

Minutes of the Committee on Biotechnological Inventions Meeting

S. Wright (GB), Secretary

Held on 9 October 2015 in Munich

In Attendance:

Bernardo Noriega, Francisco (ES)
Bogensberger, Burkhard (LI)
Brkic, Zeljka (RS)
Capasso, Olga (IT)
Chlebicka, Lidia (PL)
De Clercq, Ann (BE)
Desaix, Anne (FR)
Gerasimovic, Liudmila (LT)
Ildes Erdem, Ayse (TR)
Ilievski, Bogoljub (MK)
Jaenichen, Hans-Rainer (DE)
Jonsson, Thorlakur (IS)
Keller, Günter (DE)
Knuth-Lehtola, Sisko (FI)
Leissler-Gerstl, Gabriele (DE)

Lidén, Camilla (SE)
Mattsson, Niklas (SE)
Petho, Arpad (HU)
Pförtl, Andreas (AT)
Popa, Cristina (RO)
Primiceri, Vittoria (SM)
Sinojmeri, Diana (AL)
Speich, Stéphane (LU)
Swinkels, Bart Willem (NL)
Taravella, Brigitte (FR)
Wächter, Dieter (CH)
Weinzinger, Philipp (AT)
Witek, Rafal (PL)
Wright, Simon (GB)

Apologies:

Bencina, Mojca (SI)
Canelas, Alberto (PT)

Dragun, Tihomir (HR)
Hak, Roman (CZ)
Hally, Anna-Louse (IE)
Jensen, Bo Hammer (DK)
Makelová, Katarína (SK)
McKeown, Yvonne (IE)
Oser, Andreas (DE)
Pallard, Caroline (NL)
Pieraccioli, Daniele (IT)
Sansone, Luigi (MT)
Schouboe, Anne (DK)
Sergejeva, Valentina (LV)
Stefanova, Stanislava (BG)
Thoresen, Liv-Heidi (NO)
Tombling, Adrian (GB)
Vogelsang-Wenke, Heike (DE)

1. Opening

Ann De Clercq opened the meeting at 10:30.

2. Adoption of the Provisional Agenda

The Agenda was adopted. Noted that many of us knew about the Australian Court decision on the Myriad case.

3. Matters arising from the minutes of the last Biotech Committee Meeting

None

4. Stem cells

It was noted that there appears to have been a change in the EPO policy to stem cells. We are not expecting any formal announcement, but the EPO will make it public. The previous policy had placed the cut-off on which you could rely on stem cell deposits as the Chung paper (published in January 2008). Since the ISCC case decided "parthenotes" are not embryos, the cut-off may be taken back as far as 2003. We are expecting to have more information from the EPO during a forthcoming meeting with the directors (12.10.15).

5. Sequence Listings

We had received a further letter from BASF. We agree that the burden on Applicants should be minimised. The BASF letter cites three examples for consideration. Ann De Clercq will draft a written reply. The Committee will review BASF's suggestions, and will agree on a response.

We continue to want EPO Examiner's to give an alignment of prior art sequences with the sequences being claimed. Also, we want a copy of the translation of prior art if the Examiner relies on this.

Most users do not use the BISSAP software, instead using PatentIn. We will also contact the OCC in this regard and take it up with the EPO, perhaps on a different and higher level.

We wonder whether BISSAP requires more information. We do not understand why the EPO developed it. We wonder how many sequences filed at the EPO used BISSAP (perhaps in percentage terms), and if it is not very many we wonder whether the EPO could consider stopping the project.

6. Plants

This topic came up at the last CPL (Committee for Patent Law) meeting, and there are some countries who are concerned about the EPO's Tomatoes/Broccoli decision. Indeed, this places some countries' national law (DE, NL) at odds with the EPO's position. It seems as if this topic will be postponed within the CPL for the time being.

A CPL meeting is planned dealing only with this topic. No date has been set until now for this meeting but might be set as soon as the EU group publishes its report. We will be informed when the meeting is scheduled.

It was noted that at the last CPL meeting Heli Pihlajamaa gave a presentation on this topic. Apparently only 125 cases are affected, and 15 have been granted since the Tomatoes/Broccoli Decision.

A discussion is ongoing at certain levels about the need for purpose bound protection of genes. We discussed this at our Committee Meeting and decided to prepare a statement on this for the next **epi** Council Meeting in November.

7. National Decisions

It was noted that France (Communication published by the French IPO) does not allow the patentability of plants obtained by essentially biological processes, and this too goes against EPO law. However, it only applies to French national patents, not EP (FR) patents.

We will update the table of our national law regarding plants, and Anne Desaix (FR) will translate the appropriate law from INPI and send this to Ann De Clercq.

8. ARTICLE 123(2) EPC

It was noted that there was a seminar on this topic at the EPO earlier this year. The EPO had changed the Guidelines, to present a more liberal view, in particular, as a result of a decision headed by the Board member Christopher Rennie Smith. Then we had a more strict decision from the Board chaired by Oswald, and so the Guidelines will be changed again (possibly this November).

9. Procedural Matters

The EPO has a new IT system for Examiners, which shows the priority of files that they should work on. One member noticed that if you phoned an Examiner, you did not get given their direct number but got a "ticket" and the Examiner was expected to phone you back. If they picked up the file after you had spoken to the Examiner then they must deal with the matter in a few days, so that is one way of having your file prioritised.

10. Meetings with the EPO

It was noted that this Committee had been leading by having meetings with EPO Directors for many years now, and the **epi** had decided that that format should be adopted in other areas. Indeed, there was a meeting with PAOC earlier this year. The Biotech Committee and EPPC liaise with EPPC on the topics to be brought in these meetings in the future.

11. Non-Unity

In the past years this Committee has addressed several times the applicants concerns concerning the EPO's practice regarding raising non-unity objections. This year Arpad Petho (HU) raised the issue from a somewhat different viewpoint than previously. The issue of non-unity objections was now approached from the viewpoint of the EPO's Examination Guidelines in force. Point 2.2 of Chapter VII of Part B of said Guidelines reads as follows:

"2.2 Complete search despite of lack of unity

Exceptionally, in cases of lack of unity, especially "a posteriori", the examiner is able to make a complete search and prepare a search opinion (where applicable – see BXI, 7) for all inventions with negligible additional work and cost, in particular when the inventions are conceptually very close. In those cases, the search for the further invention(s) is completed together with that for the invention first mentioned in the claims. All results should then be included in a single search report, which raises the objection of lack of unity and identifies the different inventions. It further indicates that the Search Division did not invite the applicant to pay further search fee(s) because all claims could be searched without effort justifying such

a fee. However, the search opinion (if applicable, see BXI, 7) still raises the issue of unity of invention (see BXI, 5)."

On the basis of this point, the Committee discussed the following questions (which were then also discussed with the EPO biotech directors at the October 12th, 2015 meeting):

- 1) Why does the EPO think the above defined cases being exceptional?
- 2) What is the ratio of applications with non-unity objections where a complete search was still made?
- 3) Is there any guidance for the examiners on how to determine what is "negligible additional work and cost" when considering making a complete search despite a raised non-unity objection?
- 4) As a consequence of the present system used for the evaluation of the examiners work, they are clearly counter-motivated to perform a complete search where a non-unity objection is raised. Could it be possible to change on this (i.e. by giving the examiners extra points if they perform a complete search in spite of a non-unity objection)?

The Committee agreed that a significant change in the EPO's practice with respect to the above point in the Guidelines in favour of the applicants would be very welcome, namely, the EPO should acknowledge that there are a lot more cases where a complete search and a search opinion for all inventions can be prepared with negligible additional work and cost in spite of a duly established a posteriori non-unity objection because in many of such cases the inventions are, in fact, conceptually very close. It was also agreed that giving a clear guidance to the examiners on how to define such cases would also be advisable.

12. SPCs under the Unitary Patent

It is not unusual to amend the claims post-grant in order to make it easier to get an SPC. This had been happening in at least France and the UK, although of course it was possible before the EPO as well under the central limitation procedure. There were proposals from some industry bodies to have a unitary SPC under the unitary patent.

13. Candidate Associate Members

It was agreed to admit both members who had applied for associate status, namely Jan Desomer (Bayer CropScience NV, BE) and Outi Virtaharju (Berggren, FI).

14. Review of Decisions

SMW read out the action points at the meeting.

15. Closing

The meeting closed at 4pm.