International Law Office

January 23 2023

Swedish Patent and Market Court applies new CJEU case law on reboxing medicinal products

Westerberg & Partners Advokatbyrå AB | Intellectual Property - Sweden

HANS ERIKSSON

Introduction

On 17 November 2022, the Court of Justice of the European Union (CJEU) delivered three blockbuster decisions regarding the EU Falsified Medicines Directive[(1)] and its impact on parallel trade, delivering a clear win for original manufacturers of medicinal products that wish to limit the reboxing of their medicinal products in parallel trade within the European Union in order to protect their trademark rights. In these decisions, the CJEU reaffirmed its earlier case law on reboxing and provided important guidance to the competent national medical authorities on how to assess relabelled and reboxed presentations in parallel trade.

A mere two weeks later, the Swedish Patent and Market Court in Stockholm likely became the first national court to apply the 17 November 2022 jurisprudence in a case between Novartis and Danish parallel trader 2care4.[(2)] Following on from another case between Novartis and another Danish parallel trader issued by the Patent and Market Court of Appeal earlier during 2022, the Swedish courts have confirmed that there is nothing particular about the Swedish pharma market which means that reboxing would be preferred over relabelling in Sweden and thus – in line with the CJEU's 17 November 2022 decisions – delivered similar full wins for the original manufacturers against the parallel traders.

Background

Pharma regulatory law requires parallel traders to change the medicinal product's original packaging – by, for example, including a package leaflet in the local language – when medicinal products are traded in parallel from one EU member state to another. This can either be done through relabelling (where the original outer packaging is opened, the package leaflet is changed, and the packaging is resealed and over-stickered) or by reboxing (where the outer packaging is opened and the medicinal product with the new package leaflet is placed into new outer packaging). Original manufactures generally prefer relabelling, while parallel traders generally prefer reboxing, for various reasons including the original manufacturers' argument that reboxing constitutes a graver violation of the trademark holder's rights than relabelling.

Over the years, the question of reboxing or relabelling has become a perennial trademark question. After the CJEU's important decisions in the 1990s and 2000s,[(3)] original manufacturers and parallel traders came to a shaky truce.

This truce was upended in 2019 by the adoption of the EU Falsified Medicines Directive, which introduced a number of changes to Directive 2001/83/EC in order to combat falsified medicines, including the mandatory use of safety features in the form of a unique identifier (a barcode with information about the individual medicinal product) and an anti-tampering device (commonly a piece of adhesive tape or similar that closed the box). Parallel traders interpreted the introduction of these safety features as a substantial development in parallel trade, claiming that, as a result, it would always be objectively necessary to rebox. The parallel traders' position immediately led to a number of cases in Germany[(4)] and Denmark[(5)] that quickly made their way to the CJEU, where Advocate General Szpunar delivered an opinion that was favourable to the original manufacturers.

Meanwhile in Sweden, complementing legal proceedings regarding similar questions between Novartis and two parallel traders were initiated before the specialist Swedish IP courts. The parties decided not to take questions to the CJEU and instead went for final decisions on the merits to assess whether the particularities of the Swedish pharma market meant that it was objectively necessary to rebox certain medicinal products on the Swedish market.

Facts

In these cases,[(6)] the parallel traders focused on the particular circumstances on the Swedish market and particularly on the Swedish Medical Products Agency's view of reboxing and relabelling, as expressed through its regulations, guidelines and decisions in reboxing matters on applications from parallel traders.

While the questions answered by the CJEU in the 17 November 2022 cases concerned overarching high-level questions about the EU Falsified Medicines Directive and parallel trade, the two Swedish cases concerned the practical side of parallel trade – for example:

- the procedures by which parallel traders have to apply to the European Medicines Agency (for centrally authorised medicinal products) or the Swedish Medicinal Products Agency (for nationally authorised medicinal products); and
- the relevance of certain documents issued by the European Commission for the Swedish Medical Product Agency's assessment.

Decision

Through the decisions issued in these cases, the Swedish pharma market has received important clarifications that have led to changes at the Swedish Medicinal Products Agency.

These cases show that in order to argue that it is objectively necessary for a parallel trader to rebox a medicinal product on the Swedish market, the parallel trader needs to "have tried" to relabel by filing the necessary documentation with the Swedish Medical Products Agency. It is not enough for the parallel trader to rely on general and vague emails from the Swedish Medical Products Agency that suggest that reboxing could be necessary; there needs to be a full assessment in the individual case, based on materials supplied by the parallel trader.

The last of the decisions was issued on 2 December 2022, two weeks after the CJEU 17 November 2022 cases. Fully in line with the CJEU decisions and Novartis's claims in that case, the Patent and Market Court found that even if the parallel trader had been able to show that the Swedish Medical Products Agency did not allow relabelling, that would not have constituted objective necessity to rebox, since such decisions would violate EU law in the form of the EU Falsified Medicines Directive.

In perhaps the clearest signal that this matter is now finally settled for the Swedish market after the CJEU 17 November 2022 decisions and the two Swedish decisions, the parallel trader did not appeal the Patent and Market Court's judgment.

Comment

In the 17 November 2022 cases, the CJEU came down heavily on the side of original manufacturers of medicinal products by delivering a clear win on all counts. In fact, it is difficult to find any part of the decisions that do not strongly favour the original manufacturers and their trademark rights over the interests of the parallel traders. Though not formally part of the decisions, it is also notable that the advocate general delivered a veritable attack against the parallel trade industry in his opinion, not only finding for the companies that spend billions developing life-saving medicines over the parallel traders on the particulars of these trademark cases, but more generally questioning the utility and societal good of parallel trade of medicinal products.

In light of these cases, if original manufacturers of medicinal products in Europe wish to effectively prohibit reboxing in parallel trade, they should make sure to use "basic" outer packaging and anti-tampering devices that can easily be relabelled in accordance with this CJEU jurisprudence. The decisions confirm that parallel traders will generally have to continue relabelling and will only be allowed to rebox in situations where the medicinal products have unusual packaging that cannot be effectively relabelled, or where the original manufacturer does not object to reboxing.

The Patent and Market Court's decision in the *2care4* matter likely marks the first time the new CJEU jurisprudence on reboxing under the EU Falsified Medicines Directive has been applied by national courts. The impact of this and the other Swedish case, however, goes a step further, affirming the principle that in order to argue that it is objectively necessary for a parallel trader to rebox a medicinal product on the Swedish market, the parallel trader needs to "have tried" to relabel by filing the necessary documentation with the Swedish Medical Products Agency. It is not enough for the parallel trader to rely on general and vague emails from the Swedish Medical Products Agency that suggest that reboxing could be necessary; there needs to be a full assessment in the individual case, based on the materials supplied by the parallel trader. This important clarification applies to all types of arguments about reboxing and relabelling, including those that do not concern the EU Falsified Medicines Directive and thus contributes to greater regulatory clarity on the Swedish market.

For further information on this topic please contact Hans Eriksson at Westerberg & Partners Advokatbyrå Ab by telephone (+46 8 5784 03 00) or email (hans.eriksson@westerberg.com). The Westerberg & Partners Advokatbyrå Ab website can be accessed at www.westerberg.com.

Endnotes

(1) Directive 2011/62/EU.

(2) The author acted for Novartis in this matter.

(3) C-427/93, C-429/93 and C-436/93 BMS, C-379/97 Paranova, C-143/00 Boehringer Ingelheim I and C-348/04 Boehringer Ingelheim II.

(4) See C-147/20 Novartis Pharma and C-204/20 Bayer.

(5) See C-224/20 MSD, among others.

(6) PMT 8284-20 (2019), regarding centrally authorised medicinal products and PMT 17606-21 (2021), regarding nationally authorised medicinal products.