



Part I
**Twenty Years of Biotech Directive: an
Evaluation**

Rob J. Aerts



The Directive and the report of the Expert Group

- The Union lawmaker wanted to secure harmonized protection in the Internal Market, while safeguarding sensitive ethical issues
- In 2012, the Commission set up an Expert Group “*to assist and advise the Commission in its reporting requirement*”, i.e. the requirement under Article 16(c) Directive of reporting to the European Parliament and the Council on the development and implications of patent law in the field of biotechnology and genetic engineering [Commission decision C(2012) 7686]
- The Experts were from academia, private practice, industry, non-governmental organizations and the European Patent Office
- Many issues concerning patentability of plant-related inventions, human stem cells and gene sequences raised controversial points within the Group, and as the report notes discussions in the Group were “*thorough, fruitful and at times quite animated*”

Majority and minority views

- Consensus on the various issues could not be achieved, and it was decided to work with majority and minority views
- The Expert Group published its final report with conclusions and recommendations concerning biotech patenting in May 2016 [EO2973]
- Concerning all but one topic - that of the plant breeders' exemption – the recommendations could be based on the view of the vast majority of the Experts
- The overwhelming majority of Experts were *not in favor* of re-opening the Biotech Directive, as this was considered opening “Pandora’s Box”, resulting in a very long negotiation process not in the interest of research, industry and society

Overview

- I. The patenting of biotechnological inventions in Europe and the relationship between the Union's Biotech Directive and the European Patent Convention
- II. Major points of discussion within the Expert Group concerning plant breeding patents, patents on human stem cells, and the issue of absolute product protection of nucleic acids
- III. Summary and Conclusions

I. The patenting of biotechnological inventions in Europe

1. The Biotech Directive (Directive 98/44) governs the patenting of biotechnological inventions, but the European Patent Convention (EPC) of course governs the grant of patents in general

2. The Biotech Directive provisions on the patentability of plant-related inventions, human stem cells and gene sequences and the implementation of these Biotech Directive provisions in the EPC

The patenting of biotechnological inventions

Union law

- In Union Member States, the patenting of biotechnological inventions is governed by an instrument of Union law, the Biotechnology Directive [Directive 98/44]

European Patent Convention

- However, the actual examination and grant of a European patent or a (possibly future) unitary patent for a biotechnological invention, and any post-grant opposition procedures, are governed of course by the European Patent Convention
- For harmonization purposes, the Union's Biotech Directive provisions on patentability criteria were taken over in literal wording into the European Patent Convention

The patenting of biotechnological inventions

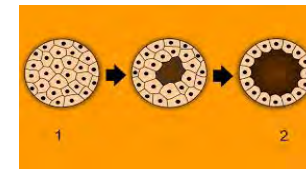
1. Essentially biological processes for the production of plants or animals (breeding) are excluded from patentability, and there is a provision stipulating that such a process consists entirely of natural phenomena such as crossing or selection

Directive Art.2(2) ► EPC Rule 26(5)



2. Provision on the exclusion from patentability of uses of human embryos for industrial or commercial purposes

Directive Art.6(2)(c) ► EPC Rule 28(c)



3. Provision on the requirement for patentability of gene sequences, namely that the industrial application of the sequence must be disclosed in the patent application

Directive Art.5(3) ► EPC Rule 29(3)



II. Major points of discussion within the Expert Group

1. Plant-related invention:

- The exclusion from patentability of methods of crossing and selection, the patentability of plants thus obtained, and the plant breeders' exemption

2. Human stem cells:

- The definitions of “human embryo” and “use of a human embryo”

3. Gene sequences:

- Absolute product protection of a gene *per se*, versus purpose-limited or function-limited protection

Plant-related inventions – Methods of breeding

- Plant breeding (crossing and selection) - indicated as an “essentially biological process” - *is not patentable in order not to mix rights*
- Article 2(2) Directive (Rule 26(5) EPC) provides that such a process consists *entirely of natural phenomena such as crossing or selection*
- In G2/07 and G1/08 (*Broccoli/Tomato I*) the Enlarged Board of Appeal found that Rule 26(5) did not give useful guidance, and the Enlarged Board provided an interpretation of the meaning of excluded breeding processes after further thorough investigation

Conclusions by the Expert Group:

- A majority of Experts (13/15) found that the Enlarged Board had at least given a minimum interpretation: further action was unnecessary
- The Expert Group did note, however, that the CJEU has not expressed itself yet on this matter

Plant-related inventions – Plant products

- Since methods of plant breeding are not patentable, the question remained whether plants obtained by such a method should still be patentable as product claims
- In G2/12 and G2/13 (*Broccoli/Tomato II*) the Enlarged Board of Appeal found that the exclusion from patentability of an essentially biological process – a *method claim* - does not hinder allowance of a *product claim* on the plant obtained, or a product-by-process claim

Conclusions by the Expert Group:

- A majority of Experts (11/15) was in favor of taking no further action
- Also here, it was noted that these decisions do not yet settle the matter under Union law, which requires a decision by the CJEU

Plant-related inventions – Breeders' exemption

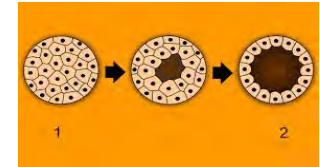
- There are fears that plant breeders may be inhibited in their activities by patent rights on plant material
- A limited breeders' exemption allows for use of the patent protected material for breeding purposes, but not for commercial exploitation of the material obtained: the question being should this breeders' exemption be included in all patent law?
- A limited exemption is taken up in national patent law in DE, FR, CH and NL, as well as in the Agreement on the Unified Patent Court

Conclusion by the Expert Group:

- This was one of the most controversial issues discussed in the Expert Group: 9/15 Experts recommended no action, of which 6 Experts were *against* any breeders' exemption in patent law as such, whereas 4 Experts *favored* a Union-wide breeders' exemption

“Human embryo” and “use of a human embryo”

Article 6(2)(c) Directive, taken over as Rule 28(c) EPC, excludes from patentability uses of human embryos for industrial or commercial purposes



Leading Case Law:

In G2/06 (*WARF*) the Enlarged Board of Appeal excluded from patentability stem cell products derived from human embryos if the preparation of the stem cell product involved the prior destruction of human embryos, even if this preparation step was not part of the claim

In C-34/10 (*Brüstle*) the CJEU defined a human embryo as any fertilized human ovum, any non-fertilized ovum with a transplanted cell nucleus, and any non-fertilized ovum stimulated by parthenogenesis

In C-364/13 (*ISCC*) the CJEU reversed the previous *Brüstle* decision, and ruled parthenotes patentable since they cannot develop further

“Human embryo” and use of a “human embryo”

- The ISSC decision was based on national UK patent applications. However, ISSCs corresponding European patent applications on the same subject-matter were even after the CJEU decision for a while prone to refusal by the EPO, stressing the disparity of the two systems

Conclusions by the Expert Group:

- Concerning the term “human embryo”, a large majority of Experts (13/15) found that the Directive provided sufficient framework for development of case law, and no further action was required
- Also concerning the term “use of a human embryo”, a large majority of Experts (13/15) agreed with case law in that a prior “upstream” destruction of a human embryo barred the patenting of cells obtained

Absolute v. purpose-limited nucleic acid protection

- Biotech Directive Chapter I Patentability



Article 5(3), taken over as Rule 29(3) EPC, requires for a gene to be patentable that the industrial application of a gene is disclosed in the patent application

Based on this provision, an extensive string of case law on gene patenting was established by Board of Appeal 3.3.08*

- Biotech Directive Chapter II Scope of Protection

Article 9 – *not taken over in the EPC* – provides that the protection of a product containing genetic information extends to material comprising the product and in which the genetic information performs its function

C-428/08 (*Monsanto*) concerned a patented gene sequence conferring herbicide resistance to soy plants - the soymeal made was not

patented
TIGENIX
Living Medicines

*Aerts R.J (2008) IIC 39(3) 282-306

Absolute vs. purpose-limited nucleic acid protection

- The CJEU ruled that Article 9 was to be interpreted as not conferring protection if the patented product (the gene) was in the soymeal, but did not perform the function for which it was patented
- However, the CJEU also ruled that Article 9 precluded absolute protection of the patented gene product, i.e. protecting genes *per se*

Conclusions by the Expert Group:

- The majority of Experts (11/15) found *for this specific case* that the reasoning of the CJEU was in principle correct, *but not in general*: for instance if DNA for a kit is shipped in lyophilized form
- The majority of Experts (11/15) found the reasoning on absolute protection hard to follow: here Chapters on patentability and scope of protection were mixed - absolute protection not precluded in Ch.I
- In practice, courts and the EPO appear to apply absolute protection

III. The Expert Group Conclusions

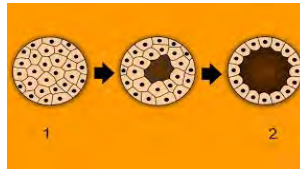
Summary and Expert Group Conclusions

- The Expert Group was of the strong opinion that the Biotech Directive should not be re-opened



- The most controversial issues are found in the field of plant-related inventions - in particular the tension between patent rights and plant breeders' rights is a major point of contention
- Furthermore, it is unclear whether the CJEU will follow the decisions of the Enlarged Board on patenting of breeding processes and plants obtained

Summary and Expert Group Conclusions



- Regarding the patenting of human embryonic stem cells, the most important terms appear to have been clarified by case law – however, here the Union law and the EPC law systems were not aligned for some time



- The scope of protection of gene sequences was clarified in one particular case (soymeal), but it was considered that this particular outcome should not be generally applicable
- The reasoning of the CJEU in the Monsanto case concerning purpose-limited protection of gene sequence claims was found hard to follow, and in practice absolute gene product protection is applied



Part II

Uncertainty in biotech patenting in Europe: Causes, consequences and possible remedies

Rob J. Aerts

Uncertainty in biotech patenting in Europe

Cause

In Europe, the patentability of biotechnological inventions in sensitive areas like stem cells, plant products and DNA and protein sequences is determined by two entirely separated legal systems:

- European Union Law
- The European Patent Convention

Consequence

- Patentability, or not, is almost a matter of chance: sometimes the Union system is fastest in deciding on patentability, but sometimes the EPC system is faster
- Which of the two takes the lead has entirely different consequences!
- Claim drafting in ethically sensitive areas remains volatile

The problem at large: how is patentability, or not, of biotechnological inventions in Europe determined?

How is patentability, or not, determined?

- Articles of the European Patent Convention (EPC) determine patentability of biotech subject-matter
- Articles of the Biotechnology Directive (Directive 98/44) determine patentability of biotech subject-matter
- Rules of the EPC determine patentability of biotech subject-matter
- The Court of Justice of the EU (CJEU) interprets Articles of the Biotech Directive
- The Administrative Council of the European Patent Organization makes law by amending the Rules of the EPC
- Boards of Appeal and the Enlarged Board of Appeal interpret Articles and Rules of the EPC
- The European Commission can give a non-binding advice on the interpretation of articles of the Biotech Directive

➤ What does this all mean for the patent applicant?



The problem dissected and exemplified

1. The heart of the matter: the very same provisions can be found in Union law and in European Patent Convention law
2. Uncertainty about what is patentable and what is not: some examples from different biotechnological fields
3. The two legal systems, Union law and EPC law, interact in an unpredictable manner
4. The fate of granted and pending claims can be uncertain
5. There is a reverse situation depending on which of the legal systems takes the lead
6. Conclusions

The heart of the matter: the very same provisions present in Union law and in EPC law

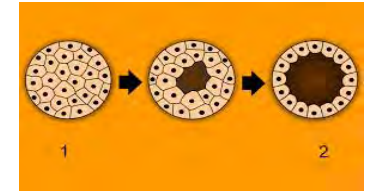
The same provisions is both legal systems

1. Provision on patenting of stem cells:

“Uses of human embryos for industrial or commercial purposes”
are unpatentable

▶ Directive Art.6(2)(c)

▶ EPC Rule 28(c)



2. Breeding (crossing and selection), indicated as “an essentially biological process for the production of plants or animals”, is excluded from patentability (UPOV Conv.) [Art.53(b) EPC; Art.4(1) BDir]

Provision defining a breeding process:

“A process for the production of plants or animals is essentially biological (*i.e. it is a breeding process*) if it consists entirely of natural phenomena such as crossing or selection”

▶ Directive Art.2(2)

▶ EPC Rule 26(5)



The same provisions is both legal systems

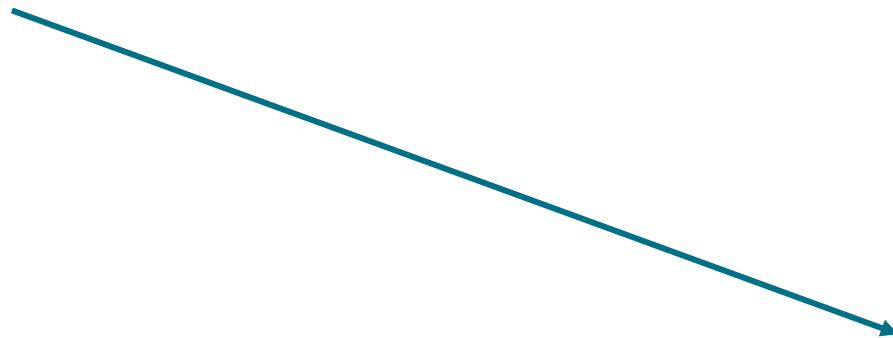
- In European Union Member States, the patenting of biotechnological inventions is governed by an instrument of Union law, the Biotechnology Directive (Directive 98/44)
- For harmonization purposes, the Administrative Council of the European Patent Organization took over these Union's Biotech Directive provisions on patentability criteria in literal wording into the Rules of the European Patent Convention, of which many countries are non-Union Contracting States
- This was a practical measure taken by the Administrative Council, since it can only amend the Rules and not the Articles of the EPC
- Changing the articles would require a drastic measure, namely a Diplomatic Conference of the Contracting States
- However, Rules are subordinate to Articles of the EPC (Art. 164(2) EPC)

Oddity: provisions are at different levels in their systems

Art.2(2) Biotech Directive

Art.164(2) EPC: Articles prevail over Rules

“entirely natural phenomena”



Rule 26(5) EPC

“entirely natural phenomena”

➤ Articles of the Biotech Directive are directly applicable and have a totally different status under Union law compared to the provisions of the same wording in the Rules of the EPC under EPC law, where Articles prevail over de Rules, and, as we will see, Rules may be completely ignored

More complexity: EPC provisions are not Union law*

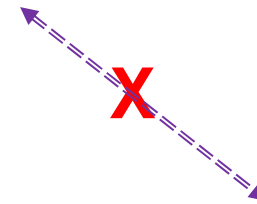
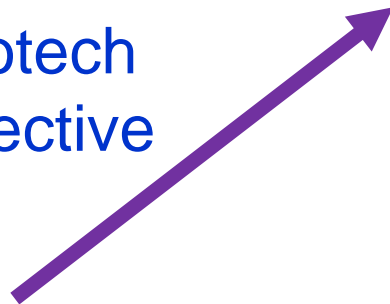
1. Opinion 1/09 of the CJEU: the only guardians of the Union legal order are courts of Union Member States in collaboration with the CJEU, to which referrals on interpretation of Union law are made by EU courts [Art. 19(1) TEU, Art. 267 TFEU, CJEU Opinion 1/09, para. 66]
2. The European Patent Office and Boards of Appeal are institutionally and judicially outside of the Union legal framework [cf. CJEU Opinion 1/09, para. 71]
3. An important consequence of being outside of the Union legal order is that it is impossible for the EPO or the Boards of Appeal to refer questions on the interpretation of Union law, like the BD, to the CJEU [G2/06, r.11; cf. CJEU Opinion 1/09, paras 79, 80, 84, 85]
4. Decisions of the CJEU are not legally binding on the European Patent Office or the Boards of Appeal [Art.23(3) EPC; T2221/10, r.38; G2/02, r.8.6]
5. The two legal systems operate each within the realm of their own competences

* Aerts, R.J. (2014) EIPR 36(2), 88-94

Within the Union there is a hybrid system*

Court of Justice of the EU

Biotech
Directive



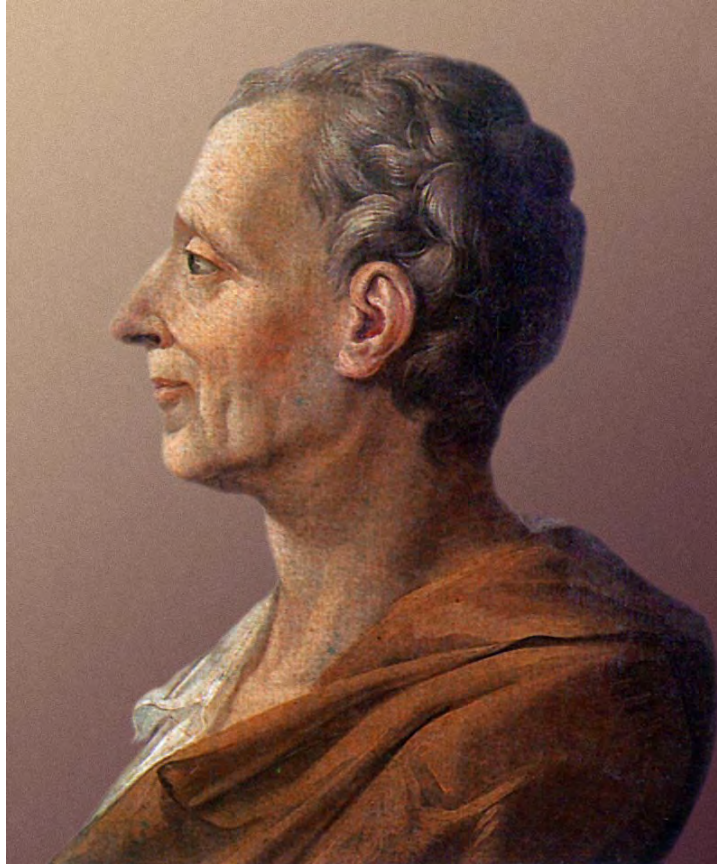
EU National Courts



Boards of Appeal
of the EPO



* Aerts, R.J. (2016) QMJIP 6(3), 287-303; Aerts, R.J. (2007) IIC 38(2), 165-182



Separate and unrelated legal systems*

	EU Law Supranational	EPC Law Intergovernmental
<u>Democratic Control</u>	European Parliament is direct law-maker	National parliaments not actively involved
<u>Separation of Power</u>	Functionally present: ECJ checks balance	Mixture of powers
<u>Rule of Law</u>	Fundamental to the system: ECJ reviews law-making	No judicial review of law-making

*Aerts, R.J. (2007) IIC 38(2), 165-182

Intermezzo

The introduction of the Unitary Patent:
Are there major changes?

The aim of the UP Regulation: uniform protection

Article 118 TFEU

- This article concerns the establishment of “uniform protection of intellectual property rights throughout the Union”

Unitary Patent Regulation 1257/2012

- Meant to foster the internal market and “making it possible to obtain uniform patent protection” [Preamble 4]
- Provides that “the scope of that right and its limitations shall be uniform” [Arts 5(1) and 5(2)]
- Thus: are all judiciaries now in concordance with each other in the new system?

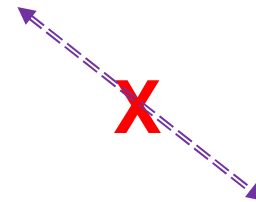
The Unified Patent Court is bound by Union law

- CJEU Opinion 1/09: Agreements may not distort the EU legal order and may not change the function of the CJEU
- Only EU Member States can accede to the Agreement [Art.2]
- The Court is subject to obligations of Union law [Art.1]
- The Court shall apply Union law and respect its primacy [Art.20]
- The Court shall cooperate with the CJEU and refer questions on the interpretation of Union law, and decisions by the CJEU are binding on the Court [Art.21]
- Again there is a sharp contrast with the status of the European Patent Office

Also the envisaged new system is a hybrid system

Court of Justice of the EU

Biotech
Directive



Unified Patent Court



Boards of Appeal
of the EPO



This implies legal uncertainty in the new system*

- When a Unitary Patent is before the *European Patent Office* during opposition, a question on the Biotech Directive **cannot** be referred to the CJEU, and claimed biotech subject-matter in the patent may be affected in a certain manner

..... while

- When the same Unitary Patent is before the *Unified Patent Court*, a question on the Biotech Directive **can or must** be referred to the CJEU, and the very same subject-matter in the patent may be affected in a different manner

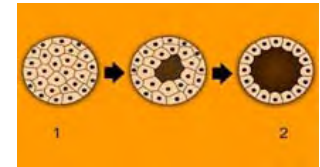
➤ Such diverging decisions imply legal uncertainty also in the envisaged new system

*Aerts, R.J. (2014) EIPR 36(9), 584-587

Uncertainty about what is patentable and what is not: some examples

Union law and patents on embryonic stem cells


- Human embryonic stem cells are contemplated for therapeutic uses
- The EU Biotech Directive excludes from patentability uses of *human embryos* for industrial purposes
- Two UK national patent applications by ISCC resulted in the referral by the UK High Court of a question to the CJEU whether parthenotes (non-fertilized human ova stimulated by parthenogenesis) are also included in the term “human embryo” and thus their use is excluded from patentability [*ISCC v Comptroller*, C-364/13]
- Parthenotes are genetically incomplete and they *lack the capacity to become a human being*
- Therefore, the Advocate-General opined that parthenotes are not included in the term “human embryo”, and as such in principle *are patentable subject-matter* [Opinion of 17 July 2014]
- This was *confirmed* by the CJEU [Case C-364/13, EU:C:2014:2451]



The European Patent Office follows after a while ...

- During these CJEU proceedings, ISCC had a corresponding European patent application with subject-matter concerning parthenotes pending before the European Patent Office
- In 2012, the EPO communicated its intention to reject the patent application under the EPC, stating rightly that *the CJEU has no jurisdiction to decide matters for the EPO* [EP 1948791; 21 Sep. 2012]
- In later communications, the EPO stated rightly that *it is not bound by CJEU decisions and that the EPC does not allow suspension of EPO proceedings because of a referral before the CJEU* [EP 1948791: Comm. of 21 Sep. 2012 and 16 July 2014]
- It took a while for the EPO to align with the CJEU and allow the patenting of parthenotes: the case was picked up again years later
- Please note: If ISCC had opted for a European patent only, and if ISCC had no parallel national patent applications that enabled the referral of a question to the CJEU, presumably ISCC would not have had patent protection

But what if the CJEU has not yet decided ...

- An “essentially biological process for producing plants or animals”, i.e. breeding, is excluded from patentability 
- The Biotech Directive explains in Article 2(2) that a breeding process “consists entirely of natural phenomena such as crossing or selection”
- This provision was taken over *verbatim* in the EPC in Rule 26(5)
- The Enlarged Board of Appeal of the EPO found after in-depth investigation that Rule 26(5) did “*not give any useful guidance*”, and *this provision was ignored* in decisions G2/07 & G1/08 on the meaning of essentially biological processes and the non-patentability of breeding processes [*Broccoli/Tomato I*, EP:BA:2010:G000207.20101209, r.4,5]
- Different levels: Rules are subordinate to Articles of the EPC
- Illustrates the tension between the two legal systems: we do not know the interpretation until a referral to the CJEU is made, and EPO judiciaries cannot refer such a question, and can ignore the Rule

The two legal systems interact in an unpredictable manner

Next issue: patentability of plant products themselves

- Since **methods** of plant breeding are thus not patentable, the question remained whether **plants themselves** obtained by such a breeding method could still be patentable as **product** claims
- In decisions G2/12 and G2/13 the Enlarged Board of Appeal made an extensive analysis of this question, taking into account the preparatory work of the Biotech Directive
[*Broccoli/Tomato II*, EP:BA:2015:G000212.20150325]
- The Enlarged Board found that such **plant products are patentable**, even when they are produced by a **breeding process that itself is not patentable**
- Once again, in Union Member States the ultimate decision on the patentability of plants obtained by a breeding process depends on the referral of an appropriate question to, and a ruling by, the CJEU

European Parliament asked advice from Commission

- After the Enlarged Board decisions, the European Parliament in its role as democratic institution asked the European Commission to advise on the patentability of plants obtained by a process that is not patentable
 - **The Commission cautioned and emphasized:**
The Commission's advice is **not binding on the Union** and the advice may change in the future because **only the CJEU can interpret** Union law: the Union is based on the rule of law and separation of powers
- In its advice, the Commission noted that Biotech Directive provisions were taken over literally into the EPC, and thus for interpretation the Directive's preparatory work should be considered [2016/C411/03]
- Based on this preparatory work, the Commission took the view – ***contrary to the Enlarged Board of the EPO*** - that it was the intention of the Union's legislator ***to exclude from patentability plants obtained by an essentially biological process*** [25 June 1997, A4-0222/97, p.38, fn 5]

Surprise response resulting in further complications*

- Rather unexpectedly, the Administrative Council (consisting of both Union Member States and non-Union Member States) decided almost unanimously to take over the Commission's advice
- Thus now new Rule 28(2) EPC provides that European patents *shall not be granted* for plants or animals exclusively obtained by an essentially biological process [EPO Notices of 29 June '17 and 3 July '17]
- **Complications:**
 - 1) The Administrative Council introduced **into an intergovernmental non-Union treaty (EPC) a non-binding advice by a Union institution**, the European Commission, on subject-matter on which the Union itself is not harmonized, and the Commission warned that it may change its position in the future, since **only the CJEU can decide** on the matter
 - 2) In addition, the Administrative Council now **overruled the decisions** by the Enlarged Board of Appeal on the patentability of plant products

*Aerts, R.J. (2018) JIPLP 13(10), 800-805; Aerts, R.J. (2018) GRUR 67(7), 721-724

Summary of interactions between the two systems

- The Union started by promulgating the Biotech Directive, which was approved by both the European Parliament and the CJEU
- The Administrative Council then took Directive provisions literally over in the Rules of the EPC; however the EPO is not bound by Union law, Rules have a different legal status than Articles, and the provisions are sometimes taken into account and sometimes they are not
- The Enlarged Board of Appeal decided that plants obtained by an essentially biological process are in principle patentable
- Upon request by the European Parliament, the European Commission gave a non-binding advice that plants obtained by an essentially biological process are *not* patentable
- Then the Administrative Council, consisting of both Union and non-Union States, took over the non-binding advice of the Commission
- Meanwhile, for Union Member States the final word is with the CJEU

The fate of granted and pending claims
can be uncertain

How would the CJEU decide on patenting of plants?

Would the CJEU follow the European Patent Organization in case in the future an appropriate question about patentability of plants is referred to the CJEU, and the Court finds itself competent to answer?

- How would the Court interpret the relevant Union law article excluding from patentability only a breeding process if it *‘consists entirely of natural phenomena such as crossing and selection’*?
- Do these natural phenomena mean that breeding assisted by very sophisticated technical steps is not excluded from patentability?
- Does this mean that products obtained by such sophisticated technical methods are not excluded from patentability?
- Does this mean that the CJEU would not follow under all circumstances the advice of the Commission for plant products when produced by precise and sophisticated technical breeding methods?

What is the fate now of granted and pending claims?

- What if future decisions under Union law partly or entirely come to a different conclusion than the exclusion from patentability of plants as implemented by the Administrative Council in the new Rule?
- Then patentees and patent applicants may have lost certain pending claims and already granted patent claims that they were entitled to
- There is no legal means of redress and there is no independent judicial review for the loss of rights under EPC law
- It was noted before that this lack of legal remedy is a fundamental shortcoming of the European patent system
[Baldan & Van Zimmeren CMLR 52, 1564 (2015); Interview 29 October 2015 by JUVE with Prof. Bross; Kluwer Patent Blog 25 May 2017; Kluwer UPC News Blogger 26 October 2017]

Resulting uncertainty

- In the opposition procedure against EP 2140023 (*Syngenta*), the patentee pointed out that the interpretation by the Enlarged Board of the EPC Article on breeding, resulting in a decision to find plants patentable, *contradicts* the new EPC Rule denying such patentability – and the Article prevails over the Rule [Resp. by patentee of 8 May 2018]

Thus:

- The Article as interpreted by the Enlarged Board: **Yes** ✓
 - The Rule as implemented by the Administrative Council: **No** x
- Opposition Division cannot help: it stated that only Boards of Appeal can review compliance of Rules with Articles of the EPC, and Examining and Opposition Divisions are bound by EPC provisions in force, including amended Rules [Opposition EP 2140023; Preliminary opinion OD of 3 August 2018, par.1.4.3]

There is a reverse situation depending on which system takes the lead

Which system leads has entirely different consequences

- The situation regarding plant-related inventions is the reverse of that regarding human embryonic stem cell inventions

Embryonic stem cell inventions

- The CJEU took the lead, based on a national patent application, and uncertainty was temporary since the EPO adapted – after a while - to the new case law issued by the CJEU in which patentability of stem cells was broadened

Plant-related inventions

- The EPC system (Administrative Council) took the lead, based on a non-binding opinion by the Commission, and it is unknown whether the CJEU would follow all elements of the Commission's opinion
- This last-mentioned situation is much more disquieting than the developments in the stem cell field, since it cannot be excluded that some plant-related patent rights are irrevocably lost

Conclusions

Conclusions

1. The patenting of sensitive biotech subject-matter is governed by two separated and unrelated legal systems in Europe
2. The two legal systems for sure closely monitor each other and seriously attempt to harmonize biotech patent law - but applicants and patentees should be prepared for unexpected developments
3. True harmonization would imply means of referral of appropriate questions by the EPC system to the Union system, which of course is presently totally impossible since the EPC is not part of Union law
4. The question of which system takes the lead in determining patentability has major consequences for legal certainty: consider a new class of inventions in the biomedical or biopharmaceutical field
5. The resulting legal uncertainty is in the best case temporary, but may in the worst case be a source of concern since it cannot be excluded that the CJEU may ultimately at least partially come to a different conclusion than the EPO, resulting in a loss of rights

The European Patent House



Thank you very much for your kind attention!