International Law Office

April 18 2022

Re-boxing of parallel traded medicinal products under EU Falsified Medicines Directive

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Introduction

In a recent case, the Patent and Market Court of Appeal (PMCA) elaborated on the concept of objective necessity to re-box medicinal products subject to parallel distribution, in light of the implementation of the EU Falsified Medicines Directive (the FM Directive),[(1)] which came into force on 9 February 2019.[(2)] In the first Swedish decision of many to come over the next year, the PMCA held that it was not objectively necessary to re-box the products at issue and thus found for the original manufacturer.

While the parallel import industry awaits the outcome in the parallel pending cases before the European Court of Justice (ECJ),[(3)] where the principal issue of re-boxing versus relabelling under the FM Directive is currently being litigated, the outcome in the Swedish case – which is fully in line with Advocate General Szpunar's opinion in the ECJ cases – is a victory for original manufacturers. It confirms that relabelling should be regarded as the starting point for parallel trade to Sweden and that re-boxing remains the exception only when objectively necessary.

Background

When medicinal products are parallel traded from within the European Union, the product packaging must be changed in order to include text in the language of the destination member state.

There are two ways of accomplishing this repackaging in a safe and efficient manner:

- relabelling, whereby the original outer (or secondary) packaging with text in the language of the supply state is opened, a new package leaflet in the language of the destination state is added and the original box is resealed with a new adhesive label bearing the necessary information in the language of the destination state; or
- re-boxing, whereby the original outer packaging is opened and discarded, and the inner (or primary) packaging is placed, along with a new package leaflet, in new outer packaging manufactured by the parallel trader, with information in the language of the destination state.

The question of whether medicinal products shall be relabelled or re-boxed in parallel trade is an evergreen trademark issue that has been subject to extensive national and international litigation. Generally speaking, original manufacturers prefer that their medicinal products are relabelled, while parallel traders generally prefer re-boxing. The ECJ has carefully weighed these competing interests in its well-known re-boxing case law.[(4)]

Through this case law, the ECJ has established that if the trademark holder demands relabelling, the parallel trader must comply, and may only re-box if it is objectively necessary for the parallel trader to access the market of the destination member state. For example, if national law or regulation in a member state demands a particular pack size, and the medicinal product is sold in another pack size in another member state, it may be considered objectively necessary for the parallel trader to re-box the medicinal product accordingly in order to sell it in the destination state.

On 9 February 2019, the FM Directive and Commission Delegated Regulation 2016/161 (the FM Regulation) entered into force. According to the FM Directive, medicinal products in Europe must now carry safety features in the form of:

- a unique identifier barcode; and
- an anti-tampering device that safely closes the packaging.

The parallel trade industry in Europe took the position that this newly introduced system mandated re-boxing on an EU-wide basis and that relabelling was no longer possible at all, or only possible under very narrow circumstances (since it was allegedly not possible to relabel with the new safety features).

This immediately led to litigation in several member states, including the Swedish proceedings discussed in this article, between original manufacturers and parallel traders. Notably, several of the cases are currently being litigated before the ECJ, and a decision could be expected soon, following Advocate General Szpunar's opinion earlier this year. Since the Swedish courts did not refer any questions to the ECJ in this case, the judgments thus became the first of their kind.

Patent and Market Court

Before the Patent and Market Court, the parallel trader argued that it was objectively necessary to re-box 11 different medicinal products based on three arguments:

- The FM Regulation mandated re-boxing and did not allow for relabelling.

- There were special circumstances in the Swedish market, in the form of the Swedish Medical Products Agency's (MPA's) and Swedish pharmacies' view that the FM Regulation required parallel traders to re-box.
- The product packaging (including safety features) of the 11 medicinal products at issue required re-boxing to be sold in Sweden.

In a non-unanimous decision, the Patent and Market Court's majority found that the evidence in the case indeed showed that the Swedish MPA had adopted a view that "preferred" re-boxing but held that this view was based on an incorrect interpretation of the FM Regulation and could not constitute an objective necessity to re-box. The minority found that the evidence in the case was sufficient to establish objective necessity to re-box.

PMCA

The parallel trader appealed to the PMCA. The parallel trader, however, only appealed on the grounds that there were special circumstances on the Swedish market that constituted objective necessity to re-box (ie, not how to correctly interpret the FM Directive), apparently in order not to overlap with the ongoing ECJ litigation, which specifically concerns the question of whether the FM Directive mandates re-boxing. In short, the parallel trader argued that the Swedish MPA's regulations, guidance and practice, along with Swedish pharmacies' interpretation of this guidance and practice, established objective necessity to re-box.

The PMCA considered the following questions:

- Does the Swedish MPA's regulation, guidelines and practice, or the Swedish pharmacies' practice, show that it is not possible to relabel medicinal products for sale on the Swedish market following the entry into force of the FM Directive?
- If the first question is answered in the affirmative, is such position in line with the FM Regulation and EU law?

On the merits of the invoked evidence, the PMCA found that, while re-boxing was generally the MPA's preferred option due to the challenges with replacing anti-tampering devices, the MPA would have to carry out an assessment in the individual case based on the materials supplied by the parallel trader. Therefore, there was no general requirement for re-boxing; relabelling thus remained an option.

As regards the MPA's statements on one of the products at issue in the case, the PMCA noted that the MPA had indeed suggested that re-boxing seemed necessary, but had not issued any definitive decision as to whether it was possible to reseal and relabel the packaging. Moreover, the parallel trader had not supplied the required materials for the MPA's assessment. In other words, the PMCA held that the parallel trader had not even tried to relabel or to show objective necessity. The PMCA held that the trader should have at least created a relabelled version to give the national agency an opportunity to review the necessary mock-ups.

As regards the claims made by the parallel trader about how Swedish pharmacies would interpret and apply the FM Regulation – in essence, that Swedish pharmacists would not dispense relabelled medicinal products, since they would believe that the relabelled packaging had been falsified – the PMCA did not find the parallel trader's claims supported by evidence. In fact, and as far as known to this date, no Swedish pharmacy has even had the opportunity to dispense a relabelled product, so it seems difficult to conclude how pharmacies would act in such a situation. Regardless, pharmacists are trained professionals who should be able to adapt their handling routines.

In the absence of any objective necessities to re-box, the appeal was dismissed. The PMCA did not allow for the judgment to be appealed and it is thus final.

Comment

While the issue on appeal in this case, as opposed to the pending ECJ cases, did not directly concern the principal implications of the implementation of the new rules on safety features in the FM Regulation, the PMCA's decision still forms a principally important win for original manufacturers as the submitted evidence indirectly addresses the implementation of these rules. In essence, the PMCA's judgment confirms that relabelling remains the main rule in Sweden and that re-boxing remains the exception, and requires evidentiary support of objective necessity by the parallel trader. There may be medicinal product packaging that carries anti-tampering devices that make it necessary to re-box, but those are not the basic cartons being litigated all over Europe.

The PMCA's judgment seems to be sound. An opposite conclusion would have entailed that many provisions on relabelling in the Human Medicines Directive[(5)] would have become irrelevant and superfluous. An opposite conclusion would have also fundamentally affected the original manufacturers' trademark rights.

As the industry awaits the outcome of the ECJ cases with great attention to settle this issue later this year, history indicates that the field of parallel trade will continue to raise new legal issues in the future. In fact, new litigation has already commenced in Sweden on this point.

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Endnotes

(1) Directive 2011/62/EU.

(2) Patent and Market Court of Appeal, PMT 8284-20.

(3) C-147/20, C-204/20 and C-224-20.

(4) Including C-427/93, C-429/93 and C-436/93 BMS, C-143/00 Boehringer Ingelheim I, C-348/04 Boehringer Ingelheim II and C-297/15 Ferring.

(5) Directive 2001/83/EC.