# Minutes of Meeting of **epi** Biotech Committee with EPO Directors on 25 November 2014 at the EPO, Pschorrhöfe Building, Bauteil VII, Room 1901, Munich

S. Wright (GB), Secretary

**In Attendance:**

Ulrich Thiele (UT, dir. 1404)
Siobhán Yeats (SY, dir. 1406)
Victor Kaas (VK, dir. 1408, Munich)
Francisco Fernandez y Brañas, dir. 1403, the Hague)
Maria Fotaki (MF, dir. 1405, Munich)
Aliki Nichogiannopoulou (AN, dir. 1401, Munich)
Sonke Holtorf (SH, dir 1405, the Hague)
Enrique Molina Galan(EMG, dir. 1401 – the Hague)
Klaus-Peter Doepffer (KPD, dir. 1412, Munich)
Bernardo Noriega, Francisco (ES)
Capasso, Olga (IT)
De Clercq, Ann (BE)
Hally, Anna-Louse (IE)
Jaenichen, Hans-Rainer (DE)
Jonsson, Thorlakur (IS)
Mattsson, Niklas (SE)
Schouboe, Anne (DK)
Wächter, Dieter (CH)
Wright, Simon (GB)
Keller, Günter (DE)
Vogelsang-Wenke, Heike (DE)
Swinkels, Bart Willem (NL)

Ms Yeats opened the meeting at 13:00, following a joint lunch.

## 1. STEM CELLS

The EPO guidelines have been amended to take account of recent practice, in particular on the Brüstle case. A recent decision T2221/10 (Technion) has confirmed the practice of the EPO concerning the 10 January 2008 cut-off. In other words, cases filed after this date may be allowed if the patentee can rely on the literature paper (by Chung) which confirms the single blastomer process (SBB) whereby a stem cell can be removed from an embryo without destruction of said embryo. This is the first decision to have to deal with the situation after the Brüstle decision. Note that while decisions of the CJEU are not legally binding for the EPO, they may be considered as persuasive.

Thus, the EPO will generally grant cases in the stem cell area if at the effective date of the application methods were available for producing embryonic stem cells that did not require destruction of human embryos at any time in the past.

T1441/13 (Asterias) took account of the SBB process, and there was a disclaimer of the non-destruction of embryos. The claims were not allowed, however, as they did not enable the "remaining" subject matter left, after the disclaimer.

There was also an attempt to introduce a disclaimer using the same wording as Rule 28(c), namely excluding embryos for industrial and commercial purposes. It was decided that this was unclear, and potentially the subject matter that was being disclaimed was not within the scope of the claim in the first place.

We are awaiting the decision from the CJEU on the parthenotes/ISCC case which has been referred to the CJEU[1].

T1836/10 concerns a case by a German researcher claiming a method for isolating embryonic stem cells by SBB. The application was refused on the basis that there was direct use of an embryo even if it was not destructive.

## 2. PLANTS

There has been a process on the seedless watermelons case – T1729/06. There was a hearing in October before the Enlarged Board of Appeal concerning the tomatoes and broccoli cases. It was noted that the French and German versions of Article 53 (c) EPC mention breeding, whereas interestingly the English version refers to processes for the production of plants, which appears potentially wider. This was an interesting decision because factually the process produced sterile fruit, and not a plant. The Board found that although the claimed process contained crossing steps, it was not an excluded essentially biological proceses for producing a plant, because no meiosis or sexual crossing took place.

The EU Expert Group on Biotechnology, set up following Article 16c, Directive 98/44/EC, is expected to deliver a report some time after the Enlarged Board of Appeal has decided on the tomatoes and broccoli cases (expected first quarter 2015).

## 3. PATENTING ANTIBODIES

There was some discussion of the scope of claims, and whether CDRs and sequences are required in the claims. Some Technical Board of Appeal decisions state that functional language is acceptable. It is still not clear how many CDRs are required by the EPO to properly define the antibodies. Decisions of relevance are T1300/05, T617/07 (where a single CDR was acceptable), T352/07 (thought possibly though to be less relevant, from Board

1 This decision has been rendered by the CJEU in the meanwhile after this meeting on December 18, 2014

3.3.2, Oswald). T067/11 is a good reflection of current practice.

## 4. ELECTRONIC TOOLS

This concerns sequence listings, colour drawings and scanning.

As far as sequence listings are concerned, these will be included in the eDossier which will start some time in 2015. Note that the EPO can re-run its earlier search at any time, and as announced on 1 October there will may be a web-based top up search facility that could be performed by the Applicant (Search For Life). The results would be sent to the Applicant only, and this would give the Applicant documents that have been published after the original search. It would not be sent to third parties, but would be part of the CMS.

As regards colour drawings, the EPC Guidelines still require them to be in black and white only. The question was asked, though, what is the status of a document that is filed at the EPO in colour in Opposition proceedings? For example, certain literature papers are published in colour, but of course are converted to black and white when filed at the EPO. The original document, as available to a skilled person, is in colour. Does the EPO consider the black and white colour version as filed to be the one that is to be considered?

The Guidelines still require prior art sequences, including fragments and variants, to be included in a sequence listing. The **epi** is of the view that this may be at odds, with decision J8/11, which suggests that prior art sequences do not need to be included in listings. The EPO suggested that if an invention is, for example, a molecule that binds residues 35 to 45 of a known protein, then one must include sequence 35 to 45 in the sequence listing (despite the fact that that is not actually the invention, and despite the fact that that sequence is already known).

The EPO argued that J8/11 suggested that you must identify (for example by accession number) the prior art sequence, but the **epi** is to investigate whether this imposes additional restrictions above and beyond what the Board stated in J8/11.

## 5. PHARMACOGENOMICS

A new Examiner group is being set up to review the EPO's practice in this area. One of the relevant decisions is T734/12. The issue here concerns statistical probability when considering novelty, in other words whether the claiming of a smaller patient group would be anticipated by a more generic disclosure of a prior art larger patient group.

## 6 ADDED MATTER

The EPO noted that the Guidelines have been amended by introducing a reference to newer case-law. Examiners have been informed about this change. The **epi** is awaiting evidence from Examiners that the standard has actually been relaxed somewhat, and that Examiners will in fact see the specification through the eyes of a person skilled in the art.

## 7. MEDICAL USE CLAIMS

T1780/12 concerns double-patenting, and decided that one could have one case with Swiss style claims, and another application with equivalent EPC 2000 style claims. Other decisions in this area are T803/10 and T2461/10. Note that T1570/09 said that a single set of claims cannot have both Swiss style claims and EPC 2000 claims, but this will probably not be followed.

## 8. SUMMONS TO ORAL PROCEEDINGS

The EPO's internal Guidelines state that the EPO should issue at least one Examination Report for Summons issued. Examiners have wide discretion, and can issue a Summons when they feel that no further progress is being made. The EPO said that following an internal instruction in February 2014, Applicants will be given at least five or six months notice before the Summons, so the period for Response should be at least the same as if the EPO issued a regular Examination Report with a six month term.

## 9. FEEDBACK TO EXAMINERS – THE RESULT OF APPEALS

The **epi** asked whether Examiners were told of the result of Appeals against their decisions, e.g. to refuse. Apparently this is not automatic, but most Examiners do in fact take an interest in the outcome of their files. Note that interlocutory revision is very rarely used – only about 5 % of cases use this procedure. The **epi** thought that it could be used more, in appropriate cases. In cases before an Examining Division where a Refusal has been issued, but that is overturned on appeal, then of course the case is returned to the Examiner for resumption of examination proceedings, so that he/she can see the result of his Appeal. The **epi** hopes that Examiners will take note of cases where they have been overturned on Appeal, although the EPO pointed out that often the facts upon which the Boards rule (claims, arguments) are different from those that formed the basis for the refusal.

## 10. DEPOSITS

The expert solution is being maintained, but as a result of lack of use the list of experts is unlikely to be updated. A procedure should be set up how to deal with the appointment of an expert.

The meeting then ended with thanks from Ms Yeats, in the chair.