Comparative Aspects of the Non-Obviousness Assessment under European and US Patent Law

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The questions of nonobviousness is “as fugitive, impalpable, wayward and vague a phantom as exists in the whole paraphernalia of legal concepts.”

Judge Learned Hand in Harries v. Air King Products, 183 F.2d, 158, 162 (2d. Cir. 1950).

“No question is so difficult to answer as that to which the answer is obvious.”

George Bernard Shaw 1856-1950

The obvious is that which is never seen until someone expresses it simply.”

Kahlil Gibran 1883-1931
Art. 52 (1):

"European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."

Art. 56 EPC:

"An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. [...]"
Inventive step: The Problem-Solution approach (not formally required but expected)

(1) determine the "closest prior art"
(2) the claimed invention with its technical effects and
(3) identify the differences between them
(4) establish the "objective technical problem" to be solved,
(5) consider whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.
Hindsight warnings in Examination Guidelines

• “It is noted that the objective **technical problem must be so formulated as not to contain pointers to the technical solution**, since including part of a technical solution offered by an invention in the statement of the problem must, when the state of the art is assessed in terms of that problem, **necessarily result in an ex post facto view being taken on inventive activity** (T 229/85, OJ 6/1987, 237).”

• “It should be remembered that an invention which at first sight appears obvious might in fact involve an inventive step. Once a new idea has been formulated, it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps. **The examiner should be wary of ex post facto analysis of this kind.**”
Avoiding hindsight in the inventive step assessment: The could -would approach

PSA step (iii):

Is there any teaching in the prior art as a whole that would (not simply could) have prompted the skilled person to arrive at the invention. (intrinsic/extrinsic hints).

....faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves?
Obvious to try & “Reasonable expectation of success”

The EPO Board of Appeal in T 296/93“Hepatitis B virus antigen production/BIOGEN:

“The fact that other person (or teams) were also working on the same project might suggest that it was ‘obvious to try’ or that it was ‘an interesting area to explore’, but it does not necessarily imply that there was a ‘reasonable expectation of success’.

‘A reasonable expectation of success’ which should not be confused with the understandable ‘hope to succeed’ implies the ability of the skilled person to reasonably predict, on the basis of the existing knowledge before the starting of a research project, a successful conclusion of the research project within acceptable time limits. The more unexplored a technical field of research is, the more difficult is the making of predictions about its successful conclusion and, consequently, the lower the expectation of success.”
Secondary indicators of an inventive step accepted at EPO

- Unexpected technical effects
- Long felt but unsolved need
- Failure of others
- Prior art that taught away
- Commercial success (rarely applied & nexus required)
Section 3 of the 1977 Patents Act provides:

“An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art…”.
1. a) Identify the notional “**person skilled in the art**”,
   b) Identify the relevant **common general knowledge** of that person;

2. Identify the **inventive concept** of the claim in question or, if that cannot readily be identified, construe it;

3. Identify what, if any, **differences**, exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed,

4. Viewed without any knowledge of the alleged invention as claimed, **do those differences constitute steps which would have been obvious to the person skilled in the art** or do they require any degree of invention?
J. Laddie in Haberman v Jackal [1999]
FSR 685 (UK)- the Haberman questions

(a) What problem did patented development addressed?
(b) How long had problem existed?
(c) How significant was the problem?
(d) How widely known was the problem and how many were seeking a solution?
(e) What prior art would have been known to those who would sought a solution?
(f) What other solutions were proposed before publication of patentee's development?
(g) What factors stood against exploitation of solution even if technically obvious?
(h) How well had the patentee's development been received?
(i) In how far was commercial success based on technical merits of the development?
Earlier UK case law: Is now anything obvious?

- Johns Manville Corporation’s Patent (1967) RPC 479

The hard line era: A very high UK threshold for obviousness:

More recent case law from the UK: Approaching Continental Europe?

**Lowering i.a. the nonobviousness threshold:**


- *Conor Medsystems v Angiotech Pharmaceuticals [2008] UKHL 49.*


HGS v Eli Lilly, [2011] UKSC 51
(Neutrokine α) – A borderline case

Read further:

Minssen, T & Nilsson, D: The industrial application requirement for biotech inventions in light of recent EPO & UK case law:: A plausible "hunting license"?, E.I.P.R. , Vol 34, nr. 10, s. 689-703 (2012).

LJ Jacob in Actavis v Novartis [2010] EWCA Civ 82.: Your doing it wrong!!!

In addition:
Is LJ Jacob right?

• Generally: points correct and recognized by EPO

• BUT: Couldn’t PSA solve these difficulties?

• \textbf{P(1)}: problem perhaps not recognized as “problem”, but “fact of life”. Finding of solvable problem could form part of inventive step. (Cf. Guidelines (C-IV 11.6)).

• \textbf{P(2)}: Problem: How to make plate to fulfill functional requirement. Solution: Completely obvious.

• But: \textit{Windsurfing} perhaps more elegant and germane.
The person skilled in the art
The mysterious “person skilled in the art”

G. Ashley (member of EPO BoA):

“The skilled person (or persons) of the EPC is not real, being of average ability for his field but having exhaustive common knowledge and aware of all things that are not technical. He is a legal creation whose purpose is to assist in providing a more objective approach to the assessment of inventive step and other provisions of the EPC. He certainly does not cut an athletic figure, and whilst being able to vault the bar of common knowledge, raising it any higher would be beyond his capability.”

Hans Rainer Jaenichen:

“a team of cautious PhD bench molecular biologists including laboratory assistants that is capable of practically applying methods known in the art, that is aware of the disclosure of pertinent prior art documents, and that has the necessary manual dexterity and lack of fatigue.”
Court must consider reality of the position at the time and combined skills of real research teams in the art.

where invention involves several skills, if it is obvious to person skilled in the art of any one of those skills, then invention is obvious.

General key question is "what problem was patentee trying to solve?" Thus consider the art in which the problem in fact lay.

It is the notional team in that art which is the relevant team making up the person skilled in the art.
Comparison with US

- NB: Most of the post KSR decisions did/would lead to exactly the same result in Europe

- **Similarities to KSR:**
  - consideration of intrinsic/extrinsic *hints* in prior art
  - obvious to try with reasonable expectation of success & finite number of identified predictable solutions
  - consideration of analogous arts (*In re Klein*)
  - secondary considerations etc..

- **Differences to KSR:**
  - ordinary creativity & common sense notions criticized in Europe
  - generally more warnings for hindsight with stronger language in Europe (one exception CAFC in *Mintz v. Watson*).

- **Particularly interesting for comparisons and practical inspiration:**

  Recent UK cases!
Conclusions/Take aways

• Many similarities but also slight difference

• PSA rather flexible but could lead to problems in US filings

• Unitary Patent: Need for harmonization, Can PSA achieve it? Was LJ Jacob right?

• Three alternatives for harmonization (unitary patent):
  1) Get rid of PSA & follow windsurfing
  2) Develop a new approach with less focus on identifying problems
  3) Apply it very carefully and with flexibility
Practical advise for global applications

• Windsurfing/PSA only approaches to mandatory final question.

• But PSA helps during EPO opposition and in litigation.

• Focus in Europe on minimum standards for Art. 57, 83, 84 EPC.

• Be aware of KSR & common general knowledge and needs! Focus in EPC applications on results, NOT on over-elaborated description of problems, common knowledge and prior art.

• Lay carefully out hints/hooks/keywords to help PSA trained examiners/judges to apply their approach in Art. 56 opposition/post grant procedures.

• How much data?: Exploit EPO’s plausibility doctrine to win the race

• Recent HGS case debatable from a general policy perpective.
The way forward: Challenges for the future

• Policy impact of high quality inventive step assessment

• Various solutions for dealing with backlogs while at the same time improving quality

• Increased transparency & public participation

• Peer to patent approaches

• Quality/relevancy threshold for material submitted by applicant

• How to deal with THOSITAS instead of PHOSITAS

• More flexible reg. exclusivities as response to non-obviousness gaps?
Questions and Comments?

Thank for your attention!

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CPH Summer school in Pharma Law & Policy:

http://copenhagensummeruniversity.ku.dk/en/courses/pharmalawpolicy
Additional slides
“[W]herever he went he would pick up bricks and compare them carefully one with another. His conduct excited comment. One man said, ‘he must be seeking the most perfect of all bricks.’ Another said, ‘he must be seeking to describe the qualities inherent in all bricks.’ Still another of a practical turn of mind said, ‘he is probably seeking a brick of just the right shape and colour to fit into his wall.’ And still another said, ‘it is possible that he is not interested in the bricks as such but in their composition. Perhaps, he would set up a kiln of his own for making bricks.’”
Facit:

Plausibility criterion will probably not pose a major hurdle for most patent attorneys due to the rapid advances in common general knowledge and technology!

In light of these advances real problem lies in proving that the results were not “obvious” or “obvious to try with a reasonable expectation of success” for a person skilled in the art.

A stringent application of the inventive step requirement will certainly improve patent quality, help to reduce “evergreening” and reserve a reasonable patent-free zone around the state of the art, but is there any risk for an “obviousness gap” in the pharma sector?
(P) Performable sufficient or performed required?

- Is wet lab evidence always necessary?
- Could high quality "in silicio" evidence be sufficient?
Three different routes for patenting and invention:

1. The international route under the PCT

2. The European route under the EPC (soon in combination with the unitary (EU) patent)

3. The national route under national law and the Biotech Directive