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Patent Litigation as a Form of Abuse – The Spanish Decision Against MSD

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On 21 October 2022 the Spanish CNMC imposed a fine of 38.9 million EUR on MERCK SHARP & DOHME DE ESPAÑA, S.A. and its parent company MSD HUMAN HEALTH HOLDING, B.V. (hereafter jointly 'MSD') for abusive practices in the Spanish market of contraceptive rings. Their breach consisted in having made baseless court claims with the aim of harassing a competitor ("*ejercicio de acciones judiciales infundadas con el propósito de hostigar a un competidor*"). A copy of the decision (in Spanish) is available here.

Vexatious litigation as a form of abuse

The decision is a rare example of a form of vexatious litigation, a type of competition law infringement that has been long in the books but is seldom applied. In the US, "*sham litigation*" is construed as an exception to the general immunity from antitrust laws that shields petitions from governmental or judicial authorities under the doctrine established in Noerr and Pennington, allowing findings of antitrust breach through unfounded claims (defined in Professional Real Estate Investors as a situation where "no reasonable litigant could realistically expect success on the merits").

On our side of the Atlantic, vexatious litigation has been considered by the CJEU in ITT Promedia, Protégé International and Agria Polska cases where the Court has imposed two cumulative criteria to challenge these initiatives under competition law: (i) that the action could not reasonably be considered as an attempt to establish the rights of the undertaking concerned and can therefore only serve to harass the opposite party and (ii) that it would be conceived in the framework of a plan whose goal is to eliminate competition.

Given the potential impact of this doctrine on fundamental rights, especially access to courts, these findings have required "*wholly exceptional circumstances*" (ITT Promedia, at 50), a restrictive approach that explains that the three above judgments address consider complaints which were rejected by the Commission, that being later confirmed by the EU courts.

The MSD decision of the CNMC

The decision of the Spanish watchdog examines the actions adopted by an affiliate of MSD to invoke its patent rights against the entry into the Spanish market of a competing product marketed by INSUD PHARMA SL ("INSUD"), an affiliate of the multinational CHEMO/EXELTIS group.

The facts of the case may be summarised as follows: Since 2002, MSD was selling in Spain the only contraceptive ring sold in Spain ("Nuvaring"), which was protected by a patent dating back to 1997. In June 2017, INSUD obtained marketing authorisation for a similar product ("Ornibel"). MSD immediately sent INSUD a warning letter claiming that the latter's product encroached on its patent (which was due to expire shortly after, in April 2018). In parallel, it requested the Juzgado de lo Mercantil n 5 of Barcelona the adoption of "*diligencias de comprobación de hechos*", an exceptional pretrial discovery mechanism in Spanish patent law that is not even communicated to the potential infringer, in order to access technical data on the product from the Spanish Medicines Agency.

Some weeks later, on 11 September 2017, MSD requested interim measures from the same court consisting in prohibiting the import and sale by INSUD of Ornibel. These measures were initially granted on 18 September without having heard INSUD, as Spanish law permits. Following the notification of these measures to INSUD, and after its allegations, the court lifted the prohibitions on 12 December 2017. MSD's appeal against this decision was dismissed one year later. By that time, MSD's patent had already expired.

The case was subsequently abandoned by MSD, with the exception of a pending claim by INSUD against MSD for the damages resulting from the two-month period where INSUD had been prevented from selling its contraceptive ring.

Main findings

In its decision, the CNMC declares that these court actions amount to an abuse of MSD's dominant position in the Spanish market of contraceptive rings.

The market definition, in this case, is remarkable and relies on an ATC 4 category, rather than the ATC 3 level commonly used in competition (especially merger) cases. Interestingly enough, MSD would likely be dominant even under ATC3 (see para 323 of the CNMC decision), but the CNMC has chosen the narrower delimitation, a decision that may signal a stricter policy going forward.

With respect to the abuse, the decision presents the exceptional tools at the disposal of patent owners to protect their rights under Spanish patent legislation (especially the limitations of the rights of defence of the potential infringer that allow the courts to make certain urgent findings without hearing them) as powers that must be used with care by dominant entities given their special responsibility under Article 102 TFEU. From that viewpoint it takes issue with MSD not having responded to certain letters from INSUD, having concealed information from the court and ploughed ahead with its court case rather than engaging in a good faith discussion with its rival. One especially unfortunate fact that appears to have weighed in a lot is the absence of direct contact with the defendant by the expert appointed by the court in the context of the "*diligencias de comprobación de hechos*", something the decision appears to attribute to MSD.

On the lack of merit of the claims raised by MSD against INSUD, the Spanish watchdog stresses the differences in design and functionality of the contraceptive rings manufactured by both. That

determination appears influenced by the presumed anticompetitive intent of MSD, whose relevance is abundantly discussed.

On the duration of the practice, the CNMC considers that the infringement commenced with the filing by MSD of the "*diligencias de comprobación de hechos*" in June 2017, despite its absence of direct impact (as above noted, the marketing prohibition was adopted only in September), probably since those measures are understood to lack justification. The conduct would have ended in April 2018, when the patents expired, despite the lift of the interim measures in December 2017.

Final remarks

The decision in the MSD case strikes as a severe application of the vexatious litigation doctrine, which as earlier noted, requires "*wholly exceptional circumstances*". The actions under scrutiny consisted of a request for access to documents and a request for interim measures which was granted by the Juzgado de lo Mercantil n 5 of Barcelona and later lifted in less than two months.

While it is easy to agree that some irregularities tainted these procedures, it may be disputed if they would qualify as a case of vexatious litigation under the traditional theory crafted by the EU courts. Rather, the decision should rather be seen in the context of the increased attention given to the pharmaceutical sector since the 2009 Pharmaceutical Sector Enquiry where, besides the "*pay for delay*" decisions in Lundbeck, Servier, Johnson & Johnson or Teva, the authorities have identified other potential infringements linked to the aggressive use of patent procedures to hinder market entry of generic alternatives, some of which are discussed in the 2019 Report on Competition in the Pharmaceutical Sector, the most recent example being the statement of objections addressed by the Commission at Teva last 10 October.

From that perspective, the analysis of the CNMC appears closer to the logic of the Astra Zeneca abusive patent filing case (a precedent discussed in paragraphs 424 ff of the MSD decision), than to a traditional vexatious litigation case. True, that precedent discussed misleading representations made before an administrative agency (a patent office) and not a court, a distinction that is relevant. That said, the MSD decision examines a case of potentially abusive litigation by a patent owner aimed at preventing the entry into the market of generic products, not just an ordinary (and potentially questionable) vigorous assertion of rights against market rivals before courts.

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