Insufficiency: recent developments in France

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Contents

1. Classical criteria for assessing sufficiency
2. The chase of *"speculation"* in the pharmaceutical field

1. Classical criteria for sufficiency (1/2)

- Sufficiency assessed in the light of the skilled person and its general knowledge
- Burden of proof lies on the one alleging insufficiency
  - *cour d'appel de Paris,* 13 January 2012, *Sandoz* v. *Eli Lilly : "proof should be provided beyond a reasonable doubt and the benefit of the doubt should be given to the patent holder"*
  - *tribunal de grande instance de Paris*, 3rd ch., 2nd sect., 6 July 2012, *Mc Neil AB v. Pierre Fabre Médicament* : the insufficiency of disclosure presuppose that there exists *"serious doubts substantiated by verifiable facts"*

1. Classical criteria for sufficiency (2/2)

- The mention of experiments or trials and the indication of research work in the patent is not mandatory
  - *Cour de cassation*, commercial chamber, 16 June 1992, *Le Foll* v. *Raveneau:*

    "the decision considers that the patent description [….] did not contain enough details as it contained no indication concerning its action on the physiological mechanisms of living beings and without prior laboratory experiments intended to verify the therapeutic effect in humans or animals […]. By thus adding to the description of the invention the requirement of a result, the cour d'appel violated the above-mentioned text"
- Examples in the description are only required if they are necessary for the skilled person to carry out the invention

2. The chase of *"speculation"* in the pharmaceutical field

2.1. Decisions chasing speculation

2.2. Comments

2.1. Decisions chasing *"speculation"* (1/6)

- New invalidity attack: the patent is *"speculative"* , i.e. does not contain (sufficient) data in support of the alleged effect, and thus is invalid for insufficiency:
  - not strictly the plausibility argument as construed by the EPO and the UK courts, but similar attack,
  - invoked in particular against patents claiming second therapeutic applications, but not only

Developments on insufficiency

2.1. Decisions chasing *"speculation"* (2/6)

- Decisions of the 3rd chamber, 1st section finding patents invalid for insufficiency on the grounds that they are "*speculative*":
  - 6 October 2009, Teva / Sepracor,
  - 9 November 2010, Teva / Merck,
  - 28 February 2013, Sanofi / Mylan
- Decision of the 3rd chamber, 1st section applying the same criteria but finding the patent valid:
  - *tribunal de grande instance de Paris*, 3rd chamber, 1st section, 20 March 2012, Teva / Eli Lilly (affirmed by *Cour d'appel de Paris*, pole 5, chamber 1, 12 March 2014)

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29/04/2014 19:48 7

Developments on insufficiency

2.1. Decisions chasing *"speculation"* (3/6)

- Reasoning of the *tribunal* in the cases finding the patent invalid:
  - in the pharmaceutical field, the sufficiency of disclosure of a drug invention requires the indication of pharmacological properties and of one or several therapeutic uses,
  - the inventor does not have to demonstrate the result, but has to indicate that this result has been sought and exists,
  - in the absence of technical information, such as experiments or plausible explanations in the description, in support of the alleged effects, the patent is speculative, and thus invalid for insufficiency

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29/04/2014 19:48 8

Developments on insufficiency

2.1. Decisions chasing *"speculation"* (4/6)

- In some decisions, the claimed result seems to have been considered doubtful:
  - 6 October 2009, *Teva / Sepracor*: two patent applications filed on the same day on the use of (+) cetirizine for the treatment of allergic rhinitis and for (-) cetirizine
  - 9 November 2010, *Teva / Merck*: drug for the treatment of androgenic alopecia

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29/04/2014 19:48 9

Developments on insufficiency

2.1. Decisions chasing *"speculation"* (5/6)

- Requirement not limited to second therapeutic applications
- Decisions concerning patents on second therapeutic applications:
  - 6 October 2009, *Teva / Sepracor*
  - 9 November 2010, *Teva / Merck*
- Decision concerning a patent claiming a pharmaceutical composition:
  - 28 February 2013, *Sanofi / Mylan*: claim to a pharmaceutical compositions containing irbesartan in combination with a diuretic

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29/04/2014 19:48 10

2.1. Decisions chasing *"speculation"* (6/6)

- Later production of experimental evidence can be taken into account
- But only if it is not the sole basis to prove the alleged effect
  - 6 October 2009, *Teva / Sepracor*

Contra: decisions of the *tribunal de grande instance de Paris*, 3rd chamber, 3rd and 4th section

- *Tribunal de grande instance de Paris*, 3rd ch., 3rd s, 11 January 2013, *Sanofi-Aventis* v. *Philippe Perovitch et Marc Maury*:
  - *"The inventors have no obligation to fulfill sufficiency to perform tests or experiences proving the real efficacy of the invention and to include them in the patent",*
  - *"The dispute of the real therapeutic effect of the described invention pertains to novelty or inventive step, and not sufficiency"*
- *Tribunal de grande instance de Paris*, 3rd ch., 4th s, 13 February 2014, *Merial / Virbac*:
  - *"It is well-established that the law does not require that specific examples be given, and this absence cannot alone cause the patent to be invalid"*

2.2. Comments (1/3)

- How far does the requirement for additional data in the specification go?
- *Teva / Merck*: the patent contained examples but the *tribunal* considered that they were not relevant:
  - example № 4 does not indicate on how many people the experiments were conducted, for how long, no comparison with people using a substrate
  - example № 5 does not evidence the alleged effect, no serious research about the efficacy of the product, was only mentioned to meet the condition of sufficiency

2.2. Comments (2/3)

- *Teva / Eli Lilly* : data in the patent considered sufficient:
  - Teva argued that the experiments in the patent were only conducted on animals, without any experiments on post-menopausal women
  - dismissed by the *tribunal*: at the time of filing, Eli Lilly had carried out most of its studies on the effects of raloxifen at least on animals so that it cannot be contended that the claimed invention was mere speculation

2.2. Comments (3/3)

- Is sufficiency the relevant grounds to invalidate "*speculative*" patents ?
- In the Sepracor case, the *tribunal* hesitated between sufficiency and inventive step and indicated that:
  - the absence of any mention of research and result proves the speculative nature of the patent application and, as a consequence, conceals the lack of inventive step,
  - inventive step implies a concrete technical solution to a given technical problem which requires at least a minimum of experiments and assays.

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Thank you for your attention

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