AIPPI Questionnaire UK Response: Apotex-Inc. v Sanofi-Aventis

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A. Utility or industrial applicability requirement

1. Does your national law have a utility or industrial applicability requirement for patentability?

   Yes

2. Please briefly describe the utility or industrial applicability requirement, including whether it is based on:

   (c) Both. The requirement is provided by statute and interpretation by case law

   Statute: Patents Act 1977.

   Section 1(1)(c): Patentable inventions

   A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say-

   (a) ……

   (b) ……

   (c) it is capable of industrial application;

   (d) ……

   Section 4: Industrial application:

   s.4(1) An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

   Equivalent provisions are provided by Articles 52(1) and 57 EPC.

   Case law on interpretation: See section 3 below

3. What must be disclosed in the patent specification to satisfy the utility or industrial applicability requirement? In particular, must the patent specification disclose:

General background

Under the EPC rule 42(1)(f), which is concerned with the content of the description on filing, it states:

'The description shall:

……

(f) indicate explicitly, when this is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.'

Rule 29(3) EPC also provides:

'The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application.'

The Guidelines for Examination in the EPO (September 2013 edition, G-III, 1) further explain that 'Industry' should be understood in its broadest sense as including any physical activity of 'technical character.'

UK law does not have an equivalent provision to EPC Rule 42(1)(f) but an application for an invention for which no conceivable use is offered in, or apparent from, the application as filed is most likely to be refused for lack of industrial application or on other grounds. (See *Chiron Corporation v Murex* discussed below).

The equivalent to Rule 29(3) EPC is provided in the UK Patents Act under Appendix C, Article 5(3).

The above provisions relate to the textual basis of the industrial application but the level of technical support is addressed by the jurisprudence discussed below.

EPO case law

(a) the utility or industrial applicability;

T 0870/04 (BDPI Phosphatase/Max Plank): *'The notion of industry must be construed broadly. It includes all manufacturing, extracting and processing*

activities of enterprises that are carried out continuously, independently and for commercial gain.'

T 00604/04 (PF4A receptors/ Genentech): *'The capability of industrial exploitation must be derivable by the skilled person from the description read with the benefit of the common general knowledge.'*

T 0870/04 (BDPI Phosphate/ max-plank); and T 0338/00 (Multimeric receptors/ salk institute) *'The description must disclose a practical way of exploiting the invention in at least one field of industrial activity.'*

(b) a basis (e.g. test data) to prove or demonstrate that the utility or industrial applicability is achieved; and/or

T 0898/05 (Hematopoietic cytokine receptor/ Zymogenetics) and T 1452/06 (Serine Protease/ Bayer): '*Nevertheless, there remains a need to disclose in definite technical terms the purpose of the invention and how it can be used to solve a given technical problem. There must also be a real prospect of exploitation which is derivable directly from the specification, if not already obvious from the nature of the invention or the background of the art.*'

(c) a basis (e.g. test data) and/ or a line of reasoning from which the utility or industrial applicability may be predicted?

T 0898/05 (Hematopoietic cytokine receptor/ Zymogenetics): '*It should not be left to the skilled reader to find out how the exploit the invention by carrying out a research programme.'*

<u>UK case law</u>

In Chiron Corporation v Murex Diagnostics [1996] R.P.C. 535, 607-608 the Court of Appeal interpreted the phrase '*capable of industrial application*' to mean that the invention should relate to something which has a useful purpose.

Subsequently, in *Human Genome Sciences (HGS) v Eli Lilly [2011] UKSC 51*, the Supreme Court clarified the general principles to be applied by the UK Courts in relation to the requirements of Article 57 EPC. In doing this, the Supreme Court considered the EPO jurisprudence in detail and sought to ensure that the UK was consistent in its approach. The Supreme Court's statements in this case were made in the context of biological material, but the first four principles in particular are relevant more generally.

At paragraph 107 of *HGS v Eli Lilly*, the Supreme Court set out:

'(i) The patent must disclose 'a practical application' and 'some profitable use' for the claimed substance, so that the ensuing monopoly 'can be expected [to lead to] some … commercial benefit' (T 0870/04, para.4; T 0898/05, paras.2 and 4);

(ii) A 'concrete benefit', namely the invention's 'use … in industrial practice' must be 'derivable directly from the description', coupled with common general knowledge (T 0898/05, para.6; T 0604/04, para.15).

(iii) A merely 'speculative' use will not suffice, so 'a vague and speculative indication of possible objectives that might or might not be achievable' will not do (T 0870/04, para.21; T 0898/05, paras.6 and 21);

(iv) The patent and common general knowledge must enable the skilled person 'to reproduce' or 'exploit' the claimed invention without 'undue burden,' or having to carry out 'a research programme' (T 0604/04, para.22; T 0898/05, para.6).'

The Supreme Court further clarified that where a patent discloses a new protein and its encoding gene:

'(v) The patent, when taken with common general knowledge, must demonstrate 'a real as opposed to a purely theoretical possibility of exploitation' (T 0604/04, para.15; T 0898/05, paras.6, 22 and 31);

(vi) Merely identifying the structure of a protein, without attributing to it a 'clear role,' or 'suggest[ing]' any 'practical use' for it, or suggesting 'a vague and speculative indication of possible objectives that might be achieved,' is not enough (T 0870/04, paras.6–7, 11 and 21; T 0898/05, paras.7, 10 and 31);

(vii) The absence of any experimental or wet lab evidence of activity of the claimed protein is not fatal (T 0898/05, paras.21 and 31; T 1452/06, para.5);

(viii) A 'plausible' or 'reasonably credible' claimed use, or an 'educated guess,' can suffice (T 1329/04, paras.6 and 11; T 0640/04, para.6; T 0898/05, paras.8, 21, 27 and 31; T 1452/06, para.6; T 1165/06 para.25);

(ix) Such plausibility can be assisted by being confirmed by 'later evidence,' although later evidence on its own will not do (T 1329/04, para.12; T 0898/05, para.24; T 1452/06, para.6; T 1165/06, para.25);

(x) The requirements of a plausible and specific possibility of exploitation can be at the biochemical, the cellular or the biological level (T 0898/05, paras.29–30).'

Moreover, where the protein is said to be a family or superfamily member, the Supreme Court set out that:

'(xi) If all known members have a 'role in the proliferation, differentiation and/or activation of immune cells' or 'function in controlling physiology, development and differentiation of mammalian cells,' assigning a similar role to the protein

may suffice (T 1329/04, para.13; T 0898/85, para.21; T 1165/06, paras.14 and 16; T 0870/04, para.12);

(xii) So 'the problem to be solved' in such a case can be 'isolating a further member of the [family]' (T 1329/04, para.4; T 0604/04, para.22; T 1165/06, paras.14 and 16);

(xiii) If the disclosure is 'important to the pharmaceutical industry,' the disclosure of the sequences of the protein and its gene may suffice, even though its role has not 'been clearly defined' (T 0604/04, para.18);

(xiv) The position may be different if there is evidence, either in the patent or elsewhere, which calls the claimed role or membership of the family into question (T 0898/05 para.24; T 1452/06, para.5);

(xv) The position may also be different if the known members have different activities, although they need not always be 'precisely interchangeable in terms of their biological action', and it may be acceptable if 'most' of them have a common role (T 0870/04, para.12; T 0604/04, para.16; T 0898/05, para.27).'

4. Is the basis for any disclosure required in the patent specification:

   (c) Statute and case law as set out above.

B. Prosecution

5. Is it necessary to demonstrate utility or industrial applicability during prosecution?

   Yes.

6. Is there requirement to demonstrate utility or industrial application based on:

   (c) – Both statute and case law

7. Is there a material date by which the utility or industrial applicability must be demonstrated?

   The EPO Decisions (in particular T0604/04, T0870/04 and T0898/05) relied upon by the Supreme Court in *HGS v Lilly* discussed above put great emphasis on the fact that the industrial application must be derivable '*from the application as filed*' and that this must be plausible or '*reasonably credible*' at the time of filing. Such plausibility can be assisted by being <u>confirmed</u> by later evidence but the

later evidence will not do on its own. (See *HGS v Lilly*, Supreme Court, para 107, points (viii) and (ix) as set out above).

During prosecution the UKIPO could ask for this extra evidence but it is clear that if the plausibility hurdle is not met on filing, then technical evidence of the actual use can be of no assistance later, either before or after grant, in supporting a finding that the industrial application requirement is met. This is expressly confirmed in the UKIPO Examination Guidelines for patent applications relating to biotechnological inventions at least at paragraph 59. There is no express precedent here in relation to pharmaceutical or other inventions in general but it must be reasonable to suppose a similar approach would apply.

As to the question of what must be supplied to meet this 'plausibility' hurdle, as discussed above, case law would suggest the bar is pretty low. A general possibility of an industrial (including medical) use to the skilled person would seem enough. Case law does not suggest any express requirement for the use suggested to be very specific, nor indeed that the use itself be inventive.

8. What evidence is required to demonstrate utility or industrial applicability

   a) See discussion above concerning post-filed evidence.

   b) The presence of industrial application can be confirmed by a range of evidence having regard to the principles above. In the case of pharmaceuticals and their uses, the evidence would be evaluated on a case by case basis. This need not be a clinical trial or other *in vivo* data. Depending on the technical situation, *in vitro* or *in silico* data could suffice. There is no equivalent of the 'sound prediction' test but insofar as this may be equated with 'plausibility' then that would need to be in the application as filed.

C. Litigation

9. Is lack of utility or industrial applicability a basis for a validity attack in litigation?

Yes

10. Is such attack permitted by reason of:

   a) Statute.

   Section. 72 Patents Act provides power to revoke patents on application on the basis that:

   (a) the invention is not a patentable invention;

It is not a patentable invention if the industrial application requirement is not met.

11. Is there a material date by which the utility or industrial application must be demonstrated?

See discussion under (7) above.

12. What evidence may the patentee adduce in response?

See discussion under (8) above.