Gray Market Pharmaceuticals: E.U. and U.S. Perspectives

Jonathan S. Jennings
Partner
Pattishall, McAuliffe, Newbury, Hilliard & Geraldson LLP
200 South Wacker Drive, Chicago, IL 60606
312-554-7937
jsj@pattishall.com
www.pattishall.com
Legal Definitions of Gray Market Goods (a/k/a Parallel Imports)

Goods of the owner of intellectual property rights – copyright, patent, or trademark – that are put on the market abroad by the owner or with the owner’s consent which are subsequently imported into the domestic market without the rights-owner’s consent.

This presentation compares the EU and U.S. approaches (under trademark and unfair competition law) and provides best practice tips primarily for U.S. enforcement.
What can be done about gray market goods?

• Prohibitions against gray market goods vary from country to country.

• Some countries or regions recognize international exhaustion of rights (no ability to take action under trademark law after first sale anywhere in the world) and others national exhaustion (legal options available if goods come from outside the country).

• EU has a distinct approach depending on whether goods are from within or outside the region.

• Not all gray goods are illegal, the law of each region or country must be reviewed.
International Regulation

• There is no international treaty on gray market goods.

• TRIPS (Trade Related Aspects of Intellectual Property) is neutral, see Ar. 4: “For the purposes of dispute settlement under this Agreement nothing in this Agreement may be used to address the issue of the exhaustion of intellectual property rights.”
International Regulation

For more information on the approach by different countries and regions to parallel imports, see the INTA position paper from 2015 which provides a good overview:

Law in the EU

• One of the fundamental principles of the EU is the free movement of goods.
• Once a product is introduced into the market in one of the Member States, a mark owner cannot object to further sale of the goods within any of the other Member States.
• Also applies to countries in European Economic Area (Norway, Iceland, Liechtenstein).
  – Note: Switzerland not included in EEA, and follows the international exhaustion approach
Legitimate Reasons – The E.U. Approach

For trade within the EU, there may be “legitimate reasons” enabling a trademark owner to prohibit the movement of goods between Member States in cases where this may amount to a risk to public health or public order (something akin to the U.S. material differences requirement noted later).
Legitimate Reasons – The E.U. Approach

It is not necessary for a mark owner to establish “legitimate reasons,” such as importation that impacts the drug’s quality, in order to prevent the entry of branded goods from non-EU sources.

For more information, see http://www.inta.org/Advocacy/Documents/2015/INTA_PIC_Position_Paper.pdf (INTA position paper).
EU Law and Pharma – Bristol-Myers Squibb
The *Bristol-Myers Squibb* Factors

- Pharma companies may be able to prevent repackaging and reselling of goods between the Member States under a public health exception.
- Pharma mark owners can challenge parallel imports of repackaged pharmaceuticals between the Member States unless:
  - The repackaging necessarily enables the product to be marketed in the relevant Member State;
  - The repackaging does not and will not affect the original condition of the goods;
  - The repackager and manufacturer are clearly identified;
  - The repackaging will not damage the reputation of the brand because the product is not defective, of poor quality, or untidy; and
  - The repackager has notified the trademark owner in advance of the planned shipment, and is ready to supply a specimen if demanded by the owner.
Boehringer Ingelheim KG v. Swingward Ltd.

- ECJ extends *Bristol-Myers Squibb* factors to relabeling.
- Burden of proof to comply with *Bristol-Myers Squibb* factors is on the parallel importer.
- Stricter notice requirement: “It follows that if a parallel importer has failed to give prior notice to the trade mark proprietor concerning a repackaged pharmaceutical product, he infringes the right of that proprietor on the occasion of any subsequent importation of that product, so long as he has not given the proprietor such notice.” (¶ 56)
Recent EU Cases

• UK case where parallel importer not allowed to sell because claimant had not introduced EPANUTIN into the UK, even though Pfizer (with whom the claimant had an agreement) had done so elsewhere in the EU—no exhaustion found

• For a good article on this case, see the December 2015 PTMG newsletter article on the subject under the UK update: [http://www.ptmg.org/images/uniflip/201512/index.html](http://www.ptmg.org/images/uniflip/201512/index.html)
Recent EU Cases

- COZAAR: Parallel importer could repackage in different sizes (Brussels Court of Appeal)
- Roche dispute: referral by German Federal Supreme Court to ECJ on parallel importation of medical devices involving translated instructions

For more information on these EU parallel imports cases, see two articles on them in the PTMG newsletter, September 2015 edition: http://www.ptmg.org/images/uniflip/201509/index.html
Eli Lilly & Co. v. 8PM Chemists Ltd (UK)

- Transshipment/parallel imports considerations
- Goods were ordered from Canadian website, originated in Turkey, sent through the UK but were never opened in UK.
- UK Court of Appeal held that mere physical introduction of goods into European Community was not “importing.”
- Losing in UK courts means that you pay the other side’s fees and costs (be careful)
Gray Market Pharma: A Problem In The U.S. For Many Years

“The price spikes and shortages of flu vaccine [in 2000] have exposed a dark corner of the drug industry, a booming gray market where medications obtained illegally are repeatedly resold, bouncing from warehouse to warehouse like so many pinballs.”

Material Differences – The U.S. Approach

Any difference a consumer would consider relevant constitutes a material difference—“for it is by subtle differences that consumers are most easily confused.” Societe des Produits Nestle v. Casa Helvetica

Establishing material differences is the linchpin to most causes of action under U.S. federal and state trademark laws (although the FDA/CBP will take action without this showing in most cases). Establishing material differences helps to overcome the First Sale Doctrine Defense, which provides the basis for an exhaustion of rights claim in the U.S.
Weapons and Allies in the Fight Against Gray Market Pharma in the U.S.

- Civil Action in U.S. Federal Court
  - Lanham Act, Tariff Act, Copyright Act
- Food and Drug Administration/Customs and Border Patrol (no private right of action)
- International Trade Commission
Option# 1:
Civil Actions in Federal Court
Lanham Act

- Lanham Act §32: registered mark and goods that are materially different leading to likelihood of confusion
- Lanham Act §42: bars importation of goods with a mark that “shall copy or simulate” a registered mark or a trade name - found actionable by courts where there are material differences
Lanham Act and Common Law

- Lanham Act §43(a): unregistered mark and goods that are materially different leading to likelihood of confusion
- Lanham Act §43(c): dilution law applies to materially different goods - focus on blurring or tarnishment
- State unfair competition and dilution laws: Similar standards as comparable federal provisions

Background on New Jersey precedent: Court enjoined importer of U.K. TIC TAC mints. Labeling different, banned colorant:

- Background precedent for pharma gray market disputes
- Consent judgment. Mexican cookies found materially different:
  - Violations of FDA regulations and the Nutrition Labeling Act
  - Violation of Customs’ regulations on country of origin
Veterinary Pharma and Gray Goods
Animal Pharma Cases

• **Bayer:** Courts in consent judgments found material differences even where medicine the same
  - Material Differences: Lack of required warning and precaution statements; No emergency or customer service numbers; Sold OTC; no information about Bayer promotions; different spellings, markings, return policies, and systems of measurement

• **Novartis:** FDA requirements not met; material differences in lack of prescription requirement through veterinarian; no geographically specific information; metric dosages improper; non-working emergency numbers
  - Importers enjoined from selling Australian version of U.S. pet medicine in U.S.

• **Lilly:** Same as above
Animal Pharma Cases

- These cases provide precedent that can be extended to human pharma cases
- FDA violations and non-conformity in packaging and inserts constitute material differences for pet and human pharma products
Abbott FreeStyle Case
Abbott FreeStyle Case

• Abbott brought case against dozens of wholesalers, pharmacists and others selling gray market diabetes test strips
• Court in the E.D. New York has granted Abbott’s motion for a preliminary injunction even though actual products the same; injunction extended subsequently to other parties
• Court found numerous material differences: no NDC number on int’l packaging, differences in instructions regarding where on the body a user could obtain blood for a test, and languages used in package inserts
Abbott FreeStyle Case

For more information on this case, see the article in the December PTMG newsletter on point: http://www.ptmg.org/images/uniflip/201512/index.html

Upshot: Bringing suit allows brand owner to better control the case outcomes and timing
Copyright cause of action against gray goods

• The U.S. Supreme Court in *Kirtsaeng v. John Wiley & Sons, Inc.* decided that copyright law would not protect against importation of most gray market works
• In the past, the copyright in packaging graphics or even logos could be asserted
• This ruling does not preclude trademark remedies against gray goods
Tariff Act

• Tariff Act § 526(a): bars the importation of a product that “bears a trademark owned by a citizen of ...the United States and is registered in the U.S. Patent and Trademark Office.”

• § 526(a) is the basis for CBP’s regulations

• Private right of action available, but no need to show material differences or likelihood of confusion: Good as an alternative claim in suit
Tariff Act

- Not used very often possibly because: (1) it is restricted to U.S. citizens or corporations; and (2) CBP interprets the Tariff Act as inapplicable where the same company owns a trademark registration in the U.S. and the country where the gray good is manufactured—an interpretation that courts need not follow, but that may be influential
Option #2: The Food and Drug Administration and Customs and Border Protection
Gray Goods Often Violate FDA Regulations

• Gray goods may be “misbranded”
• Gray goods may qualify as “adulterated”
• Gray goods may violate FDA’s requirement that prescription drugs be dispensed pursuant to a valid prescription
• See Federal Food, Drug, and Cosmetic Act §§ 301(a)-(d), 501, 502(a), 503(b)(1)-(2)
• Only manufacturing company may re-import prescription drugs
FDA and CBP Join Forces

- FDA and Customs will work together to identify, destroy and/or refuse importation of gray market pharmaceuticals that violate FDA regulations
  - FDA takes the lead and makes final admissibility decisions
  - Examines drug shipments detained with the help of the U.S. Postal Service and CBP: Only small fraction inspected due to volume
Helping the FDA and CBP Help You

• Create Product Identification Training Guide (PITG) for CBP and potentially FDA. Guide geared to helping personnel identify counterfeits, but may be helpful to stop gray goods too.

• PITG should contain company and trademark information, identify authorized importers, photos of the authentic product, gray goods, or counterfeits, expected mode of transport for gray or counterfeit goods, and any other product information that may help distinguish goods.
Helping the FDA and CBP Help You

- Record marks and trade names with CBP
- Educate CBP personnel in field (at ports, postal facilities) about your goods
- Share information about suspected shipments with FDA and CBP
Helping the FDA and CBP Help You

- FDA recommends using technology to distinguish authorized from unauthorized pharma, such as:
  - An embedded, distinctive, yet harmless chemical indicator in each capsule
  - Use of a florescent indicator with each capsule that is visible only under UV light
CBP Lever Rule Protection

- 19 CFR § 133.2(e) & 133.23(a)(3)
- Petition Customs through an application process
  - physically and materially different standard tougher than that applied in federal courts
- If CBP agrees to protection, the gray marketer may apply disclaimer label - if no action is taken, forfeiture proceedings begin
- No need to pursue Lever remedy over gray market prescription pharma: CBP and FDA will take action without this
  - Option for non-prescription drugs or medical devices
Option #3: International Trade Commission
ITC Processes and Procedures

• Independent, quasi-judicial agency that directs actions against unfair trade practices under 19 U.S.C. § 1337 (often called “Section 337”)
• Exclusion orders enforced by CBP available after required showing; cease and desist orders to stop individual importers with lesser showing
• No monetary relief; Investigatory attorney; Quick docket
SKF USA Inc. v. Int’l Trade Comm’n (Fed. Cir. 2005)

Review of ITC decision: Relief denied where not “all or substantially all” of SKF’s ball bearings were materially different.

Brand owner cannot also sell the gray goods in U.S. market.
In re Certain Energy Drink Products (2010)

ITC found material differences based on plaintiff Red Bull’s inability to exercise control over quality and safety, and lack of UPC codes and nutritional information. Separate from district court cases brought by Red Bull.
Designing an Enforcement Program

- Federal Suits: Target and investigate wholesalers/major distributors
- Sue them, obtain agreed order or default, with an injunction and possibly monetary relief
  - Demand letters may be less fruitful in obtaining prompt compliance unless you can point to precedent or a clear willingness to sue
Enforcement Program

- Relief through FDA and CBP may complement litigation, but agencies can only do so much given limited resources and the amount of product entering the U.S.
- ITC may be an effective option where the case is clear-cut, but it can be expensive, investigatory attorney may not agree with plaintiff’s position, and may not be necessary where FDA and CBP already are taking action.
Final Tips for Fighting Gray Market Pharma

• Use track and trace technology to ensure you know who handles your products along the supply chain: Lack of track and trace on foreign goods may also be evidence of material difference
• Educate your employees about unauthorized sales
• Create an internal process for reporting suspected unauthorized sales
Final Tips for Fighting Gray Market Pharma

• Where possible, clearly prohibit unauthorized exports/imports in agreements with distributors in the U.S and other countries (anti-trust or anti-competition concerns should be considered, especially in the EU before taking this step).

• Investigate wholesalers that may be dealing in gray market pharmaceuticals and attempt to curb their sales through business contacts if possible.
Final Tips for Fighting Gray Market Pharma

• Work closely to educate FDA/CBP about your products and identifying gray goods
• Work with ports and field offices, including those monitoring incoming mail
Thank you!