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Dosage claims refused once again in France

Isabelle Romet, Dora Talvard (Véron & Associés) · Tuesday, January 27th, 2015

The non patent eligibility of a new dosage for the same disease was reiterated by a decision issued by the *tribunal de grande instance de Paris*, 3rd chamber, 3rd section, handed down on 5 December 2014 in the infringement proceedings between Akzo Nobel NV, MSD OSS BV and MSD France SAS, on the one hand, and Teva Santé SAS, Ratiopharm GmbH, Merckle GmbH and Cemelog-BRS Ltd, on the other hand.

Teva was sued for launching a generic of the reference drug *Cerazette* a few months before the expiry of MSD's supplementary protection certificate based on European patent № 0 491 443 relating to a contraceptive preparation containing progestogen only, more precisely desogestrel, 3-ketodesogestrel, or mixtures thereof, in a specific daily dosage.

The court admits Teva's invalidity counter-claim for non patentability to invalidate claim 1 of the basic patent, covering "*a combination and contraceptive kit comprising sequential daily dosage units for oral administration each containing as the sole contraceptively effective ingredient from 70 to 80 micrograms of desogestrel, 3-ketodesogestrel, or mixtures thereof*".

The decision explains that progestogen-only contraceptives were already known in prior art and that the patent purported to a specific dosage form of desogestrel or 3-ketodesogestrel presented in the specification as inhibiting ovulation more effectively, while still avoiding some secondary effects.

It construes claim 1 as covering a second therapeutic application of a known molecule for the treatment of the same disease in the same administration form, the specific dosage form being the only new element.

It recognizes the possibility to protect new therapeutic indications of a known substance.

It also admits the possibility to claim a new dosage of a known substance for the treatment of a new disease:
"*Consequently, it is possible to patent a substance by indicating an efficient dosage scale to solve the posed problem that is the treatment of a first disease and then to patent the same substance by indicating a different efficient dosage scale but to solve*

the posed problem that is a second illness"

But it considers that a new dosage form of a known substance for the treatment of the same illness should not be patentable because, according to the decision, the choice of a dosage for a drug is the exclusive work of the physician, in consideration of the specificities of his patient, notwithstanding the indications given by the pharmaceutical laboratory on the drug leaflet, so that dosage claims would amount to seeking protection for a therapeutic method:
" *(…) however, it is impossible to treat the sole posology adapted for the treatment of the same disease as by doing so, one attempts to patent a therapeutic method, which is excluded in order to belong to the field of care and to depend only on the concomitant freedom and responsibility of each doctor.*"

The reported decision echoes the previous decision of the *tribunal de grande instance de Paris*, 3rd chamber, 1st section, *Actavis / MSD* of 28 September 2010, relating to finasteride and it reproduces several of its paragraphs.

Non patentability of a dosage form was also briefly mentioned by the *tribunal de grande instance de Paris*, 3rd chamber, 1st section, in a decision of 20 March 2012, *Teva / Eli Lilly*, affirmed by the *cour d'appel de Paris* on 12 March 2014.

However, it should not be concluded that the controversy about the patent eligibility of a new dosage is closed in France: the debate remains open.

Claim 1 of the disputed patent is also found invalid for lack of inventive step, like the other asserted claims: the *tribunal* considers that the person skilled in the art already knew from prior art the efficacy of a 60 micrograms dosage (it is not usual that French decisions rule upon a second ground for nullity after having already found a claim invalid and the decision probably suggests that the patentee should have no regret because claim 1 would in any case be found invalid).

In parallel proceedings in Germany, the *Bundespatentgericht* also found the patent invalid for lack of inventive step in a decision of 6 May 2014, after a preliminary injunction ordered by the *Landgericht Düsseldorf* was reversed by the *Oberlandgericht Düsseldorf* on 7 November 2013.

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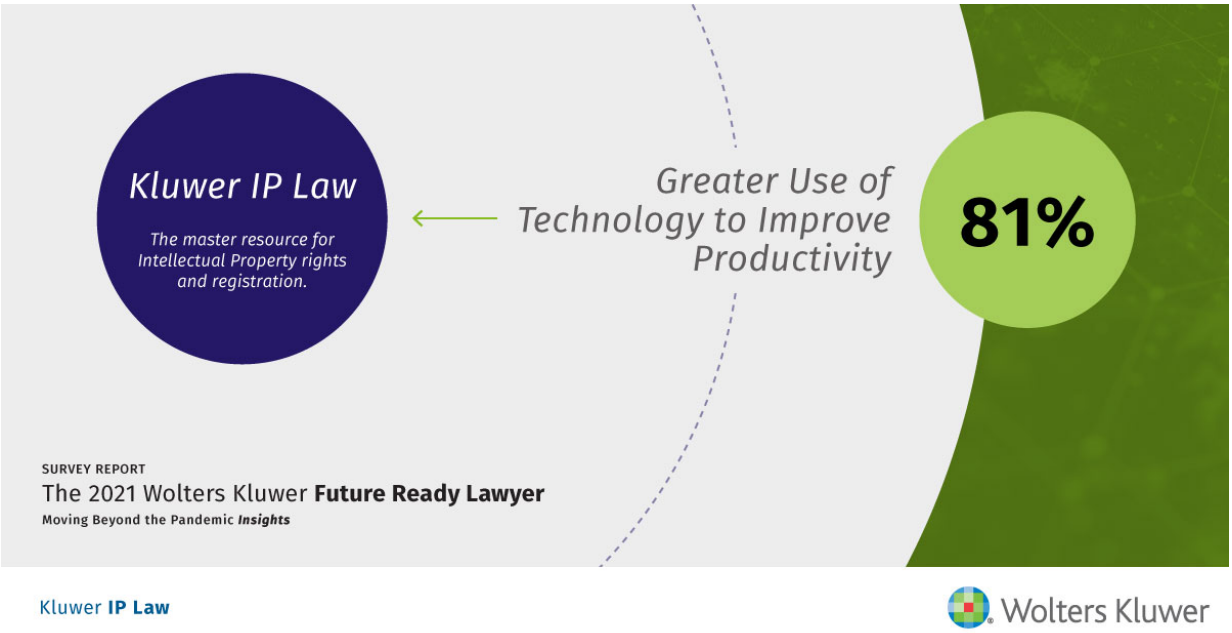

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