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Osimertinib SPC's: the Law of Numbers

Matthieu Dhenne (Ipsilon) · Thursday, May 13th, 2021

In mathematics, the law of numbers makes it possible to interpret the probability as a frequency of occurrence, thus justifying the principle of surveys, and presents the expectation as an average. This theory alone could very well summarize the decision of the Paris Court of Appeal regarding the Osimertinib SPC's rendered on February 9, 2021.

The SPC application was filed by Wyeth and the General Hospital Corporation on the basis of European patent No. EP 1848414 filed on February 2, 2006 and of marketing authorization (MA) No. EU/1/16/1086 granted in 2016 to Astrazeneca for Tagrisso[®] (osimertinib mesylate). Tagrisso[®] is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations, and in particular for treating those patients who harbor a T790M mutation-positive EGFR (i.e. the amino acid threonine (T) in position 790 of the EGFR is substituted by a methionine (M)). Osimertinib is a Tyrosine Kinase Inhibitor (TKI) which irreversibly inhibits EGFRs harboring sensitizing-mutations (EGFR_m) (i.e. mutations causing cancer) and the TKI-resistance mutation T790M.

This application was refused by the INPI (i.e. French Patent and Trademark Office) on August 1, 2019 pursuant to Article 3(a) of Regulation (EC) No. 469/2009. The Office decided that while the claims of the basic patent did implicitly and necessarily relate to osimertinib, they did not specifically relate to it, since osimertinib was neither mentioned in the specification of the patent nor identifiable as such. Although the evidence produced by the applicant (subsequent patents relating to osimertinib, scientific publications) demonstrates that the basic patent undoubtedly contributed to the state of the art and enabled research into an EGFR receptor inhibitor to progress, it does not in any way make it possible to establish that the active principle osimertinib, which led to the medicine that gave rise to the marketing authorization, was not the result of an autonomous inventive step within the meaning of the Royalty Pharma jurisprudence. Moreover, several years of research were needed to precisely and specifically identify osimertinib as an active product, since osimertinib was only claimed in a patent on July 25, 2012 by Astrazeneca, which confirms that upon reading all the information contained in the basic patent in the light of its knowledge, this product was unknown to the person skilled in the art at the filing date in 2006. The

skilled person could not directly and unequivocally infer osimertinib from said patent, its discovery being the result of several years of complex research.

As pointed out in the introduction, the law of numbers could well summarize the Court's reasoning here. Let us note, firstly, that this confirmation of a rejection of a SPC by the Paris Court of Appeal is part of a general trend clearly favorable to the INPI with a confirmation rate of 100% over the last 5 years (since 2016).

Secondly, and more importantly, the Court takes a quantitative approach to AstraZeneca's research work to deduce that the invention covered by its patent (EP'985) required an inventive step, which distinguishes it from the invention covered by the first patent of 2006 (EP'414). The method used by the Judges is open to criticism in several respects. Firstly, it is not possible to link the inventive step entirely to the number of citations of a patent without risking a misleading view of the importance of the invention. Besides, the exclusion of taking merit into account in this assessment of the inventive step is precisely aimed at ensuring that a qualitative and not quantitative approach prevails. Last but not least, such a method disregards the real importance of the documents that cite the patent, although few minor publications will not have the same impact as a single major publication.

To conclude, it seems to me that here, as too often in patent law, it would be advisable to forget that there is no really objective assessment and that by denying subjectivity too much, it ends up coming back at a gallop.

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