Court of Justice of European Union Is Asked Preliminary Questions on Application of Falsified Medicines Directive to Parallel-Traded Medicines

By judgment of 27 February 2020, the Regional Court of Hamburg (the ***Hamburg Court***) referred four questions for a preliminary ruling to the Court of Justice of the European Union (the ***CJEU***) seeking to receive clarification regarding the application of the requirements of the Falsified Medicines Directive (Directive 2011/62/EU of 8 June 2011) in the context of parallel trade in medicines. The referral was made in legal proceedings initiated by Novartis Pharma GmbH (***Novartis Germany***) against the parallel importer Abacus Medicine A/S (***Abacus***). The request for a preliminary ruling was lodged with the CJEU on 23 March 2020 and was registered under case number C-147/20.

Factual Background

Abacus intended to make parallel imports into Germany of an original Novartis medicine, "Votrient® 200 mg film-coated tablets" and "Votrient® 400 mg film-coated tablets" (together ***Votrient®***). Votrient® is indicated for the treatment of advanced renal cell carcinoma (RCC) and advanced soft tissue sarcoma (STS) and its original packaging is equipped with an anti-tampering device. To be able to create a packet suitable for distribution in Germany, Abacus had to open the product's original packaging, including the anti-tampering device. When submitting its sample packets for review to Novartis AG (***Novartis Switzerland***), the product's trade mark proprietor, Abacus announced that it would repackage the product rather than sell it in its original packaging. Abacus claimed that it had no other choice but to repackage the product as it would be impossible to:

(i) affix a new anti-tampering device on Votrient®'s original packaging without leaving visible traces of opening (as a result of which the new safety features would not be effective); and

(ii) affix the unique identifier (UI) to the original packaging by means of a label as such a label can be removed again due to the silicone coating of Votrient®'s packaging.

Novartis Switzerland contested these allegations. It argued that Abacus would have no problem in affixing its own anti-tampering device on the opened original packaging, for instance by using a slightly larger seal that completely covers the traces of previous opening. In addition, Abacus could indicate that it had affixed the new seal in its capacity of parallel importer as part of an authorised repackaging process.

Court Proceedings and Questions Referred For Preliminary Ruling

As Abacus was not responsive to the arguments put forward by Novartis, Novartis Germany decided to initiate legal proceedings before the Hamburg Court to prevent Abacus from placing on the market and/or promoting Votrient® in repackaged configurations, subject to a penalty. Novartis Germany had been authorised by agreement to represent Novartis Switzerland in the legal proceedings.

The discussions before the Hamburg Court centred around whether the so-called "*BMS*"-criteria which the CJEU developed in *Bristol-Myers-Squibb* (Case C-427/93) to identify legitimate forms of parallel trade

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in medicines are satisfied in the case at hand. The CJEU held in *Bristol-Myers-Squibb* that parallel imported products can be repackaged: (i) if repackaging is objectively necessary to market the product in the country of importation; (ii) if the repackaging does not affect the original condition of the product inside the packaging; (iii) if the new packaging clearly states who repackaged the product and indicates the name of the manufacturer; (iv) if the presentation of the repackaged product is not liable to damage the reputation of the trade mark or of its owner; and (v) if the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product. If these five conditions are satisfied, the trade mark owner cannot object to the further marketing of a repackaged pharmaceutical as such an objection would contribute to the artificial partitioning of the markets between EU Member States.

The Hamburg Court decided to stay the proceedings and to refer four questions to the CJEU for a preliminary ruling.

First, the Hamburg Court inquired whether an artificial partitioning of the markets may arise if the parallel trader retains the original packaging and replaces the safety features of the original packaging in such a way that visible traces of opening remain after the original safety features have been partly or fully removed and/or covered.

Second, the Hamburg Court wanted to know if it is relevant for answering the first question whether the traces of opening become visible only when the medicinal product has been thoroughly inspected by wholesalers and/or pharmacies or may be overlooked during a superficial inspection.

Third, the Hamburg Court wondered whether it is relevant for answering the first question whether the signs of opening become visible only when the packaging of a medicinal product is opened, for example by a patient.

Finally, the Hamburg Court inquired whether Article 5(3) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015"*supplementing Directive 2001/83/EC by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use*" (***Article 5(3)***) is to be interpreted as meaning that the barcode containing the unique identifier must be printed directly on the packaging and that Article 5(3) is not complied with if a parallel trader affixes the unique identifier to the original outer packaging using an additional external sticker. Article 5(3) provides that "[m]*anufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface*".

The CJEU's judgment is expected to follow within the next 9 to 12 months.

The European Commission has published a Q&A document on the "*safety features for medicinal products for human use*" (available at: https://ec.europa.eu/health/human-use/falsified_medicines_en) of which some answers could have to be revised in the light of the CJEU's ruling in the *Novartis Pharma* case (*see*, in particular, questions 1.20, 1.21, 1.22 and 2.21).

(CJEU, *Novartis Pharma*, Case C-147/20)

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