Technical Effects – A Comparison Between the EPO and the National Practice

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Why Is Experimental Data Important?

- Problem-solution approach
  - definition of the technical problem

- AgrEvo requirements (T 939/92):
  - beneficial *effect* to be considered for definition of objective technical problem *only if accomplished by essentially all claimed embodiments*
The EPO Approach to Inventive Step

• The „Problem-and-Solution-Approach“:
  • Determine the closest prior art
  • Assess the technical difference between the closest prior art and the claimed subject matter (i.e. the differing features)
  • What is the resulting technical effect of these distinguishing features?
  • Formulate the objective technical problem solved on the basis of this effect
  • Was it obvious for the skilled person to use the differing features to solve the objective technical problem?
Objective Technical Problem

• Once it is established that in comparison to the closest prior art, the claimed subject-matter exhibits a **technical effect**, which
  ▪ has its origin in the **distinguishing features**,
  ▪ is achieved **over the whole scope** claimed, and
  ▪ is **derivable** from the application as filed,

• then **the objective technical problem** to be solved in view of the closest prior art relates to the **provision of this technical effect**.

• If there is **no technical effect**, the **objective technical problem** relates to a **provision of an alternative** to the closest prior art.
The AgrEvo Case (T939/92):
Broad Markush claim for herbicides

Claim 1

x x x
x x x
x x x
x

x Examples

Application refused by ED under Art. 84 EPC (Lack of Support)

BoA: Art. 84 EPC: satisfied
claim supported by description (disclosing the same Markush formula)

But Inventive step denied
„The question as to whether or not such a technical effect is achieved by all the chemical compounds covered by such a claim may properly arise under Article 56 EPC, if this technical effect turns out to be the sole reason for the alleged inventiveness of these compounds“ (Reasons, Nos. 2.4-2.6)
Obviousness of the Solution

• Provision of a Technical Effect:
  • Is there a prior art teaching suggesting to provide this effect by adding the differing features?
    ➢ Obvious!
  • Is this effect (or the extent thereof) unexpected?
    ➢ Usually inventive!

• Provision of an Alternative:
  • in case of similar structures and/or overlapping scope with respect to the prior art
    ➢ Obvious!
Use of Post-published Evidence/Data?

Criteria:

• **Relevant point in time** for inventive step assessment is the effective date of the application

• **Application must make it at least plausible that that its teaching solves the problem it purports to solve**
  
  • “absolute proof” of the achievement of an effect is not required for the effect to be “plausible”– common general knowledge may be used to interpret the teaching (T716/08)

• As to **NCEs** and their formulation, use, etc.: post-published data are generally accepted by the EPO (since T181/82)

• For **NBEs**, more caution is required in view of T1329/04: post-published evidence may not serve as the sole basis to establish that the problem is solved
Can comparative tests evaluate a technical effect that is not explicitly described in the application?

- T386/89; **any effect** provided by the invention may be used as a basis for reformulating the problem, **as long as this effect is derivable** from the application as filed.
- “**derivable**” = implied by or related to the technical problem initially suggested.
- Adhesion of cutting tool not derivable from disclosed wear resistance (T 344/89)

**Examples from the pharmaceutical area**

- Summary of cases discussed in the Case Law of the Boards of Appeal.
### Reformulation of the Technical Problem – Examples (I)

<table>
<thead>
<tr>
<th>Case</th>
<th>Application</th>
<th>New effect</th>
<th>Derivability Y / N</th>
</tr>
</thead>
<tbody>
<tr>
<td>T 0440/91</td>
<td>Acetylcysteine salts with improved solubility</td>
<td>Enhanced therapeutic activity, avoidance of side-effects</td>
<td>Yes</td>
</tr>
<tr>
<td>T 1062/93</td>
<td><strong>Synergistic</strong> effect on hypertension</td>
<td>Therapeutic effects on hypertension and renal function</td>
<td>Yes</td>
</tr>
<tr>
<td>T 2245/10</td>
<td>Higher efficacy, <strong>reduction of side effects</strong></td>
<td>Higher efficacy with higher doses</td>
<td>No</td>
</tr>
<tr>
<td>T 1422/12</td>
<td>Crystalline form of tigecycline with <strong>increased purity</strong></td>
<td>Improved stability to epimerization</td>
<td>Yes</td>
</tr>
<tr>
<td>T 0777/08</td>
<td>Crystalline form of atorvastatin with therapeutic effects</td>
<td>Improved filterability and drying characteristics</td>
<td>Yes</td>
</tr>
<tr>
<td>Case</td>
<td>Application</td>
<td>New effect</td>
<td>Derivability</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>T 0457/95</td>
<td>Avoidance of problems due to nonspecific binding of avidin</td>
<td>Avoidance of specific binding of avidin to endogenous biotin</td>
<td>Yes</td>
</tr>
<tr>
<td>T 1211/07</td>
<td>Reliable and noninvasive detection of glucose</td>
<td>Improved light penetration in body tissue</td>
<td>No</td>
</tr>
<tr>
<td>T 2233/08</td>
<td>Reduced hazards and difficulties</td>
<td>Improved yield and purity</td>
<td>Yes</td>
</tr>
<tr>
<td>T 0716/07</td>
<td>Recovery of an unstable compound with high purity</td>
<td>Recovery with increased yield and purity</td>
<td>Yes</td>
</tr>
<tr>
<td>T 1188/00</td>
<td>Preparation of copolymer with sufficient glass transition temperature</td>
<td>Combination of short curing time and good usability properties</td>
<td>No</td>
</tr>
</tbody>
</table>
Biotechnology: Plausibility of the Problem Being Solved

T1329/04 – GDF 9

- Patent claimed new member of the TGF-β superfamily (GDF-9)

- But:
  - Structural differences: New protein had low homology and lacked one of the seven cysteine residues typical for TGF-β family members
  - Functional differences: Expression data differed slightly from GDF-1, but there was some overlap

- Inventive step denied: Application as filed did not make it plausible that the problem of providing a new family member has been solved. Post-filed data cannot serve as the sole basis for inventive step.
Comparison EP / DE practice

German courts do not strictly follow the “problem-solution approach”

- EPO concept of “closest prior art document” rejected
- Inventive step needs to be demonstrated vis-à-vis several documents
- Technical problem to be determined objectively
  - But no reformulation of problem based on post-published data (with the exception of substance patents? – FCJ Imidazoline)
- Agrevo type inventive step arguments rarely considered

Common general knowledge considered to a much greater extent in DE

Core issue: **Inducement** (“Veranlassung”) of the skilled person to solve the technical problem in the same manner as the invention
FCJ X ZB 2/71 – *Imidazoline*

- “The problem underlying a chemical invention is the provision of the new substance.”
- The information about the technical or therapeutic effect of the claimed substances does not form a part of the subject-matter of the chemical invention
- The technical or therapeutic effect needs not to be disclosed in the application for a new chemical entity (NCE)
- Later submission of data to make an effect credible accepted
- ≠ EPO requirement for “derivability” of the problem from the application (G 1/03, Reasons, point 2.3.3, T 13/84)
Main challenge regarding the use of comparative data in DE proceedings: more flexible approach of DE courts regarding inventive step assessment

- **FCJ Xa ZR 28/08 – Fettsäurezusammensetzung (fatty acid composition)**
  - "an additional technical effect, even if unexpected and surprising, cannot be the reason for the presence of an inventive step for a combination of known compounds if the provision of the combination was rendered obvious by the prior art"

- **FCJ X ZR 68/99 – kosmetisches Sonnenschutzmittel I (cosmetic sunprotectant I)**
  - Claim: sun protectant with nanosize oxides and UV absorbing silicone
  - FCJ: reduced UV absorption of nanoparticles induced countermeasures leading to the claimed combination - synergistic effects of a claimed combination of compounds can be appraised as indicia in favor of inventive step
Significance of Unexpected Technical Effects

**FCJ X ZR 128/09 – Repaglinid**

- **Inducement:** prior art suggested that claimed (S) enantiomer (= Repaglinid) more active than (R) enantiomer
- **FCJ considered it obvious to take any of several different ways in order to solve the problem**
- **Remarkable pharmacokinetics considered a bonus effect**
- **Unexpected effects did not help at all!**
Technical effects: Support for Inventive Step?

Much lower significance of comparative data than in EP proceedings

- Unexpected therapeutic benefits or surprising technical effects alone do not provide evidence of non-obviousness if the prior art sufficiently induces the skilled person to solve a problem in the manner as claimed (bonus effect)

- For non-obviousness to be substantiated:
  - lack of reasonable expectation of success
  - provision of claimed solution amounts to undue burden
  - no inducement in the prior art
  - sufficient alternatives in the prior art with better expectation of success
United Kingdom
**Formulation**

- Hospira v Genentech, Court of appeal, [2016] EWCA Civ 780

“MyEvol obviousness”

- Idenix v Gilead, [2016] EWCA Civ 1089
- Merck Sharp & Dohme v Shionogi, [2016] EWHC 2989
EP(UK)1516628, EP(UK)2275119

Claim 1 (‘628 as amended):
1. A formulation comprising a lyophilized mixture of a lyoprotectant, a buffer, a surfactant and an antibody, wherein the lyoprotectant is trehalose, wherein the buffer is histidine, wherein the surfactant is polysorbate 20 and wherein the antibody is huMAb4D5-8, obtainable by lyophilizing a solution containing 25 mg/ml huMAb4D5-8, 5mM histidine pH 6.0, 60 mM trehalose and 0.01% polysorbate 20.

Prior art (Carter):
Teaches that trastuzumab is in Phase II clinical trials for breast cancer (as a PBS formulation)
**EP(UK)1516628, EP(UK)2275119**

**EPO**: Opposition rejected, patent maintained in unamended form

**UK**: High Court, Mr Justice Birss, [2014] EWHC 3857
None of the claims involve an inventive step over Carter

Court of Appeal, Lord Justice Kitchin, [2016] EWCA Civ 780
Appeal dismissed
Multi-factorial assessment

[9] "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."

Generics (UK) Ltd v H. Lundbeck A/S [2007] EWHC 1040
In my judgment all of the differences between the claim and Carter are the result of nothing more than the application of routine screening techniques to common general knowledge excipients by a skilled team motivated in the way I have described already. (see [226], High court)

It is not true to say that a real team would arrive at a formulation consisting of polysorbate 20, histidine and trehalose. […] But what Hospira's submission is getting at is that the claimed result can be reached by the application of nothing other than routine approaches applied to excipients which were part of their common general knowledge. In my judgment on the facts of this case that is correct. (see [234], High Court, emphasis added)

Appeal dismissed.
EP(UK)1 523 489

Claim 1:
1. A compound of Formula (IX):

or a pharmaceutically acceptable salt thereof, wherein:

R1 and R2 are independently H; phosphate; straight chained, branched or cyclic alkyl; acyl; CO-alkyl; CO-aryl; CO-alkoxyalkyl; CO-aryloxyalkyl; CO-substituted aryl; sulfonate ester; benzyl, wherein the phenyl group is optionally substituted with one or more substituents; alkylsulfonyl; arylsulfonyl; aralkylsulfonyl; a lipid; an amino acid; a carbohydrate; a peptide; or a cholesterol; X is O; Base* is a purine or pyrimidine base; R12 is C(Y3)3; Y3 is H; and R13 is fluoro.

Teaching to use compounds as antiviral agents to treat Flaviviridae infections

Revoked during EPO opposition proceedings under Art 83 EPC, appeal pending.
EP(UK)1 523 489

EPO: Revoked in opposition proceedings under Art 83 EPC, appeal pending.

UK: High Court, Mr Justice Arnold, [2014] EWHC 3916
   Claims lack inventive step, inter alia

   Court of Appeal, Lord Justice Kitchin, [2016] EWCA Civ 1089
   Appeal dismissed
Court of appeal

[114.] In my judgment the same approach should be adopted in considering obviousness and whether a technical effect is plausible in the light of the teaching in the specification and the common general knowledge. There must be a real reason for supposing that the claimed invention will indeed have the promised technical effect.

Agreed with Judge Arnold:
- The claims are “stupendously broad”.
- There is nothing in the specification by way of experimental data to suggest that substantially all of these compounds are effective against Flaviviridae. Moreover, there is nothing in the specification by way of a theory or rationale as to why the claimed compounds may be effective.
- On the face of the Patent, the assertion that the claimed compounds may be effective appears to be no more than speculation.
1. Use of a compound of formula (I)

wherein, RC and RD taken together with the neighboring carbon atoms form a 5- to 6-membered ring which may contain (a) heteroatom(s) of N and/or O and may be condensed with a benzene ring, Y is hydroxy; Z is O ; R A is a group shown by

(therein, C ring is a 5- to 6-membered N-containing aromatic heterocycle which may contain 1 to 4 of O, S and/or N atom(s), wherein at least one atom neighboring to the atom at the bonding-position is non-substituted N atom; the broken line shows the presence or absence of a bond), or by

[....] ; or a pharmaceutically acceptable salt or solvate thereof,

for the preparation of a pharmaceutical composition for use as an integrase inhibitor for preventing or treating a viral disease.

EPO:
Patent maintained in amended form during opposition, appeal pending.
- General principles as laid out in Generics v Yeda ([2013] EWCA Civ 925)
- Idenix v Gilead ([2016] EWCA Civ 1089)

"... a claim to a class of products said to possess a useful activity must be based upon the identification of a common principle which permits a **reasonable prediction** to be made that substantially all the claimed products do indeed share that activity. Further, it is **not permissible** to by-pass that requirement simply by adding a functional limitation which restricts the scope of the claim to all the products which do have the relevant activity, that is to say all those which 'work'. ...“ (emphasis added)

- The judge considered it implausible that substantially all claimed compounds are integrase inhibitors, even less so that they have antiviral activity and are an effective drug.

**Lack of inventive step.**
Italy
The EPO’s problem-solution approach in national proceedings

- Inventive step (Art. 48 IPC): “An invention is considered as implying an inventive activity if, for a person who is an expert in the field, it is not evident from the prior art [...]”

- Concept of technical invention: “a (technical) solution of a technical problem to make a technical progress or an improvement of the prior art” (Confirmed by Supreme Court decisions 26.2.2016 n.° 3805 & 6.12.2016)

- The Italian Supreme Court decisions confirm the applicability of EPO problem-solution approach (& EPO Guidelines) in national proceedings
Technical effects not mentioned in the patent application

- Difficult to rely upon if it is **not** present in, or derivable from, the patent disclosure (Supreme Court decision 4.11.2009 n.° 23414)

- The “**technical problem can be reformulated as indicated in the EPO Guidelines**” (T. Milano 11.2.2016 n.° 4570/2016)
Extent of improvement over the prior art

- It depends on the technical field: “In the pharmaceutical field research may have a routine character, thus the average activity of the technician involves research and experimentation on known compounds”

- It may also depend on whether the type of (technical) problem solved by the invention was already felt before the patent application priority date (T. Roma 7.7.2010 n.° 17937/10)
Data support in the application and breadth of claims

- Sufficient description (Art. 51 co. 2 IPC): “The invention must be described in a sufficiently clear and complete manner so that any person who is an expert in the field can implement it [...];”

- The patent application “has to disclose in detail at least one embodiment to carry out the invention“ (Art. 2 co. 3(e) M.D. 27.6.2008)

- “The skilled person must be able to implement the invention without any difficulty and without carrying out any research activity or new investigation or new experiment” (T. Milano 7.4.2017 n.° 4033/2017)
Conclusion

In Italian patent litigation, the technical effects are assessed in accordance with the EPO practice.
Spain
The EPO’s problem-solution approach in Spain

- Inventive step (Art. 8.1 Law 24/2015): “An invention is considered as implying inventive step if it does not result from the state of the art in an obvious manner to a person skilled in the art”

- SPTO guidelines recognize the problem-solution approach as one of the methods to evaluate inventive step (SPTO Guidelines, July 2016, part E, 6.6)

- Due to relatively scarce judicial precedents from the Supreme Court, Spanish Courts have a tendency to follow EPO’s problem-solution approach and rely on its case law (e.g. 43/2013 29.04.2013 Barcelona Com. Court No. 4)
Should the Technical Problem be defined in the application?

- **Art. 3.2(c)** of the rules for implementation of Law 24/2015 (Royal Decree 316/2017) corresponds to **R.42(1)(c) EPC** and requires that the description:

  - contains an explanation of the invention as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood

  - further stating, if appropriate, the **advantages** of the invention with respect to the state of the art
Can the technical problem be reformulated?

- A recent decision from the Supreme Court (RJ 2016/3682, 20.05.2016) confirms that the “technical problem can be reformulated” in alignment with the EPO practice (GL 2016, G-VII, 5.2)

- The SC sustains that the description should be understood as a “starting point” and in case the claimed technical effects are not supported by the application or the state of the art used to define the problem was not appropriate, it should be assessed which other problem was objectively presented.
Should advantageous effects be mentioned?

- **Art. 3.2(c)** requires that the description indicates if appropriate the advantages of the invention with respect to the state of the art

- The SPTO guidelines mention that the examiner should not be influenced by the various advantages referred by the Applicant, should these be not directly derivable from the technical difference with respect to the state of the art

- It is further highlighted that there should be a causality between the technical difference and the technical effect (SPTO Guidelines, July 2016, part E, 6.6.1)
Conclusion

The Spanish Courts tend to follow EPO’s problem-solution approach and assess technical effects in agreement with the EPO practice.
Thank you for your attention!

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