ORDINE DEI CONSULENTI IN PROPRIETA' INDUSTRIALE / EPO EXAMINERS' DAY – 2012

GENERAL QUESTIONS

Question 1

Art 123(2) EPC and chemical general formulae amendments

We would like to have a clarification about :

- functional features in claims: what may be acceptable?
- unity of invention

Question 2

For chemical inventions defined by parameters, in opposition proceedings, Art.83 has become - together with Art.123(2)and(3) - a major cause of revocation. Incidentally, this also represents an Achilles' heel for patents enforceability. It has become of paramount importance that in the description of methods for measuring such parameters, all the conditions that have an influence on the result are specified. I believe it would be helpful to expand on this issue in light of recent case law (e.g. T 85/03).

Question 3

Recently it has been noted that in claims like the following in which a feature of a plant has been defined in terms of the achievable results like, for example:

"... hight being the minimum which guarantees an efficient inertial separation",

this had been considered as lacking clarity. In the past this objection was less frequent.

Is this corresponding now to a more strict approach from the EPO?

Question 4

How the "raising the bar initiative" applies to the biotech field? Practical examples?

- If and how much experimental evidence should be given in the description to correctly support wide claims? Practical examples?
- Following G2/06, are to be considered patentable claims directed to products which at the filing date could be prepared by a method which does NOT necessarily involve the destruction of human embryos?

Question 5

Dosage regimen in view of G2/08. Which will be the requirements for supporting the claims? Recent decisions relating to dosage regimen patents?

Question 7

Stem cells decision of ECJ: position EPO?

Question 8

Biological material: requirement of sufficient disclosure vs availability. (The biological material has been described in a scientific publication, with its isolation and species classification, but it has not been made available by a Deposit under Budapest Treaty: is it sufficiently described by reference to the publication? Which are the essential characteristics to be disclosed in order to avoid the deposit of biological material and satisfy sufficiency of disclosure?

Question 9

Generally, when claiming a general formula covering many chemical compounds, there may be some of them not so active in the biological tests but it may be difficult to exclude from such formula. Is the disclaimer of such compounds acceptable? Or can they be described in the experimental section and claimed in any case?

Question 10

May the EPO work together inside the IP5 group in order to harmonize the requirements needed for describing chemical compounds with biological/pharmacological activity?.

Now, it is necessary in China to list all the single values of the biological activity for each compound exemplified in order to get a patent granted. The objection of lack of support in the application as filed can't be cured subsequently as it happens in other Countries. Ranges are not accepted that are commonly accepted by US or European Examiners. This issue is causing a lot of problems to the pharmaceutical companies and changing the way of drafting patent applications.

Question 11

Expert procedure acc. to R32 EPC? Clarify.

Question 12

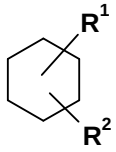
Sufficiency of disclosure and experimental work. Sinergy is stated in the patent Application without experimental confirmation. Is a post-published evidence useful to confirm the statement on a synergistic effect in the Application (see T 1642/07)?

Question 13

We would like to know the current evaluation inside EPO in view of the recent Decision of the EBA G2/10.

We have received the following question about Discalimers:

Let's assume that we have, an EP patent application claiming a compound of Formula (I)



Formula I

wherein

R^1 is a1, a2, a3, a4 or a5; and

R^2 is b1, b2, b3, b4 or b5.

Assume that a prior art document (D1) is cited against this application (D1 being either an accidental disclosure or a prior application according to Art 54(3) EPC) and D1 discloses *inter alia* compounds encompassed by Formula(I), having R^1 being a2, a3, a4 or a5 and R^2 being b2, b3, b4 or b5.

In theory, the applicant could amend his claim to read:

a compound of Formula (I)

wherein

R^1 is a1~~, a2, a3, a4 or a5~~; and

R^2 is b1~~, b2, b3, b4 or b5~~.

However, would a disclaimer (i.e., provided that R^1 is **not** a2, a3, a4 or a5; and that R^2 is **not** b2, b3, b4 or b5) aimed to exclude subject matter disclosed by D1, be allowed, even if no specific compounds presenting such a combination (i.e., R^1 is a1 and R^2 is b1) is described in the patent application under examination?

In other words following the reasoning of T7/86, and to the light of G1/03 and G02/10, would a disclaimer (aimed at removing an anticipation) infringe A 123(2) if it excludes a specific sub-group corresponding to compounds undisclosed specifically in the application under examination?

“T7/86: …// A class of chemical compounds defined only by a general structural formula having at least two variable groups does not specifically disclose each of the individual compounds which would result from the combination of all possible variants within such groups.”