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Parallel imports of pharmaceuticals: rebranding or not rebranding?

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It is quite uncommon to have an administrative law Court ruling on IP matters, but sometimes it happens. The Tribunale Amministrativo Regionale del Lazio (Lazio Regional Administrative Court, hereinafter TAR) was recently (decision of T.A.R. of Lazio No. 9050 of 29 August 2018) called to rule on pharmaceuticals parallel imports, more specifically whether or not pharmaceuticals may keep the name used in the country of origin and who bears the burden of proof.

Medifarm s.r.l. requested AIFA (the Italian Medicines Agency) authorization to import to Italy from France a pharmaceutical for treatment of allergic conjunctivitis, marketed in France by Menarini under the name BILASKA. Menarini also marketed in Italy the same medicament under the name ROBILAS. AIFA authorized the parallel import under the name BILASKA. Medifarm appealed AIFA's decision to TAR, arguing that a marketing authorization for BILASKA rather than ROBILAS, constituted a restriction of free circulation of goods and artificial partitioning of EU markets. Moreover, Medifarm argued that marketing two analogue pharmaceuticals with different names could cause a risk for public health.

TAR Lazio held that parallel importers have no "right" to obtain an authorization to replace the original name, and while it is true that national authorities may authorize replacement of the original name with the name used in the country of destination, this possibility must be narrowly interpreted. A change of the original name might be admissible only if "necessary" to prevent obstacles to the effective access to the market of the Member State of importation, for example, when the use of the original name causes a restriction to importations or when it causes confusion for public health because in the local market there are already other pharmaceuticals with identical or similar names used to treat different diseases (§ 43 of C-397/97 "Upjohn"). Additionally, for TAR, the burden of proof of the necessity of rebranding lies on the parallel importer, which has to provide evidence of either risk for public health, or artificial partitioning of EU markets.

In the case at issue, TAR rejected the appeal because Medifarm had neither shown any real obstacle to the effective access to the market, nor provided the court with any evidence regarding a risk for public health caused by a medicinal preparation bearing a name similar to BILASKA for the treatment of different diseases. The request

appeared dictated by the intention to achieve a commercial advantage, by introducing in the market a cheaper product with a name "which already enjoys a certain degree of preference and commercial penetration with the category of consumers and patients".

While the outcome was hardly surprising (if only because Medifarm had not asked for a change of name when it first requested AIFA the authorization), TAR's reasoning was not entirely convincing. TAR reiterated the Upjohn holding that mere economic advantage, which the parallel importer would gain, is not enough to allow rebranding. Fine enough. However, it is unclear why and from where TAR found it appropriate to place the burden of proof about the artificial partitioning of EU markets and risk for public health on the parallel importer.

Indeed, both Upjohn and before Bristol-Myers Squibb and Others v Paranova (joined Cases C-427/93, 429/93 and 436/93) had indicated that "*the requirement of artificial partitioning of the markets* ***does not imply that the importer must demonstrate*** (emphasis added) *that, by putting an identical product on the market in varying forms of packaging in different Member States, the trade mark proprietor deliberately sought to partition the markets between Member States*". Thus, if the parallel importer should not need to show an *artificial partitioning of the market,* (although TAR said it should), why should it be requested to show the risk for public health? After all, in repackaging – which is equivalent to replacing a trademark – it is the trademark owner who must show that the condition of the goods was changed or impaired after they had been put on the market.

Perhaps, taking in consideration the interests of consumers to have access to cheaper pharmaceuticals, TAR could have adopted a more balanced approach, like first asking the trade mark owner to justify why it used different names for the same products, while only then asking the importer to show the presence of risk for public health (which is a more objective fact) . Maybe in another future case…

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