Report of the Joint Meeting epi-EPPC Healthcare/Pharma subCommittee with EPO Healthcare-Biotech-Chemistry Directors

Date: 17 October 2019 (13:30-16:30H)

Place: EPO Bayerstrasse 115

Participants:

EPO

Karin Seegert (COO)

Peter Albrecht (Principal Director Operations)

Anne Glanddier (Director Munich)

Francisco Fernández (Director Munich)

Sjoerd Hoekstra (Director The Hague)

Sönke Holtorf (Director The Hague)

Suzanne Herrera (Director Munich Oppositions)

Thomas Eijkenboom (Director Munich and contact)

Anna Bacchin (Lawyer, Department Patent Law, DG5)

Stefan Härtinger (Senoir Expert)

Tessa Donovan-Beermann (Senior Expert)

EPI EPPC Pharma Group

Ruurd Jorritsma (Chair of the EPPC Pharma group, private practice, NL)

Francisco Bernardo (secretary, private practice, Spain)

Einar Karl Friðriksson (private practice, Iceland)

Micaela Modiano (private practice, Italy)

Alain Henri Werner (industry, Sanofi, FR)

Martin Wilming (private practice, Switzerland)

Simon Wright (private practice, UK)

The EPO welcomes the meeting, which allows an open discussion on patent practice between EPO directors and senior experts, and the patent professionals represented by the epi subgroup.

The EPO requested during the meeting that no minutes be published to favour a frank discussion and allow an exchange of personal views. Therefore, the present report, and

what was said during the meeting, cannot be used later in proceedings before the EPO or other meetings.

1. Opposition Practice and experience with OCFD

Suzanne Herrera gave a presentation on the experience with Opposition and Centralized Formalities Directorates (OCFD) after 2 years of their implementation.

There are about 500 EPO examiners doing oppositions, of those about 250 are from HBC because they have more than half of total oppositions. The examiners in general spend 30% of their time in opposition, the rest in examination.

The Opposition Division is usually formed by the first member and chair from OCFD, and 2nd member from the line to bring technical knowledge (in most cases first examiner). Optionally a legal member from DG5. The composition can depend on the practice in each directorate. If a divisional is pending, then the Opposition Division usually includes the examiner handling the divisional as 1st member.

The aim of the new structure was to harmonize opposition and sharing best practice. The EPO has seen gains in efficiency and quality, due to specialisation of examiners. For example, summons to Oral Proceedings are now sent with complete opinion, which helps patentee and opponents to focus on relevant issues.

There is also a knowledge development of examiners, with workshops and specific training. They have made surveys among opposition parties and the satisfaction levels have improved (2016-17-18: 71%-69%-74%).

There is an Operational Quality Control, checking the summons, decisions and formalities.

As to the procedures (operations) there are centralized examiners specialized in the opposition proceedings. Since July 2019 they prepare consolidated lists of the cited documents, which is updated and present in the EPOLINE file under CONLIST. This is not done for old cases, although occasionally for cases from 2018 onwards. The list is not sent to the parties because it is constantly updated. For efficiency reasons, the EPO wishes that parties to the proceedings adhere to the document numbering contained in the consolidated list.

2. New Rules of Procedure of the Boards of Appeal

Anna Bacchin from DG5 (Patent Law) explained that the review of the Rules of Procedure of the Boards of Appeal are part of the structural reform of DG3. There was a user consultation. The aim is to improve efficacy and streamline the Appeal procedure, and to codify what was already in the case law, as well as harmonize the practice of the different BoAs.

The main feature is a basic convergence approach, the focus of the appeal will be the revision of first instance decisions. There are 3 levels of convergence: at start of appeal, at summons and at oral proceedings. The approach is strict, and a Board will have

discretion to admit new documents. This will have an impact on the practice of examining and opposition divisions.

There is also a difference in the remittals to first instance, which according to the new rules will not be done unless there are special circumstances (for example serious procedural violation).

Suzanne Herrera commented here that there is an EPO working group on how the oppositions will be affected. For the moment there are no changes in the legal framework (rules, guidelines) to take into account of the new BoA rules. The opposition divisions will continue working as now: complete summons, same practice on late filing. Because of efficiency, what is important is whether facts, evidence and arguments are present on file, not if they have all been discussed.

The EPO asked the representatives to keep the cases manageable and focus on the relevant requests, showing relationships between them, and trying to avoid the EPO having to decide on a high number of requests.

Ruurd J. asked if there will still be a remittal in a situation where one ground was not discussed (for example a division deciding on an Art. 123 EPC issue, but novelty and inventive step not yet discussed in first instance). This touches the question whether there will always be two instances or not. The Directors said they did not know, and took note of the concerns of patent attorneys.

3. EPO Strategic plan 2023

Karin Seegert (COO HBC) gave a presentation on the strategic plan for 2020-2023. [*note: presentation will be provided*]

After explaining the EPO mission (European Patent Office to deliver high-quality patent and efficient services that foster innovation) and vision ("A sustainable office committed to excellence"), she explained the 5 goals of the strategic plan:

1. People: build an engaged, knowledgeable and collaborative organization
2. IT: simplify and modernise EPO IT systems
3. Quality: deliver high-quality products and services efficiently
4. External: build a European patent system and network with a global impact
5. Sustainability: secure long-term sustainability

As examples she mentioned several initiatives under discussion:

- Providing as a new service a superfast search within 1 week if requested. Patent attorneys said that it could be of high interest for some clients (goal 2).
- Providing fast track (12 months), normal track (24 months) and slow track (36 months) examination. She mentioned that UDEC (deferred examination) was dropped because after consultation they saw that users were divided.
- New countries signing validation agreements with EPO: Georgia (very soon) and other Asian and African countries such as Jordan, Angola, (OAPI?) (goal 4)

- They will create an observatory to analyse global trends, and organize events on new developments (goal 4)
- They are studying how to maintain financial independence once the backlog will disappear and they are in a steady state.

Ruurd stated that quality is considered as the most important for patent attorneys, and congratulated the EPO with the strategic plan, and the implied cooperation and transparency.

4. Quality including Timeliness

Sönke Holtorf gave a presentation on quality, explaining that it is a commitment of EPO top management. The aim is to provide legal certainty with a reliable, efficient and effective service.

Searches: they have access to 5 billion documents, using sophisticated tools for searching such as specific classification schemes. They have access to Asian language (only) documents, and use tools to translate automatically. It is helpful that the CPC classification is now becoming the global system of classification, for example it is used by China and Korea.

Sönke also discussed the results of the User Satisfaction Surveys, they are done every two years and the results have improved.

He mentioned that EPO is considering the designation of an ombudsperson for the applicants, to deal with complaints. At present complaints are handled at directorate level, it may be seen by applicants as biased.

5. Adaptation of the Description

Sjoerd Hoekstra said that the examiners still adapt the description, as they are required by the Guidelines. Usually only if there is discrepancy between subject-matter claimed and what is said in the description.

EPI explained that the issue is whether examiners are or should be aware of the role of claim interpretation and scope of protection after grant (infringement proceedings and the like), that depends on the description. The take-away for EPO is to have another look at examiners' understanding of claim interpretation so that they are aware of the impact that amendments can have in post-grant proceedings.

6. Selection from broad ranges

Martin Wilming (epi) refers to decisions of the BoA (T261/15 and T279/89) where the third requirement (purposive selection) is not taken into account to assess novelty, because it is considered to relate to inventive step.

Tessa Donovan (EPO) explains that the change in approach has been included in the new guidelines, and that there are no problems or concerns. The examiners will follow

the new guidelines, so they should not ask for the third requirement. She explained that examiners shall consider case law referred to in the Guidelines as more generally applicable and confirmed (by CPL) to be guiding.

7. Role of end points for novelty of selection inventions (T261/15)

Martin Wilming and Micaela Modiano mention the problem with second criterion (selected sub-range sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range), which is put into question by T261/15. The board considered that *"the limit values of a known range, although explicitly disclosed, are not to be treated in the same way as the examples. The person skilled in the art would not, in the absence of further teaching in this direction, necessarily contemplate working in the region of the end-points of the prior art range, which are normally not representative of the gist of the prior art teaching"*.

EPO (Tessa) said that this will depend on the circumstances of the case, and that they will follow the guidelines, which still include the second criterion.

8. Polymorphs

Stephan Härtinger (EPO senior expert) discusses T777/08 (atorvastatin polymorphs). The approach is that starting from an amorphous form of a compound, it is obvious to try to find crystalline forms and polymorphs. To have inventive step, it is important to show unexpected properties with convincing evidence. It is harder now, but not impossible (e.g. when polymorphs show unusual non-trivial combination of unexpected features), because the technology of polymorphs screening has become routine. In fact it is a question of selection invention. EPO has established practice and it is followed.

9. Enantiomers

Stephan Härtinger mentions that case law is old and well-established. The skilled person will expect advantages of enantiomers, so an applicant has to bring evidence as to why they are inventive (T600/95).

A disclosure of a flat structure is a disclosure of a racemic mixture, nothing else.

10. Purity of compounds

Micaela Modiano mentions a new decision regarding purity of compounds (T1085/13) and asks if there is a change in approach.

Stephan Härtinger says that the new guidelines still refer to the old case law (for example T360/07). The examiners will follow guidelines, thus the old case law.

T1085/13 accepts novelty of a claim to a compound with a higher degree of purity on the basis that this was not straightforward from the prior art. In fact, his new case is a specific

case not leading to potential new global approach by the EP examiners, and this specific new decision is more on the difference between novelty and inventive step.

11. Plausibility of claimed effects

Stepha Härtinger: reference is made to T488/16 and T950/13. In the pharmaceutical area data are needed in the application, if they are not present, when either:

- it is not plausible that the invention was solved (T488/16), or

- common general knowledge has to support plausibility (T950/13).

In T488/16 the problem was that there was a broad Markush formula, with dasatinib not singled out, statement that all compounds inhibited a kinase, and post-filed data did not support this statement because some compounds were not active.

In T950/13 - directed to a parallel case which is now under a new appeal - there was one specific compound, dasatinib, that inhibited a specific kinase, specifically linked to a leukemia. No data present in the specification. The common general knowledge made the invention plausible. The remaining question - remitted to the Opposition division - was directed to inventive step. Alain Werner (epi) comments on the problem of starting clinical trials and patent applications for second medical use; for example, for a sub-group of diseased patients and/or dosage regime. If the application is filed before the clinical trial starts, it may lack data and therefore plausibility can become a potential issue; if filed after the clinical trial, it may lack novelty because now there is a regulatory and mandatory requirement of transparency and therefore publication at early stage of information related to clinical trials (e.g.: at early stage, some of the information related to the protocol is published, the results being not available since the trial is not completed (see for instance 'early' summaries published in ClinicalTrials.gov database).

Stephan Härtinger explains that EPO does not require clinical trials or data on humans, preclinical data is sufficient. He also mentions case law (T158/96) where novelty was not prejudiced by a prior publication informing of a phase I clinical trial of the compound for the same indication, but without results being given (with some further conditions, see Headnote of decision).

12. Use claims vs. Method claims

Martin Wilming explains that a use claim ("Use of X for achieving/producing Y") and a corresponding method claim ("A method of achieving/producing Y comprising applying X") can have a different scope and this is the reason patent attorneys sometimes insist in having both types of claims. However, some examiners strictly apply rule 43 EPC and insist on deleting one of them referring to the Guidelines F-IV, 4.16.

In post-grant proceedings the evidence needed to show infringement of one or the other type of claim may differ considerably. A use claim is typically considered as a purpose-limited product claim, e.g. someone selling X specifically for the protected use Y will be a direct infringer. On the contrary, there need not be direct infringement of a corresponding method claim.

Tessa Donovan says that not all examiners are aware of the difference and consequences in post-grant proceedings.

Stephan Härtinger refers to the guidelines on clarity (H) that explains the differences between use and method claims.

It was suggested that it is important that examiners become aware and understand what happens with patents in litigation.

13. Conclusion

The meeting was found useful by all participants, with a lively exchange of opinions on topics of interest.

The EPO and epi agree to continue the meetings on an annual basis. Ms Seegert proposed to combine the meeting with those of Chemistry and Biotech, having a general part in common and then split according to specialty.