INTELLECTUAL PROPERTY - SWEDEN

Objective necessity to rebox in parallel trade and implementation of EU Falsified Medicines Regulation

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Introduction

In a recent case,(1) the Patent and Market Court (PMC) (the Swedish IP court of first instance) elaborated on the concept of objective necessity to rebox medicinal products subject to parallel distribution in light of the implementation of the EU Falsified Medicines (FM) Regulation (2016/161) that came into force on 9 February 2019. In short, the PMC's decision answers the question that has given rise to several pending cases across the European Union of whether the implementation of the EU FM Regulation's new provisions on safety features entails that all parallel distributed medicinal products require reboxing. In a non-unanimous fashion, the PMC found that it was not established that reboxing was objectively necessary and that parallel traders will thus have to settle for relabelling.

Background

In 2019 a global pharmaceutical manufacturer brought trademark infringement proceedings against a parallel distributor following a notice that the distributor intended to rebox several of the claimant's medicinal products using the claimant's trademarks and launch them on the Swedish market. The claimant argued that it had a legitimate reason to oppose the distributor's reboxing as it would be sufficient to relabel the products to obtain access to the Swedish market. The distributor disputed the action on the basis that there was an objective necessity to rebox the products, due to the implementation of the new rules on safety features in the EU FM Regulation and the specific circumstances on the Swedish market.

Decision

The PMC initiated its reasoning by addressing whether the circumstances on the Swedish market necessitated reboxing and noted that the Swedish Medical Products Agency's (MPA's) general position that reboxing was necessary to gain access to the Swedish market was based on an interpretation of the EU FM Regulation and not the actual circumstances on the Swedish market. In the court's opinion, the MPA's position did not constitute an objective necessity to rebox the products. Similarly, the court held that the invoked testimony of a pharmacy employee who testified on the problems with relabelling from a safety perspective did not constitute an objective necessity, as the reasoning was in turn based on the MPA's position.

The PMC proceeded to examine whether under the EU regulatory landscape it is no longer possible to relabel medicinal products in parallel trade. The PMC stressed that it was clear from Item 29 in the preamble of the EU Falsified Medicines Directive (2011/62/EU) (which implemented the provisions on safety features in the EU Human Medicines Directive) that that directive was without prejudice to IP law provisions.

Moreover, the court referenced the wording of Article 47a of the EU Human Medicines Directive (2001/83/EC), which states that safety features may be covered if certain conditions are met. In the court's view, this indicated that relabelling was permitted after the implementation of the EU FM Regulation. In addition, the court highlighted that the legislature's use of safety features in plural indicated that not only the safety seal but also the unique identifier may be covered. Since these wordings are reflected in the Swedish MPA's own regulation, which should be constructed in light of the EU Human Medicines Directive, the court concluded that the Swedish regulatory framework did not prohibit the sale and marketing of relabelled products.

Turning to the implications of the EU FM Regulation, the PMC pointed out that it is a delegated regulation. On this basis, the court stated that if the EU FM Regulation would be interpreted as prohibiting the relabelling of parallel distributed medicinal products, it would override the commission's authority as it would entail a significant amendment of the EU Human Medicines Directive. Moreover, the court noted that the EU FM Regulation included provisions indicating that relabelling is possible (Articles 16, 14 and 15) as well as provisions that set out the necessary measures when covering or removing safety features (Articles 16 and 36n). Further, the defendant's argument that the requirement of a printed barcode identifier under Article 5.3 of the EU FM Regulation made relabelling impossible was countered by the court's interpretation that this requirement is directed solely to manufacturers. Consequently, the PMC concluded that parallel distributors need not print barcodes directly on boxes as they could instead be printed on a label attached to the original box.

Lastly, the court held that the packaging itself did not mean that it was impossible for the parallel trader to reseal the packaging with new safety features. Accordingly, relabelling was considered possible and the court thus found for the claimant.

One of the three assigned judges dissented due to a contrary conclusion based on the published information on the MPA's website as well as replies from the MPA to the defendant on relabelling queries relating to some of the medicinal products at issue in the case. In the dissenting judge's opinion, the information from the MPA which pointed to the need for reboxing constituted an objective necessity to rebox the products.

Comment

The case and the many pending parallel cases throughout the European Union concerning related issues underline the fact that the EU legislature might have overseen the need for clarifications on the relationship between the recently implemented EU FM Regulation and the EU Human Medicines Directive in parallel trade.

As regards the implications of the EU FM Regulation, the PMC's reasoning is sound from a legal hierarchy perspective and an opposite conclusion would have entailed that many provisions on relabelling in the EU Human Medicines Directive would have become irrelevant and superfluous. In addition, and in line with the court's construction, the printed barcode requirement in Article 5.3 of the EU FM Regulation explicitly references manufacturers and not parallel traders.

The PMC's decision is a significant victory for originators, as it confirms that relabelling is still the main rule in Sweden and that reboxing remains the exception and requires evidentiary support of objective necessity by the parallel trader.

The case has been appealed to the Patent and Market Court of Appeal, which, at the time of writing, is yet to rule on the issue of leave to appeal.

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Endnotes

(1) Patent and Market Court, PMT 4308–19 and 4496–19.