Court of Justice of European Union Is Asked Preliminary Questions on Rebranding of Parallel Imported Generic Medicines as Branded Medicines

In judgments of 25 May 2020, the Brussels Court of Appeal (the ***Brussels Court***) referred three questions for a preliminary ruling to the Court of Justice of the European Union (the ***CJEU***) seeking to receive clarification as to whether it is possible for a parallel trader to import a generic version of a medicine and repackage and rebrand it with the brand name of the pioneering substance in situations where the trade mark owner of that brand and that of the generic version of the medicine are economically linked.

The referrals were made in appeal proceedings initiated by the parallel importers Impexeco NV (***Impexeco***) and PI Pharma NV (***PI Pharma***) against Novartis AG (***Novartis Switzerland***) (Case C-253/20) and against Novartis Switzerland and Novartis Pharma NV (***Novartis Belgium***; together with Novartis Switzerland ***Novartis***) (Case C-254/20). Both requests for a preliminary ruling were lodged with the CJEU on 9 June 2020.

Background

Impexeco and PI Pharma obtained a parallel import (***PI***) licence for the importation of generic medicinal products (Letrozol Sandoz® 2.5 mg and Methylphenidate HCl Sandoz® 10 mg[1]) from the Netherlands into Belgium after repackaging and rebranding them with the trade marks of the originator reference products in Belgium (respectively Femara® 2.5 mg and Rilatine® 10 mg[2]). Both generic medicines are identical in composition to their branded counterparts.[3] Having been notified by Impexeco and PI Pharma of the PI licences and the planned parallel import, Novartis objected to the planned import on the ground that its trademark rights in respect of Femara® and Rilatine® had not been exhausted. It put forward that the products had not been placed on the market in the Netherlands under the Femara® and Rilatine® trade marks but, instead, under their International Non-proprietary Name followed by the Sandoz® trade mark. In addition to the trade mark right infringements, Novartis also raised an unfair market practice in that the rebranding amounted to misleading the public.

Despite Novartis' objections, Impexeco and PI Pharma proceeded with the commercialisation of the repackaged and rebranded medicines in Belgium.

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1 Sandoz BV is the marketing authorisation holder (***MAH***) of these generic medicines in the Netherlands. The Belgian MAH of Letrozol Sandoz® is Sandoz NV. Methylphenidate HCl Sandoz® is not marketed in Belgium. Sandoz is the division of the Novartis Group that is engaged in the sale of generic medicines.

2 Novartis Belgium, which is engaged in the sale of branded medicines, is the MAH of Femara® and Rilatine® in Belgium.

3 Femara®/Letrozol Sandoz® is a prescription medicine indicated for the treatment of breast cancer. Rilatine®/Methylphenidate HCl Sandoz® is a prescription medicine indicated for the treatment of attention deficit disorder combined with hyperactivity (ADHD) and for the treatment of narcolepsy.

Court Proceedings

Novartis decided to initiate cease-and-desist proceedings before the President of the Dutch-language Brussels Commercial Court (now Enterprise Court) for infringement of its trade mark rights. The President upheld Novartis' action and ordered Impexeco and PI Pharma, on pain of a penalty payment, to cease and desist the trade mark infringement. Impexeco and PI Pharma appealed the President's judgment to the Brussels Court.

The discussions before the Brussels Court centred around the question whether Novartis' opposition to the further commercialisation in Belgium of generic medicines rebranded as originator products is liable to lead to an artificial partitioning of the markets of the EU Member States for the purposes of Articles 34 and 36 of the Treaty on the Functioning of the European Union (***TFEU***), *i.e.*, the rules on the free movement of goods. Furthermore, the parties disagreed as to whether it was necessary to assess the situation under the so-called "*BMS*" criteria which the CJEU developed in *Bristol-Myers-Squibb* (Case C-427/93) to identify legitimate forms of parallel trade in medicines[4] .

Novartis submitted that "*generic medicines and branded medicines are different products that operate in different market segments*" and that, as a result, "*prohibiting a parallel importer from rebranding a generic medicine as a branded medicine cannot be said to* [artificially] *partition the market*". In this regard, it noted that generic and branded medicines are distinct (i) from a regulatory point of view; (ii) from a medical point of view (substitution by pharmacists is prohibited in Belgium; moreover, letrozol-based medicines are "no switch" products, which means that it is not possible to switch to another medicine during treatment); (iii) from the point of view of pricing and reimbursement policy; and (iv) in terms of public perception. Novartis also argued that an assessment against the BMS criteria is not at issue and that it is irrelevant that the medicines are identical in composition and are placed on the market by economically linked companies.

Contesting Novartis' submissions, Impexeco and PI Pharma argued that "*the question whether the markets have been artificially partitioned should not be assessed on the basis of product markets (as Novartis does) but on the basis of territorial markets (the EEA Member States)*". In their view, there is but a single pharmaceutical market on which branded medicines and their generic counterparts are fully fledged alternatives that are interchangeable (same therapeutic efficacy). They added that a parallel trader should be entitled to rebrand under the BMS conditions when a trade mark proprietor starts to use different brand names for the same product in the EEA, irrespective of whether the product is a branded medicine or a generic medicine. Furthermore, the imported (generic) medicine does not even have to be

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[4] 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.

100% identical to the Belgian (branded) reference medicine as Article 3(2) of the Royal Decree of 19 April 2001 on parallel imports[5] does not require 100% identity.

Questions Referred for Preliminary Ruling

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

First, the Brussels Court inquired whether an artificial partitioning of the markets may arise under Articles 34 to 36 TFEU if a trade mark proprietor objects to the further commercialisation of the generic medicine by a parallel importer after the repackaging of that generic medicine by the affixing of the trade mark of the branded (reference) medicine in the country of importation and if the generic medicine and the branded medicine have been put on the market in the EEA by economically linked companies.

Second, assuming the answer to the first question is in the affirmative, the Brussels Court wanted to know if the trade mark proprietor's opposition to that rebranding must be assessed by reference to the BMS conditions.

Third, the Brussels Court wondered whether it is relevant for answering the first two questions that the generic medicine and the branded (reference) medicine are identical or have the same therapeutic effect as referred to in Article 3(2) of the RD of 19 April 2001.

The CJEU's judgments is expected to follow within the next 12 months. While both cases are characterised by the fact that the parallel traded product and the reference product in the Member State of import have a "*common origin*"[6], the CJEU completely ignored that requirement in its *Delfarma* judgment of 3 July 2019 (*see*, *Van Bael & Bellis Life Sciences News Alert* of 5 August 2019). As a result, the upcoming judgment might have far-reaching implications for parallel trade in medicines and the innovative pharmaceutical sector across the EU. It is remarkable that Letrozol Sandoz® is available on the market in both the Netherlands and Belgium, which means that Impexeco also could have selected that product (rather than Femara®) as the reference product in Belgium. The fact that Impexeco considers it necessary to rebrand the parallel imported Letrozol Sandoz® as Femara® for ostensibly commercial reasons would seem to give weight to Novartis' argument that branded medicines and generic medicines are sold in different markets. In addition, it is unclear why such a choice should be allowed to override the intellectual property rights of the MAH of the reference product. Lastly, the further question arises whether commercial reasons alone can dictate the outcome of a case that should be

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5 Royal Decree of 19 April 2001 on parallel imports of medicinal products for human use and on parallel distribution of medicinal products for human and veterinary use (*Koninklijk Besluit van 19 april 2001 betreffende de parallelinvoer van geneesmiddelen voor menselijk gebruik en de parallelle distributie van geneesmiddelen voor menselijk en diergeneeskundig gebruik / Arrêté royal du 19 avril 2001 relatif à l'importation parallèle des médicaments à usage humain et à la distribution parallèle des médicaments à usage humain et à usage vétérinaire* – the ***RD of 19 April 2001***).

6 As follows from the CJEU's case law, a "*common origin*" is considered to exist if the imported product and the reference product have been manufactured by (i) the same manufacturer; (ii) a manufacturer which operates as an associated company (*i.e.*, which is part of the same group of companies); or (iii) a manufacturer which operates under licence on behalf of the manufacturer of the reference product (*see*, for instance, CJEU, judgment of 27 October 2016 in Case C-114/15, *Audace And Others*, ECLI:EU:C:2016:813, §47).

decided in the first place on public health grounds and on the premise that the reference product and its generic versions are distinct medicines subject to separate marketing authorisations.

(CJEU, *Impexeco*, Case C-253/20 and CJEU, *PI Pharma*, Case C-254/20)

Brussels, 10 September 2020
Van Bael & Bellis