inaugural meeting in May 1969 chaired by Haertel. WP-I began with a version of Art. 9(2) [Art. 52(2) EPC 1973], which read:

(2) Inventions within the meaning of paragraph 1 shall in particular exclude:
  (a) scientific deductions and theories as such;
  (b) the mere discovery of materials occurring in nature;
  (c) purely aesthetic creations;
  (d) methods of financing and book-keeping, the rules of games and other systems, in so far as they are of a purely intellectual nature;
  (e) methods of treatments, including methods of diagnosis.

At the first meeting of WP-I in July 1969, the UK and Swedish delegations suggested that the list of subject-matter that should not be deemed to be inventions should be placed in the EPC Rules rather than in Art. 9 [Art. 52 EPC 1973]. WP-I disagreed, arguing that the list 'was a substantial provision fixing the conditions for the grant of patents'. Regarding the contents of the list, WP-I incorrectly commented that it was based on draft PCT Rule 39. This was incorrect since, to a large extent, the list corresponded to Art. 9(2) CEPL 1965. The exclusion of presentations of information and computer programs had not been suggested at this stage. The draft of Art. 10 [Art. 53 EPC 1973] was based on Art. 2 SPC (Document BR/7/69: 9–10).

Following the first meeting of WP-I, Art. 9(2) [Art. 52(2) EPC 1973] was amended to include methods of surgery and to make minor amendments to sub-paragraphs (a) and (d):

(a) scientific and mathematical theories as such; …
(d) commercial, financial or book-keeping methods, the rules of playing games and other systems, in so far as they are of a purely intellectual nature;
(e) therapeutic or surgical methods for treatment of the human or animal body, and diagnostic methods. (Document BR/6/69)

Although the July 1969 text of Rule 39.1 PCT included computer programs and presentations of information, the text of Art. 9(2) [Art. 52(2) EPC 1973] remained essentially unchanged until January 1971, that is well after the PCT rule was proposed and indeed after the PCT had been finalised in June 1970.

The second IGC in January 1970 considered the case of computer programs, which had been made unpatentable in the revised French patent law of 1968, but considered that 'the present state of developments did not allow it to be determined whether computer programmes could be the subject of a patent' (Document BR/26/70: 7).

WP-I returned to the list of exclusions in Art. 9(2) [Art. 52(2) EPC 1973] in its seventh meeting in January 1971, and generally followed the German delegation's suggestion to align the text with the PCT rule (e.g. deleting 'as such' from sub-paragraph (a)), but decided to leave the treatment of animals, computer programs and presentations of information for further discussion (Document BR/94/71: 10). By the end of January 1971 the exclusions in Art. 9(2) [Art. 52(2) EPC 1973] thus came to read:

(a) scientific and mathematical theories;
(b) the mere discovery of materials occurring in nature;
(c) purely aesthetic creations;
(d) schemes, rules or methods of doing business, performing purely mental acts or playing games;
(e) methods for treatment of the human [or animal] body by surgery or therapy, as well as diagnostic methods;
(f) [mere presentations of information;]
(g) [computer programmes.] (Document BR/88/71)

At the fourth IGC in April 1971 it was agreed that WP-I should re-examine Art. 9(2), in particular the bracketed provisions, in view of the comments made by interested parties. It was also asked to consider whether Art. 10(b) [Art. 53(b) EPC] was compatible with the nature of plant and animal varieties as non-inventions (Document BR/125/71).

WP-I addressed these points at its ninth meeting in October 1971, agreeing to the Swiss proposal to change 'mathematical theories' to 'mathematical methods', to the deletion of the brackets around 'animals' in sub-paragraph (e), and to the deletion of the brackets around sub-paragraphs (f) and (g). It rejected proposals to exempt from sub-paragraph (b) 'materials isolated and defined for the first time', to exempt from sub-paragraph (e) new therapeutic applications of known substances and processes and laboratory equipment used for diagnosis, and to delete 'animals' from sub-paragraph (e). The first of these rejections is notable in view of the Rules introduced into the EPC September 1999

following the adoption of the EBD. Regarding processes and laboratory equipment, it was considered that processes would be excluded insofar as they were used by doctors and that the equipment was in any event not excluded. On the subject of computer programs, the UK delegation had argued that they should not be patentable and that a computer program 'was merely the mathematical application of a logical series of steps in a process which was no different from a mathematical method excluded under [sub-paragraph] (a). However some form of protection might be desirable for computer programmes but this, which might be considered by WIPO, called for some new form and not under existing patent laws'. The UK's definition was not adopted, the decision being to leave this to the EPO and the national courts. It was considered that some protection might be given to computer programs, but *not* patent protection (Document BR/135/71: 47–50).

Yet again the UK's proposal to delete Art. 9(2) [Art. 52(2) and (4) EPC 1973] and to place the exclusions in the Rules (where they could be altered on the basis of a simple majority in the EPO's Administrative Council) was rejected on the basis that 'amendments to the rules [*sic*] on patentability were of such importance that it was undesirable to allow the provisions to be amended by the [EPO's] Administrative Council. The development of patent law should be left to the courts and *the question of amendment should be left to revision by a Diplomatic Conference*' (Document BR/135/71: 51, emphasis added). This should later have given the Boards of Appeal clear guidance that the EPC Rules should not be used to construe the exclusions narrowly and that judicial sleight of hand should not be used to emasculate the exclusions.

On the question whether Art. 10(b) [Art. 53(b) EPC] was incompatible with UPOV, it was agreed that it was not. Moreover, the UK delegation's suggestion to delete 'essentially biological processes' from this exclusion was rejected.

As a result, Art. 10 was left unchanged and sub-paragraphs (a) and (d) to (g) of Art. 9(2) [Art. 52(2) and (4) EPC 1973] were revised to read:

(a) scientific theories and mathematical methods; …
(d) schemes, rules or methods of doing business, performing purely mental acts or playing games;
(e) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods;
(f) mere presentations of information;
(g) computer programmes. (Document BR/139/71)

The exclusions were considered again by the fifth IGC in January/February 1972, where yet again it was necessary to reject proposals to

delete the exclusions of Art. 9(2) [Art. 52(2) and (4) EPC 1973] or to shift them into the Rules. The IGC rejected these proposals 'since it considered it necessary, from the entry into force of the system, to create the greatest possible legal certainty in this field' (Document BR/168/72: 9). Likewise it stated that '[s]ubject to final drafting, paragraph 2 will thus remain in the Convention, and it may only be amended by means of a revision of the Convention'. Certain of the delegations had thought it '*was inappropriate to insert a fundamental subject such as that of patentability in the Implementing Regulations which were subordinate to the Convention*' (Document BR/168/72: 12, emphasis added). As we noted earlier, one would have thought that such comments would have made it clear to the EPO Examiners and Appeal Boards that they should not ignore or interpret away the exclusions set down in the Articles of the EPC and to the members of the Administrative Council that they should not amend the EPC Rules so as to restrict the scope of the exclusions. Sadly, this was not sufficiently clear, as will be explained in this book.

The IGC also rejected a suggestion to make the list of exclusions in Art. 9(2) exhaustive 'so as to retain the flexibility necessary to the system' (Document BR/168/72: 9). The wording of Art. 9(2), however, was not fully to the IGC's satisfaction and WP-I was instructed to review several points: the Yugoslav delegation had asked that scientific discoveries be added to the exclusions of sub-paragraph (a); the possibility of combining sub-paragraphs (a), (d), (f) and (g) was to be evaluated; the retention of 'animals' in sub-paragraph (e) was to be pondered over; the manner of protecting new medical indications for drugs was to be investigated; the exclusion of only 'physical' methods of therapy was of concern; and just what might be an excluded method of diagnosis came to the surface. This last issue is of interest since the act of diagnosis, unless performed by a computer, is a mental act, and the wording of an exclusion of methods of diagnosis might readily allow it to be side-stepped. The exclusions of presentations of information and of computer programs were generally accepted but it would be inaccurate to say that the exclusion of computer programs was trouble-free and unanimously approved.

In their eleventh meeting, in February/March 1972, WP-I addressed these issues, agreeing to revise sub-paragraph (a) to exclude scientific discoveries 'as such' (a Swiss proposal) and to delete sub-paragraph (b). Here it must be remembered that the words 'as such' have immense importance to the exclusions of Art. 52(2) EPC. The relocation of the exclusion of computer programs to sub-paragraph (d) was considered, with the UK delegation being concerned that this might allow such

programs to 'be able to obtain patent protection by indirect means and that, broadly speaking, the free development of precedents – which is of paramount importance in this still very uncertain field – would be hindered'. Most of WP-I agreed with the relocation as the inclusion would 'make for the exclusion of computer programs as such, while allowing precedents to be used to assess the patentability of any related inventions'. The majority were concerned that a sub-paragraph devoted *only* to computer programs might be interpreted as excluding inventions *related to* a program. WP-I agreed to add 'the use of computers' to the exclusions of sub-paragraph (d). Despite the assertion that this would change little, happily the proposal was not followed (Document BR/177/72).

On the question of the new therapeutic use of a known substance, there were concerns as to how this could be covered: 'It was recalled that, at least in practice, it was not open to the proprietor of such a patent to institute legal proceedings against a person infringing the patent, namely a doctor or possibly a pharmacist'. Patent protection via purpose-limited product claims was considered by WP-I to be the more satisfactory route and sub-paragraph (e) was amended following proposals by the French delegation. The applicability of the medical treatments exclusion to animals was confirmed, and the French proposal to restrict the excluded diagnostic methods to those 'applied to the human or animal body' was accepted. WP-I agreed that the medical treatments exclusion did not cover psychological procedures or autopsies, and that diagnostic apparatus would in principle be patentable. The Dutch delegation had suggested that surgery for destructive purposes (e.g. sterilisation of insects) should explicitly not be excluded. WP-I agreed that such treatments should not be excluded but thought that no amendment was needed (Document BR/177/72: 4–6).

As of May 1972, the list of non-inventions read as follows:

(a) scientific theories, discoveries and mathematical methods as such;
(b) purely aesthetic creations;
(c) schemes, rules and methods for performing purely mental acts, playing games or doing business, and programs for computers;
(d) methods for treatment of the human [or animal] body by surgery or therapy and diagnostic methods practised on the human [or animal] body; this provision shall not apply to inventions having as their subject-matter substances or compounds, whether or not known, which are used for the first time for the purposes of practising such methods;
(e) mere presentations of information. (Document BR/199/72: 56)

At this stage, the 'as such' qualification of the exclusions, which occurs in Art. 52(3) EPC, began to be a topic of concern. At the third meeting

of the Co-ordinating Committee in June 1972, the Swiss delegation argued that any mathematical methods and their use should be considered as 'intellectual activities and therefore excluded from patentability'. The Committee agreed and considered that the words 'as such' in sub-paragraph (a) should apply to discoveries only (Document BR/218/72: 4).

The sixth and last IGC took place later in June 1972. The endgame would lie in the Munich Diplomatic Conference of September/October 1973. The Swiss had been concerned that 'as such' in sub-paragraph (a) should apply only to discoveries, and the importance of this term was coming to centre stage. The IGC agreed. The Swiss felt that prophylactic treatments should be mentioned explicitly – the IGC disagreed. The Dutch and Austrian delegations were concerned about the wording of the exclusion as applied to the treatment of animals. The IGC disagreed, holding that 'the intention behind this text was merely to exclude from patentability all therapeutic treatments practiced on animals, the aim of this provision being to exclude from patentability treatments falling within the meaning of treatments intended to cure or alleviate the suffering of animals' (Document BR/219/72: 8–11).

The question of patent cover for compounds found to have a use as a drug or another such use was becoming more pressing. The IGC:

> noted that extending the scope of [the first medical use provision in Art. 54 EPC] beyond instances of use for the first time in an absolute sense comprised a modification of the compromise proposal … [and indeed] it did not appear justified to exonerate for the purposes of patentability use for the first time of a substance or composition whether or not known, from the conditions of patentability referred to in [Art. 52(1) EPC]. (Document BR/219/72: 11)

Patent cover for known substances found to have (different) medical uses was therefore not yet settled.

2.8 The home straight – the Munich Diplomatic Conference of September/October 1973

In December 1972 the draft of the EPC that would be considered at the Munich Conference was ready. The exclusions, now in Arts. 50 and 51 [Arts. 52 and 53 EPC 1973] were listed as:

(a) discoveries as such, scientific theories and mathematical methods;
(b) purely aesthetic creations;
(c) schemes, rules and methods for performing purely mental acts, playing games or doing business, and programs for computers;

(d) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body;
(e) mere presentations of information.

…

(a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof. (Document M/1)

The 'as such' provision of Art. 52(3) EPC had yet to appear, and the patent-eligibility of substances found for the *first* time to have medical utility was now provided for by a special exemption to the definition of novelty in Art. 52(5) [Art. 54(5) EPC 1973].

In the months before the conference, delegations made further submissions and suggestions for amendment. In March 1973 the UK delegation wished it understood that 'therapy' was 'concerned with the treatment of illness or disease and does not extend, in the case of animals, to treatments effected with a view e.g. to increasing the quantity or quality of the ultimate product' and generally expressed concern with the introduction of purpose-limited product claims (Document M/10: 42–43). Under UK patent practice, a purpose limitation for a product had simply been interpreted as meaning that the product was *suitable for* the specified purpose and not as meaning it required an intention that it be used for that purpose, that is requiring the state of mind of a potential infringer to be relevant to the question of whether infringement had occurred.

The German delegation, also in March 1973, made particularly crucial proposals to limit the effect of the exclusion of things not considered to be inventions, by the inclusion of a separate paragraph applying the 'as such' qualification to *all* such exclusions and to remove medical methods into a separate paragraph *not* qualified by the 'as such' provision. Since the very first proposal that medical methods should be excluded, it had been appreciated that their placement in a clause of their own or with the exclusions of Art. 53 EPC 1973 had been considered to be equivalent. Qualifying words such as 'purely', 'merely' and 'as such' had *never* been used in relation to the medical methods exclusion. Indeed, twenty-seven years later the medical methods exclusion would eventually find its way into Art. 53(c) EPC.

In 1973, however, the legal fiction that medical methods were not susceptible of industrial application was the German delegation's

preferred route: 'Pursuant to paragraph 2(a), discoveries – as such – are not regarded as inventions within the meaning of paragraph 1. A similar limitation is also contained in (e) (mere presentations of information). This could lead to the erroneous conclusion that a broad interpretation should be given to items not limited in this way in paragraph 2' (Document M/11: 64).

This was not a recommendation that the exclusions be construed narrowly. It was simply a suggestion that an unnecessarily broad construction of an exclusion without the qualification might be the unintended result. The German delegation continued with their recommendation:

> The limitation should therefore be set forth in a general manner in a separate paragraph. In addition it might be considered illogical to include (d) [i.e. the medical methods] in the list since it [(d)] deals with inventions proper, according to the normal use of the term, which are traditionally excluded from patentability because they are not susceptible of industrial application. The items covered in paragraph 2(d) should therefore be the subject of a separate provision in a separate paragraph. (Document M/11: 64)

In June 1973 the Dutch delegation indicated that the reassurance that substances and compositions are not excluded from patentability, simply because medical methods using them were, should extend to apparatus too. It also sought clarification that the exemption in the definition of novelty, permitting purpose-limited product protection, should be limited to the first medical use. This was reiterated in September 1973 (Documents M/32 and M/52/I/II/III).

The Conference took place in September and October 1973, with the final text of EPC 1973 being agreed after much deliberation. In Main Committee I the chairman (Haertel) commented on the exclusion of programs for computers saying that, at the sixth IGC in June 1972, the attempt to define programs had been in vain and that '[t]he European Patent Office would simply have to be relied upon subsequently to interpret this expression unequivocally' (Document M/PR/I: 28).

Regarding the medical methods exclusion, Main Committee I 'endorsed the United Kingdom delegation's interpretation of the text (see M/10 …) whereby "treatment of the animal body by therapy" means the treatment of illness or disease and not, for example, treatment effected with a view to increasing the quality or quantity of the production of an animal product' (Document M/PR/I: 28). The German delegation had suggested that the medical methods be placed in a separate exclusion as actual inventions for which only the industrial application was lacking. Main Committee I agreed to put this to the Drafting Committee (Document M/PR/I: 28). The

Dutch delegation wanted it to be made clear that medical instruments should not be excluded – Main Committee I agreed to put this to the Drafting Committee, but the German delegation thought it unnecessary (Document M/PR/I: 28).

Various parties, in particular the UK and Ireland, yet again proposed putting the Art. 50(2) [Art. 52(2) and (4) EPC 1973] exclusions into the EPC Rules. The German delegation '*thought it was inadmissible, as a matter of principle, for the question of the patentability of such subject-matter or activities to be left to the Administrative Council to decide*'. This position was supported by Yugoslavia, Sweden and Portugal. The French delegation pointed out that 'Article 50 [Art. 52 EPC] was a fundamental Article of the Convention. The provisions governing patentability should not be left to the Administrative Council; the latter *ought not to be able, irrespective of the legal and technical means employed, to amend the individual provisions on its own responsibility*.' The Swiss delegation agreed that the provisions should not be moved and the UK delegation renounced the idea (Document M/PR/I: 28, emphasis added).

On a proposal from the German delegation (Document M/11: 64), Main Committee I agreed to specify in paragraph 3 that 'the patentability of the subject-matter and activities listed in paragraph 2 was excluded only to the extent to which an application or patent related to the subject-matter or activities as such' (Document M/PR/I: 29).

Regarding the Swiss suggestion (Document M/54/I/II/III: 7) that in Art. 51(a) [Art. 53(a) EPC 1973] the reference to 'publication' be deleted, the chairman appeared to be clearly unhappy and the Swiss delegation backed down (Document M/PR/I: 29). The suggestion was later revived and followed in the 2000 revision of the EPC.

On the special provision for purpose-limited product claims for substances found for the first time to have medical use, the Dutch delegation wanted the wording improved. 'It said that on no account did it wish, with its proposal [Document M/32], to break away from the principle that only the first application in respect of the use of a known substance or composition in a method for treatment of a human or animal body by surgery or therapy is patentable, and not the second and subsequent applications'. Main Committee I referred this to the Drafting Committee (Document M/PR/I: 29). The Yugoslav delegation thought the wording unclear and the chairman clarified that:

> [T]he aim … was to make clear that a known substance (or a known composition) which, since it formed part of the state of the art, was no longer patentable, nevertheless could be patented for the first use in a method for treatment of the human or animal body by surgery or therapy; however, a further patent

could not be granted if a second possible use were found for the same substance, irrespective of whether the human or animal body was to be treated with it … The Chairman noted that his views were shared by the Governmental delegations. (Document M/PR/I: 29)

UNICE (Union des Industries des pays de la Communauté européenne) suggested that a first human use would not prevent a first animal use and vice versa, but the chairman (Haertel) pointed out that Main Committee I did not want to endorse that position (Document M/PR/I: 29). Rapporteur Paul Braendli (later the second president of the EPO) reported that Main Committee I confirmed that the Art. 50(2) [Art. 52(2) EPC] exclusions were basic principles of the Convention and that only the *first* medical use was patentable by virtue of Art. 52(5) [Art. 54(5) EPC 1973] (Document M/Annex I: 184).

The exemption to the provisions relating to novelty that allowed the purpose-limited product protection of substances found for the first time to have a medical use was contained in Art. 54(5) EPC 1973.

In parallel with the EPC, work had continued on a patent convention covering the European Union. This, the CPC, was signed in 1975 and applies the same criteria for patentability as the EPC. However, as of December 2011 the CPC has yet to come into force.

The EPC and the PCT came into effect in July 1978 and the national laws of the EPC Contracting States were brought substantially into line with the EPC.

2.9 Discontent sets in

In the early years of the operation of the EPO, there were numerous amendments to the EPC Rules but none to the Articles. However, even in those early years it became clear that certain of the exclusions to patentability were hindering the possibilities for patenting subject-matter in certain industries, in particular computing, pharmaceuticals and agrochemicals.

From February 1980 to June 1985 attempts were made, unsuccessfully, to strengthen patent protection globally by amendment of the Paris Convention, which, like the PCT, is administered by WIPO (Sell 1998: 107–40). In October 1983 the European Commission indicated that the legal situation within the EU concerning biotechnology suffered from deficiencies and discrepancies in statute law and a general shortage of case law, and recommended that it should work out proposals for a European approach to intellectual property rights in this field (Document COM(83) 672 final/2: Annex). In June 1985 the European

Commission announced its intention of proposing measures concerning patent protection of biotechnological inventions (Document COM(85) 310: 37).

In March 1986 the 'Intellectual Property Committee' was founded by Pfizer, IBM and eleven others: Merck, General Electric, DuPont, Warner Communications, Hewlett-Packard, Bristol-Myers, FMC, General Motors, Johnson and Johnson, Monsanto and Rockwell International. This organisation was to play a key role in the negotiation of TRIPS in the context of the Uruguay round of the General Agreement on Tariffs and Trade (GATT), which began in September 1986 and which, from the outset, was intended to address the question of intellectual property rights. In June 1988 the basic framework for agreement between Japan, the USA and the European Union on intellectual property rights had become clear.

In October 1988 the European Commission put forward its proposal for the EBD (Document COM(88) 496 final SYN 159). In the document accompanying this first draft, it was stated that:

> The provisions of the Directive systematically *adapt* existing patent law principles to the field of biotechnology with the aim of securing the application of patent laws in this important area as effective [*sic*] as possible … [T]his Directive should allow inventors and investors in the Member States to benefit from patent protection as effective as that in the competitive markets of Japan and the United States of America. (Document COM(88) 496 final SYN 159: 6, emphasis added)

The Commission acknowledged the existence of the EPC and the EPO, but indicated that the position with the EPC was unsatisfactory:

> Although the solutions provided for in the Examination Guidelines of the EPO offer valuable guidance for the examining organs of the EPO, … they are handicapped by the fact that they are neither binding on the Board of Appeals of the EPO … nor on national courts … There is no mechanism in the EPC, such as by Examination Guidelines, to provide for *mandatory* guidance on the questions arising in respect of patenting biotechnological inventions … As regards the scope of protection of biotechnological inventions and the interrelation between the effects of patents and plant breeders' rights, the EPC does not regulate these issues and thus no competence of the European Patent Office exists. (Document COM(88) 496 final SYN 159: 17, emphasis added)

Paying lip service to the fact that the EPC is not an EU instrument and thus that the EU has no power to impose its own interpretation of the provisions of the EPC, the Commission commented that: 'The proposed Directive is intended to coexist, and not to interfere with, the existing international legal network in which the EPC, the UPOV

Convention and the Budapest Treaty are the cornerstones. It is therefore indispensible that any proposal must be compatible with the provisions of these conventions' (Document COM(88) 496 final SYN 159: 22). Thus the Commission argued that the proposed Directive 'respects the limitations existing under the pertinent provisions of the EPC' and that it was therefore primarily based on four assumptions concerning the EPC's exclusions. However, two of the assumptions that were listed were clearly incorrect: 'plant and animal varieties *as such* … are excluded from patent protection' and 'methods for treatment of the animal body by surgery or therapy and diagnostic methods practised on the animal body are not regarded as inventions which are susceptible of industrial application *if practised for a therapeutic purpose*' (Document COM(88) 496 final SYN 159: 23, emphasis added). Moreover, the Commission considered that it was 'clear that the proposed Directive will not interfere with the EPC, nor will it establish any interdependence in a legal sense between the two bodies of law' (Document COM(88) 496 final SYN 159: 25).

Almost in the same breath, the Commission demonstrated that the intention was *not* to maintain compatibility or avoid interference with the EPC: 'It is clear that the framework of the current rules on the patenting of living matter now reflects incorrect assumptions … [T]he Directive provides for principles which will ensure that such rules remain strictly limited to their original aim' (Document COM(88) 496 final SYN 159: 24). Likewise, it commented that '*on the whole* the proposed Directive corresponds to the EPC' (Document COM(88) 496 final SYN 159: 24, emphasis added). The EBD *was* intended to coerce the judgments of the EPO: 'where provisions of the Directive clarify questions not yet answered in the Examination Guidelines of the EPO, they do so with the necessary legislative authority … [T]he Directive will offer the EPO firm grounds on which to develop further its patent granting practice according to the latest needs of industry and science in biotechnology' (Document COM(88) 496 final SYN 159: 25).

Art. 3 of the first draft EBD read as follows:

1. Micro-organisms, biological classifications other than plant or animal varieties as well as parts of plant and animal varieties other than propagating material thereof of the kind protectable under plant variety protection law shall be considered patentable subject matter …
2. Notwithstanding the provisions of paragraph 1, plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously known biotechnological process. (Document COM(88) 496 final SYN 159: 75)

Draft Art. 3(1) would have overridden Art. 53(b) EPC by categorically stating that only plant and animal varieties in integral form, that is as such, and any plant propagating material protectable by plant variety protection should be excluded from patentability. Draft Art. 3(2) overrode Art. 3(1) and went even further – the only plants and plant materials that could be excluded were those produced by the non-patentable use of a known *biotechnological* process.

In the commentary on the draft, the Commission pulled out of thin air the *ratio legis* for Art. 53(b) EPC as being that the excluded subject-matter lacked industrial applicability. Likewise it confirmed that its intention with Art. 3(1) was that: 'it is not plants and animals in general which are excluded from patentability but only plant and animal varieties *as such*, i.e. in the genetically fixed and stable form of a variety. Thus, Article 3 first sentence will establish the principle that patent protection is available for plant and animal material which is not a variety' (Document COM(88) 496 final SYN 159: 34–5). The reader will recall that the 'as such' qualification of Art. 52(3) EPC applies to the exclusions of Art. 52(2) EPC and *not* to those of Art. 53 EPC.

Art. 4 of the first draft of the EBD read as follows: 'Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject matter' (Document COM(88) 496 final SYN 159: 75). This of course is contrary to the 'essentially biological processes' exclusion of Art. 53(b) EPC.

Art. 6 of the first draft of the EBD provided that: 'A process consisting of a succession of steps shall be regarded a microbiological process, if the essence of the invention is incorporated in one or more microbiological steps of the process' (Document COM(88) 496 final SYN 159: 75). This clearly would have placed a constraint on the interpretation of the word 'essentially' in Art. 53(b) EPC. That this was intended is clear from the commentary: 'The Article will make it necessary for the principle to be adopted that a multi-step process in which the essence of the invention is incorporated into a microbiological step is not deprived of its microbiological character simply because the process contains other, non-microbiological, steps' (Document COM(88) 496 final SYN 159: 40). This of course would make the question of whether a multi-step process is 'essentially biological' one of presentation and of comparison with the prior art.

The meaning of 'essentially biological processes' was returned to in Art. 7 of the draft EBD, which stated: 'A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter' (Document

COM(88) 496 final SYN 159: 76). This in effect is a redefining of 'essentially' as 'purely'. This is confirmed in the accompanying commentary:

> [I]t is necessary to lay down a principle of patent laws which establishes the extent to which human intervention is required in order to ensure that an invention will be considered patentable subject matter. In this connection, it is important to distinguish between traditional breeding activities and other forms of human intervention in biological matter … Article 7 of the Directive … is intended to exclude only traditional biological breeding activities based upon selection and as such may be regarded as slightly more liberal than the Guidelines [for Examination in the European Patent Office]. … Any human intervention aside from selection … would remove the process from the field of 'essentially biological' processes. (Document COM(88) 496 final SYN 159: 40–1)

The EBD was intended to satisfy the interests of industries besides the agro-industry. The exclusion of 'discoveries' in Art. 52(2) EPC, of concern to the biotech industry in general and to the pharmaceutical industry, was addressed in the drafts of Arts. 8 and 9 EBD:

> A subject matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered unpatentable for the reason only that it formed part of said natural material …
>
> A subject matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered as an unpatentable discovery or as lacking novelty for the reason only that it formed part of said natural material. (Document COM(88) 496 final SYN 159: 76)

This is saying that a natural product, when isolated or purified, shall be patentable as a product per se, and that it is not only its novel and inventive *use* that may be patented. The accompanying commentary considered that: 'Where a substance is claimed in a form which results from human intervention in the material world, it is more than a mere discovery, irrespective of whether the intervention is simple or complex. Article 9 is necessary to ensure that this distinction is correctly applied in patent law' (Document COM(88) 496 final SYN 159: 43).

In March and May 1990 the EU and the USA submitted their draft proposals for TRIPS, which would form part of the Uruguay round of negotiations on GATT. A first draft of TRIPS was ready by December 1990, and a 'final' draft was issued by Director General Dunkel in December 1991. In 1993 the North American Free Trade Agreement (NAFTA) was signed, including TRIPS-like provisions on intellectual property rights. TRIPS was eventually signed in April 1994 and came into effect in January 1995 (see e.g. Drahos and Braithwaite 2002, Sell

2003, Matthews 2002). Art. 27 TRIPS mandated minimal requirements for patent protection of inventions:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions … in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application …
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes.

While it will be clear to the reader that the list of potentially unpatentable inventions permitted by TRIPS closely follows the exclusions in the EPC, as otherwise the signing of TRIPS would have required extensive and time-consuming EPC modification, some modification of the EPC would nevertheless become required.

After passing though many stages, the amended proposals for the EBD were considered by the European Parliament in May 1994. The Parliament's proposed amendments were, to some extent, adopted (Document COM(94) 245 final) and by January 1995 a compromise text was put forward. By this stage biotechnology had become a sore topic in Europe and in March 1995 the European Parliament rejected the draft EBD. A revised text was produced in December 1995 (Document COM(95) 661 final). Art. 2(3) of the 1995 draft stated that, for the purposes of the EBD: '"essentially biological process for the production of plants or animals" means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal-breeding process' (Document COM(95) 661 final: 30).

Art. 3(2) of the draft EBD stated that 'the subject of an invention capable of industrial application which relates to an element isolated from the human body or otherwise produced by means of a technical process shall be patentable, even if the structure of that element is identical to that of a natural element' (Document COM(95) 661 final: 30). Art. 8 provided that biological materials should not be considered to be

discoveries simply because they existed in the natural world. In effect, this was intended to assert that *things* could not be discoveries, just ideas, phenomena and processes.

In line with T-19/90 Onco-mouse/HARVARD (see Chapter 8), Art. 9(2)(b) of the draft EBD declared unpatentable: 'processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and also animals resulting from such processes, whenever the suffering or physical handicaps inflicted on the animals concerned are disproportionate to the objective pursued' (Document COM(95) 661 final: 31).

In July 1997 the European Parliament approved the draft EBD, subject to certain amendments being made. The amended text was produced in August 1997 and approved by the European Parliament in May 1998. The EBD was published in July 1998, on the same day that the Technical Board of Appeal of the European Patent Office (TBoA) 3.3.04 issued its written decision in T-1054/96 (I) Transgenic plant/NOVARTIS, referring questions on the patentability of plant varieties to the Enlarged Board of Appeal of the European Patent Office (EBoA).

The final form of the EBD contained many passages that sought to impose particular meanings on the exclusions of the EPC. Perhaps the most egregious is the definition of 'essentially' in Art. 53(b) EPC as meaning 'entirely'. Thus Art. 2(2) EBD reads: 'A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.' This left open the question as to what else would be 'natural phenomena' if the crossing and selection techniques used by breeders were considered to be natural.

This emasculation of the Art. 53(b) EPC exclusion of 'essentially biological processes' was reinforced by Art. 4(3) EBD, which provided that the acknowledgement in Art. 4(1)(b) EBD that essentially biological processes were unpatentable should 'be without prejudice to the patentability of inventions which concern a microbiological or other technical process'. In other words, involvement of a *single* step in a multi-step process that is 'technical' or 'microbiological' would be sufficient for the exclusion to be evaded.

In Art. 2(3) EBD a definition was given for 'plant variety': 'The concept of "plant variety" is defined by Article 5 [CPVRR].'

Acknowledging that 'plant and animal varieties' were not patentable, Art. 4(2) EBD proceeds to allow plants and animals to be patented if claimed at a *higher taxonomic level* than 'variety': '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.' However, this wording does permit the alternative interpretation that it is the patentability of *processes* performed on or with plants or animals that is being recognised. Nevertheless, the EPO currently follows the first interpretation when applying the exclusion of plant and animal varieties.

One addition to the exclusions of the EPC that was included in the EBD was that of '[t]he human body, at the various stages of its formation and development' (Art. 5(1) EBD). This, however, we suspect, was already excluded by the contrary to morality or 'ordre public' provisions of Art. 53(a) EPC. Indeed, it seems instead to be a back-door way of relaxing the Art. 52(2) EPC exclusion of discoveries, since Art. 5(2) EBD goes on to state that: 'An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.'

Art. 6(1) EBD anticipated the elimination of 'publication' and the qualification of 'exploitation' by 'commercial' in the wording of Art. 53(a) EPC (changes which occurred in the 2000 revision of the EPC). Art. 6(2) EBD then went on to list examples of subject-matter that should be unpatentable under Art. 53(a) EPC. Many of these seem likely to have been excluded by Art. 53(a) EPC without need of clarification from the EBD.

In September 1999 the EPC Rules were amended to introduce provisions closely mirroring the terms of the EBD and shortly thereafter, in December 1999, the EBoA issued its decision G-1/98 Transgenic plant/NOVARTIS II, which generally followed the EBD. From then, it was not until G-2/07 Broccoli/PLANT BIOSCIENCE, in December 2010, that the EBoA was prepared to acknowledge that there was a conflict between what was deemed patentable for EU countries according to the EBD and what was deemed unpatentable under the EPC.

2.10 The 2000 revision of the EPC

In 1997, that is after TRIPS but before the EBD had been agreed, the then president of the EPO (Ingo Kober) had come to believe that revision of the EPC was desirable. However, in January 1998 the European Commission's representative at the sixth meeting of the EPO's Committee on Patent Law (CPL) commented that the proposed

EBD 'was compatible with the EPC, and therefore, no revision of the EPC would be needed' (Document CA/PL PV6: 22).

At the seventh meeting of the CPL in May 1998, the EPO took up the question of deleting computer programs from the exclusions of Art. 52(2) EPC. It should be noted that TBoA 3.5.01's landmark decision T-1173/97 Computer program product/IBM, deciding that computer programs were patentable, was issued in written form in March 1999. At the meeting: 'the EPO emphasised the importance of protecting software-related inventions. Deleting Article 52(2) would send an important psychological signal … In revising Article 52(2), discussions would not be confined to computer programs, but would extend to all the Article's exceptions' (Document CA/PL PV7: 9). In reply: 'The Portuguese delegation opined that the fathers of the EPC did not consider that computer programs constituted inventions, and that this view should be taken into account' (Document CA/PL PV7: 9). The Belgian delegation doubted that the time was ripe for deleting the exclusion (as a European Directive[15] on the patentability of computer-implemented inventions was then under consideration which has since fallen by the wayside): 'and the EPO confirmed it was preferable to wait for the developments in Brussels' (Document CA/PL PV7: 10).

In November 1998, at the eighth meeting of the CPL, after the EBD had been agreed and published, and before G-1/98 Transgenic plant/NOVARTIS II had been issued, the EPO commented on the need to adapt the EPC to comply with the EBD: 'Regarding the adaptation of the EPC to confirm with [the EBD] … the Office emphasised that the [EBD] merely reflected the existing practice of the EPO and the boards of appeal. For the time being, it would be sufficient to amend the Implementing Regulations; the Administrative Council would have to authorise the Committee to study the necessary modifications' (Document CA/PL PV8: 1).

On the question of immoral inventions, as covered by Art. 53(a) EPC 1973, at that meeting the attendees were told that 'The EPO took the view that inventions relating to anti-personnel mines *per se* should be excluded from patentability as contrary to "ordre public" and morality; administrative measures to this effect had already been taken' (Document CA/PL PV8: 5). The reader should note that in September 1977 the United Nations had produced the UN Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of

[15] Document COM(2002) 92 final. Interestingly, this did not suggest that computer programs *themselves* might be patentable, just programmed apparatus and processes carried out on such apparatus through the execution of software.

Anti-Personnel Mines and on their Destruction, a convention to which all EPC Member States are signatories.

Computer programs would not go away. The CPL was advised in January 1999 of the discussions of the Standing Advisory Committee before the EPO (SACEPO)[16] in September 1998, which gave unanimous support for the deletion of computer programs from Art. 52(2) EPC and '[s]upport for clarification to the effect that genetically modified plants and animals may be patented and appropriate steps to be taken to align the EPC to the EU biotechnology directive' (Document CA/PL 2/99: 1–2).

Following the SACEPO meeting, in March 1999 the president of the EPO (Ingo Kober) addressed the question of drawing the teeth of the exclusions from patentability found in the EPC. On the medical methods exclusion of Art. 52(4) EPC 1973, the president commented:

> The exclusion of medical methods from patenting is based on the assumption that, for ethical and social reasons related to ensuring provision of medical services for the public, the exercise of medical skills should not be restricted or hindered by patents as a matter of principle. A doctor is not in 'industry' [van Empel 1975: 63]. The Enlarged Board of Appeal has noted in this regard that the intention of this provision is to free from constraint non-commercial and non-industrial medical and veterinary activities (G 5/83 [Second medical indication/EISAI]). (Document CA/PL 7/99: 1)

The president continued:

> As part of the deliberations on the revision of the EPC, it is necessary to examine whether it is still justifiable to exclude all medical methods from patentability … and whether the real intention of the provision to exempt medical practitioners and veterinary surgeons from patent rights when treating individual patients directly should not be achieved in other more appropriate ways. In this regard it is necessary to examine whether it is justifiable to exclude entirely from patentability useful inventions for maintaining or restoring health of humans and animals and thereby run the risk of failing to use or impeding the role of patent protection in promoting innovation in this technical field of public interest. (Document CA/PL 7/99: 2)

In the same month the president suggested various revisions to the EPC, in particular the insertion into Art. 52(1) EPC of the words 'in all fields of technology' (in order to make the EPC TRIPS-compliant) *and the deletion of Art. 52(2) EPC in its entirety* (Document CA/PL 6/99). Even the first of these proposals was not as innocent as it might seem. It was an attempt to set in stone the 'technical character' approach set

[16] An organisation set up by the first president of the EPO, van Benthem, and containing representatives from industry, the patent professions and academia.

out the week before by TBoA 3.5.01 in T-1173/97 Computer program product/IBM:

All attempts to establish a suitable definition of the term 'invention' which would meet with the approval at European or even international level have so far failed. It has, however, been part of the European legal tradition since the early days of the patent system that patent protection should be reserved for creations in the technical field. The subject-matter of a patentable invention must therefore have a 'technical character' or – to be more precise – involve a 'technical teaching', i.e. an instruction addressed to a person skilled in the art as to how to solve a particular technical problem using particular technical means … The non-inventions listed by way of example in Article 52(2) EPC confirm that only a technical invention understood in this way can and should be patentable. The subject-matter and activities in Article 52(2) either contain no technical teaching at all, such as discoveries and scientific theories, or cannot be deemed part of the realm of technology, such as rules and methods for performing mental acts or doing business, even though all these things may well be susceptible of industrial application. Rules [42 and 43] EPC also give a clear indication that patentable inventions must have a technical character. (Document CA/PL 6/99: 1)

The president also attempted to minimise the extent to which the exclusions in the EPC should be considered to have been well thought through:

The list of non-patentable subject-matter in Article 52(2) EPC was the subject of lively discussion both in the lead-up to and at the Munich Diplomatic Conference in 1973. There is no such list in the Strasbourg Convention of 1963 … It was enshrined in European patent law in close adherence to the PCT (Rules 39.1 and 67.1 PCT), which had been drawn up shortly before, and partly based on national provisions. It was proposed at the time of the Munich Conference that part or all of the list be transferred to the Implementing Regulations in order to be able to take better account of scientific and technical developments. But there was no support for these proposals because the list was considered to cover fundamental rules of substantive patent law, and it was felt that their amendment could not be left to the Administrative Council. (Document CA/PL 6/99: 2)

Turning to the exclusion of computer programs, the one 'dealt with' by the '*technical character*' approach, the president commented:

As regards the exception provided for in Article 52(2)(c) and (3) EPC, which excludes 'programs for computers' as such from being regarded as inventions, the Office and the boards of appeal have always interpreted and applied the EPC in such a way that this exception in no way excludes appropriate protection for software-related inventions, that is inventions whose subject-matter consists of or includes a computer program. This practice can be summarised as follows: an invention which when viewed as a whole makes a technical

contribution to the prior art, e.g. by means of a particular technical effect, is patentable even if a computer program is involved in its implementation. (Document CA/PL 6/99: 3)

This of course justifies patent protection for computer-implemented inventions rather than for computer programs per se. Mentioning that there had been pressure for reform on computer programs and business and mathematical methods, the president continued:

Nor is the argument convincing that computer programs are always of a technical character. This is not the case merely because they are intended for use in the operation of computers. A computer program may or may not involve a technical teaching. On the other hand, the current wording of Article 52 EPC does not completely exclude the possibility of a computer program being deemed not to be patentable even if it is of technical character … There now appears to be broad consensus that Article 52 should be amended, at least as far as this point is concerned. (Document CA/PL 6/99: 4–5)

On the question of simply deleting Art. 52(2) EPC, as repeatedly proposed by the UK during the negotiations leading up to the adoption of the EPC in 1973, the president went on to say:

It is further proposed that paragraphs 2 and 3 of Article 52 EPC be deleted, as they are no longer necessary or desirable. If Article 52(1) EPC were to be amended as proposed, thus making it clear that only technical inventions are patentable, there would no longer be any need for the exceptions in paragraph 2 … The deletion of Article 52(2) and (3) EPC would get round the problems associated with the application and interpretation of any exception to patentability (what is a computer program as such?), but would not mean that the subject-matter and activities currently listed in Article 52(2) would then suddenly become patentable. Discoveries, scientific theories, mathematical methods, aesthetic creations, and purely mental or business acts, in particular, will continue not to be eligible for patent protection as long as they do not involve a technical teaching … Patentability would continue to depend solely on whether the claimed subject-matter, considered as a whole, had a technical character or not. The task of determining this can be left to the departments of the EPO, its boards of appeal and the national courts, who are best equipped to do it. They are better able than the legislator to take the right decision in each individual case, as well as to take account of technical advances and thus promote the pragmatic development and harmonisation of European patent practice. (Document CA/PL 6/99: 6–7)

At the ninth meeting of the CPL in March 1999 a proposal to make methods of treatment patentable was not approved, but in January 2000 the president made further suggestions for amendment (Document CA/PL 4/00). In the president's proposals of March 1999 the question of the second and further medical uses of pharmaceuticals was addressed.

The acceptability of a Swiss-type use claim to a second indication had been addressed by the first decisions of the EBoA in December 1985, but the validity and enforceability of such claims had remained in doubt and the president and other parties wished to settle this in a manner acceptable to the pharmaceutical industry:

> The national courts and appeal divisions of the patent offices of the contracting states to the EPC have taken issue to various degrees with the case law of the Enlarged Board of Appeal relating to the 'second medical use' in the so-called 'Swiss form of claim', although for the sake of uniform interpretation they have mainly followed the Enlarged Board's decision … In a more recent decision of the UK High Court handed down in 1998 … substantial doubts were expressed as to the novelty of 'Swiss claims' … This legal uncertainty has to be eliminated, as it is difficult to predict with any certainty whether European patents with so-called 'Swiss claims' directed to a 'further medical indication' will ultimately be found to be valid by the national courts in the contracting states to the EPC. Moreover, there are considerable doubts as to whether patents of this type will actually guarantee the intended protection sufficiently and whether they can be enforced accordingly … It is therefore proposed that Article 54(5) EPC be amended to unambiguously permit patent protection for the second and each subsequent medical use of a substance or composition known for a medical use, in the same way as for its first medical use, in the form of purpose-related product protection. (Document CA/PL 4/00: 2)

The president then proposed a new paragraph for Art. 54 EPC that would allow purpose-limited product claims for drug substances found to have *further* medical uses: 'The provisions of paragraphs 1 to 4 [of Art. 54 EPC] shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that this use is not comprised in the state of the art' (Document CA/PL 4/00: 3).

This, of course, was not adopted, since it would remove the basis for the very broad first indication claims that were being accepted by the EPO, of 'substance X for use in medicine', and would allow purpose-limited product claims only when the end use was specified narrowly. This was pointed out by epi (the Institute of Professional Representatives before the European Patent Office) (Document Info/2PL 12).

In the meantime, the EPO's Administrative Council had, in June 1999, advised that the EPC Rules were to be amended to bring them into line with the EBD and the new Rules came into effect in September 1999.

At the twelfth meeting of the CPL, in February 2000, the suggestions of the EPO president and of epi were considered. The Austrian and German delegations considered the matter was political and should

be referred to the Administrative Council. According to the German delegation: 'protection for later indications [constituted] an encroachment on the therapeutic freedom of the medical practitioner in the performance of his duties' (Document CA/PL PV12: 5).

The EPO president set out the EPO's major proposals (Document CA/PL 25/00: 37–44) for the revision of the EPC in June 2000, in advance of the fourteenth meeting of the CPL in July 2000. The proposed revisions were the insertion of 'in all fields of technology' into Art. 52(1) EPC to achieve compliance with TRIPS, the deletion of Art. 52(2) EPC and the insertion of whatever equivalent was necessary into the Implementing Regulations, the restriction of Art. 53(a) EPC to commercial exploitations that were contrary to morality or 'ordre public', and the displacement of medical methods from Art. 52 EPC to Art. 53 EPC, that is the abandonment of the legal fiction that they were not susceptible of industrial application. Apart from the deletion of Art. 52(2) EPC, this was uncontroversial.

The president explained that Art. 52(1) EPC was to be made TRIPS-compliant, to make 'it plain that patent protection is available to technical inventions of all kinds' and that the exclusions of Art. 52(2) EPC, with the exception of that of computer programs, which was to disappear, were to go into the EPC Rules. On computer programs, he commented that: 'There now appears to be a broad consensus that computer programs should disappear from the list of non-patentable inventions … [R]ecent decisions of the Boards of Appeal (see T-1173/97 [Computer program product/IBM] …) have confirmed that computer programs, as a rule, are patentable subject-matter under the EPC. Therefore, the current exception concerning computer programs has become *de facto* obsolete' (Document CA/PL 25/00: 37).

Again, the president sought to validate the '*technical character*' approach recently adopted by TBoA 3.5.01 in T-1173/97 Computer program product/IBM:

> [T]he transfer of Article 52(2) and (3) EPC would offer a welcome opportunity to combine these provisions with a Rule providing some sort of definition of the term 'invention' as it should be understood throughout the EPC. Such a rule implementing Article 52(1) EPC could read as follows: '"Invention" within the meaning of this Convention shall be understood as being a teaching addressed to a person skilled in the art as to how to solve a technical problem using technical means'. (Document CA/ PL 25/00: 37–9)

On the subject of the exclusion of medical methods, the president commented that: 'While these surgical or therapeutic methods constitute inventions, they have been excluded from patentability by the fiction of

their lack of industrial applicability. It is undesirable to uphold this fiction since methods of treatment and diagnostic methods are excluded from patentability in the interests of public health' (Document CA/PL 25/00: 41).

From here on, the *travaux préparatoires* are those for the Munich Diplomatic conference of November 2000. The Administrative Council of the EPO produced its draft revision of the EPC in October 2000 (Document MR/3/00). In Art. 52(1) the words 'all fields of technology' were to be inserted, in Art. 52(2) computer programs were to be deleted, methods of treatment were to be moved from Art. 52(4) to Art. 53(c), 'publication' was to be deleted and 'commercial' inserted in Art. 53(a), and a new second medical use clause, Art. 54(5), was to be added allowing purpose-limited product claims for any specific use when that specific use was not known (Document MR/3/00: 9–11).

On 17 November 2000 the French delegation proposed the reinsertion of the exclusion of programs for computers, giving the reason that:

> A lively debate is under way in Europe about whether and how patent protection for software inventions should develop. The European Commission has also just published a consultation paper on the subject, and the economic stakes are considerable. Simply deleting the words 'and programs for computers' might be interpreted as signalling a wider range of patentable subject-matter. The risk of uncontrolled drift towards patents for business methods in particular must be avoided. Rather than adopt a premature position, and without calling existing EPO practice into question, the French delegation therefore suggests that the decision on amending Article 52(2)(c) be deferred. (Document MR/8/00: 3–4)

This position was supported by the Danish delegation:

> The patentability of software is a highly controversial issue which has considerable economical impact … We are not convinced that the deletion of the words 'computer programs' from Art. 52(2)(c) EPC is more or less a formality which will have no impact on Board of Appeal decisions. Furthermore, the European Commission has recently launched a consultation within the member states with the purpose of having a thorough discussion of the issue and possibly establishing proper means for harmonisation on this issue within the Community. We find it imperative to await the outcome of the Community initiative before any further action on this matter is taken in relation to the EPC. This issue is considered by our government to be of crucial importance for our assessment of the Basic proposal as a whole. (Document MR/15/00: 1)

The exclusion of computer programs was reinserted (Document MR/3/00 Rev. 1).

Later in November 2000, the Swiss delegation proposed a new wording for the novelty exemption for purpose-limited product claims to cover second and further medical uses. The actions of the Swiss in this area are important to note since they appear to have misled the delegates from the other countries as to the effect of their proposed changes. The proposed wording would have had Art. 54(5) EPC read:

> Notwithstanding paragraphs 2 and 3, the provisions of this article shall not exclude the patentability of any substance or composition referred to in paragraph (4) for any specific use in any method referred to in Article 53(c), provided that such use is not comprised in the state of the art. (Document MR/18/00)

More specifically, the Swiss delegation suggested that:

> The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the 'Swiss type claim'. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a 'Swiss type claim'. (Document MR/18/00: 2)

As will be explained in Chapter 5, however, allowing purpose-limited product claims for second and further medical uses worsened the position of the physician seeking to use a generic medicine in place of the patented equivalent.

The Drafting Committee put forward a draft revised text on 27 November 2000, incorporating the 'TRIPS-compliance' amendment to Art. 52(1) EPC to refer to 'all fields of technology', placing medical methods into Art. 53 EPC, incorporating a purpose-limited second and further medical use exemption into Art. 54 EPC, but maintaining all of the Art. 52(2) EPC exclusions (Document MR/DCD 1/00).

The Diplomatic Conference at which the amendment of the EPC was agreed took place in Munich from 20 to 29 November 2000. The chairman, the director of the Swiss Patent Office, Roland Grossenbacher, opened the conference stating in relation to the revision process that: 'There are … several "tough nuts to crack", to coin a phrase. Some of these are major legal issues, whilst others have extended beyond the purely legal aspects and thus taken on a strategic importance; one example is the proposal to delete the exclusion of computer programs, which is really only intended to codify existing practice' (Document MR/24/00: 4–6).

As a proposal for an EU Directive relating to the patenting of computer-related inventions was then under discussion, the question of the retention of computer programs in the exclusions list of Art. 52(2) EPC was prominent. The head of the German delegation, in his opening statement, commented that: 'the draft Revision Act contains one proposal whose effects in our view have not yet been fully explored and which we believe should be postponed to a later date. I am referring to the proposal to delete computer programs as such from the list of non-patentable inventions in Article 52(2) EPC' (Document MR/24/00: 9). The head of the Irish delegation commented that the computer programs provision needed at least some clarification. However, in view of the European Commission consultation process, Ireland felt that a deletion was not desirable at this stage. Luxembourg concurred. The Dutch delegation considered that the computer program exclusion was 'obsolete in the eyes of the Netherlands' but that they would 'not go along with patenting business methods as such'. The Belgian delegation said that their country had always supported the removal of the computer programs exclusion, but in view of the EU's consultation exercise it felt that the status quo should be maintained. The Danish delegation felt it imperative not to take any decision on programs for computers until the outcome of the EU's consultation process was known. In the end, France, Denmark, Germany, Finland, Monaco, Sweden, Ireland, Italy, Belgium, Spain, Luxembourg, Cyprus, Portugal and the UK wanted to keep the computer program exclusion; Switzerland, Liechtenstein, Austria and The Netherlands wanted to see it go; and Turkey would not vote on the subject (Document MR/24/00: 17–38).

The TRIPS-compliance amendment to Art. 52(1) EPC was agreed. The limitation of the morality clause (Art. 53(a) EPC) to inventions that were contrary to morality or 'ordre public' when *commercially* exploited went through. Moving the medical methods exclusion from Art. 52 to Art. 53 EPC was agreed. The Swiss proposal to allow purpose-limited product claims was accepted after the Swiss had argued that:

> [A]s regards second or further medical uses, the case law evolved by the EPO Enlarged Board of Appeal should be enshrined in the Convention. For the sake of transparency and legal certainty the aim of the Basic Proposal was to keep the legal status quo for medical uses … The proposed reform satisfied the demand users had long been making for the existing loophole in respect of the patenting of the second and further medical uses to be closed. The Basic Proposal met this demand without extending protection beyond the legal status quo. (Document MR/24/00: 71–72)

The revised EPC came into force in December 2007 and since then there have been no major legislative changes. Arts. 52 and 53 EPC now read as follows:

Article 52 – Patentable inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
  (a) discoveries, scientific theories and mathematical methods;
  (b) aesthetic creations;
  (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
  (d) presentations of information.
(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter as such.

Article 53 – Exceptions to patentability

European patents shall not be granted in respect of:
  (a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
  (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;
  (c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

The Art. 52(2) EPC exclusions are governed by the 'as such' qualification of Art. 52(3) EPC and, with one exception, are covered in Chapter 2. The exception is the exclusion of discoveries, which has been directly affected by the EBD and which is dealt with in Chapter 4. The Art. 53 EPC exclusions are dealt with individually in Chapters 5 to 8.