ES – Aventis et al. v. Hospira / Docetaxel / Supreme Court

Aventis Pharma S.A., May & Baker Ltd. & Sanofi Aventis S.A. v. Hospira Productos Farmacéuticos y Hospitalarios S.L., Supreme Court (Civil Chamber, 1st Section), Spain, 14 April 2015, Docket No. 1809/2013.

The Spanish Supreme Court definitely ruled and put a term to the patent litigation brought in 2010 against Hospira by Aventis, together with its exclusive licensee May & Baker and sublicensee Sanofi-Aventis, in relation to the former's Docetaxel generic medicinal products authorized for and marketed in Spain. In its Judgment of 14 April 2015, the Supreme Court confirmed Hospira's contributory infringement of claims 5 to 8 of Aventis' EP 827745 patent (as limited within the Court proceedings under Art. 138(3) EPC).

In April 2010, Hospira obtained a marketing authorization from the Spanish Agency of Medicines and Medical Devices for the generic drug Docetaxel Hospira (perfusion solution). This medicine contains Docetaxel as the active ingredient and is intended for hospital use only. The Summary of Product Characteristics (SmPC) and the package leaflet of Docetaxel Hospira mentioned, among the indications for use and dosage information, certain combined therapies for treatment of various forms of cancer, using Docetaxel with other substances, such as Trastuzumab, Cyclophosphamide, Cisplatin, 5-fluorouracil or Doxorubicin.

Aventis (together with May & Baker and Sanofi-Aventis) sued Hospira, among others, for committing contributory infringement of three of its combination patents for therapeutic use which protected combinations of Docetaxel and different substances for the treatment of cancer and neoplastic diseases: EP 667771 (Docetaxel + Doxorubicin; 'EP 771'), EP 827745 (Docetaxel + Cyclophosphamide, Docetaxel + 5-fluorouracil, 'EP 745') and EP 1169059 (Docetaxel + Trastuzumab; 'EP 059'). In the plaintiffs' opinion, Hospira provided physicians with an essential element to be used for putting these inventions into practice, together with the instructions or indications in the SmPC and package leaflet, to use Docetaxel with other substances in combined therapy against cancer neoplastic diseases. The above, according to the plaintiffs, constituted a contributory infringement of their patent rights under Art. 51(1) of the Spanish Patents Act (*"A patent shall also entitle its owner to prevent a third party from handing over or offering to hand over to unauthorized persons without his consent elements related to an essential part of the invention to be used for putting the invention into effect, when the third party knows, or the circumstances make it obvious, that such elements are capable of putting the invention into effect and are to be used for that purpose"*).

In its defense, Hospira, apart from challenging the validity of the enforced patents, contested to the claims for contributory patent infringement arguing that, in order to commit same, it is necessary for the means to have been handed over or for there to be an offer to hand over to unauthorized persons, and for them to infringe directly. According to Hospira, physicians cannot not be regarded as "unauthorized persons" as they do not perform exploitation activities; rather their work is limited to the treatment of patients. Additionally, Hospira considered that the therapeutic use of a combination of patented substances is excluded from the prohibition.

In the first instance, Commercial Court no. 1 of Granada found in its Judgment of 6 November 2012 that claims 5-8 of the EP 745 patent (limited within the proceedings under Art. 138(3) EPC) and the EP 059 patent were indeed valid, and so declared the existence of contributory infringement thereof on the basis that Hospira provided Docexatel to medical staff with enough information to obtain the protected combinations and the way to administer them to patients in combined therapy for oncological treatment. The final solution obtained infringed Aventis' patents. The exceptions alleged by Hospira had to be rejected since, on the one hand, it is only the patentee who has the right to authorize the exploitation by including in the SmPC of its own product (TAXOTERE) the indications for use, which are then worked by authorized physicians, and on the other hand, the therapeutic use of a combination of patented substances is not envisaged in the law as an exception to the patentee's rights.

Hospira appealed before the Court of Appeals of Granada. In the Judgment rendered on 11 June 2013, the Court of Appeals also considered that claims 5-8 of the EP 745 patent were contributorily infringed as sufficient medical information was provided with the SmPC or the package leaflet for putting the patented invention (i.e., the use of the known active ingredient in the new therapy) into practice, making it possible or effective. The Court considered that the recipients of the information are not persons authorized to exploit the invention, as per Art. 51, when they carry out acts for private use, or prepare medicines in connection with the patent contents. Nevertheless, the Court stated that the matter was not about the supposed infringing conduct of the physicians, but rather about verifying the infringing conduct by a third party that provides the means in order for an unauthorized person to put into effect the invention. In these circumstances, the Court of Appeals confirmed the Judgment under appeal on this point (the EP 059 patent was revoked, though).

Hospira then appealed this new Judgment before the Supreme Court. On its cassation appeal, and as a basis thereof, Hospira alleged that the Court of Appeals had found that physicians would not directly infringe the EP 745 patent.

However, the Supreme Court also confirmed contributory infringement of the said patent by Hospira in its Judgment of 14 April 2015. The Supreme Court noticed that Hospira's basis for the appeal was wrong as the Court of Appeals did not actually conclude that physicians would not directly infringe the patent, but it had only remarked that the point was to verify whether Hospira provided physicians with sufficient information for putting the invention into practice, under the provisions in Art. 51. Thus, the grounds for the cassation appeal had to be dismissed in the absence of the alleged defect supporting same.

By aligning with the earlier findings of the Court of Appeals, the Supreme Court thus confirmed in this Judgment, as a general teaching that is inferred therefrom, that contributory patent infringement is proven when the provided elements related to an essential part of the invention (in this case, the information contained in the SmPC and package leaflet) are enough for putting the patented invention into practice. Contributory infringement does not require proving or substantiating an ulterior direct infringement by the recipients, but only the handing over or offer to hand over of those elements by the third party, irrespective of whether or not the recipients actually make use thereof to work the invention, which is deemed irrelevant.