PARALLEL TRADE OF PHARMACEUTICALS AND MEDICAL DEVICES IN THE EU/EEA

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Overview

I. Background

II. BMS-Conditions

III. Reasons to object

IV. When to object

V. Summary

I. Background

- Parallel Trade: Within the member states of the EU/EEA there are different price-levels for original pharmaceutical products/medical devices. Products are purchased by the trader in a “low price country“ and the product shall be sold in a “high price country“.
- Rationale: Price difference between source and destination country
- Legal Basis: Free movement of goods & exhaustion of rights within the EU/EEA.

I. Background

- AIMS:
  - Protection of the patients from receiving poor quality/dangerous products
  - Protection of the brands/reputation
  - Highest quality of imports

II. BMS-Conditions

The Court of Justice of the European Union (ECJ) provided the conditions of the allowed parallel trade in the judgment dated 11 July 1996 in the joint cases C-427/93, C-429/93 and C-436/93 (“Bristol-Myers Squibb").

1. Repackaging must be “necessary“ in order to market the product in the “importing state“.
2. Repackaging must not affect the original condition of the product inside the packaging.

II. BMS-Conditions

3. Repackaging must clearly state who repackaged the product and the name of the manufacturer.
4. The presentation must not be liable to damage the reputation of the trademark and/or its owner.
5. Importer must give notice to the trademark owner before the repackaged product is put on sale and, if requested, provide a sample.

III. Reasons to object

1. Unnecessary repackaging/relabeling
   - Language
   - Pack sizes
   - Labeling requirements

2. Repackaging must not affect the original condition of the product
   - Additional stickers on the back of blisters
   - Tablets are hard to access
   - Failure to respect cold-chain where relevant

III. Reasons to object

3. Presentation must not be liable to damage the reputation of the trademark and/or its owner
   - Poor quality boxes
   - Sharp edges

4. Violation of trademark/reputation
   - Meeting all regulatory law requirements (e.g. correct labeling, name of the medicinal product must also be placed on the outer packaging in braille)

III. Reasons to object

5. Repackaged product needs to be reviewed by third party
   - Pharmaceutical products: EMA/national authorities
   - Medical devices: Additional conformity assessment

6. Failure to notify the trademark owner/failure to send a sample on demand

IV. When to object

- After having received the notification the trademark owner should object as soon as possible
- The trademark owner should request a sample
- The trademark owner should object the sample as soon as possible
- If the parallel trade product will be placed on the market without meeting the objections the trademark owner may take action on trademark law grounds and/or on unfair competition grounds (in Germany)

IV. When to object

Note: If objections are missing and the parallel trade product has been marketed for some months/years, it may not be possible to take any legal actions on trademark right grounds any more, since the missing objection leads to the impression that the trademark owner accepts the sample provided.

V. Summary

- It is key for the trademark owner to asses the sample of the parallel traded product very carefully at the earliest stage
- If the parallel trader meets all the BMS-conditions, the “aims“ will be met!

Thank you very much for your attention!

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