International Trademark Association
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December 5, 2003

Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth
New Jersey, 07033-0530
USA

Re: *Schering-Plough Ltd v. European Commission and EMEA*

Dear Sir or Madam,

The International Trademark Association (INTA) has prepared this letter to assist the Court of First Instance of the European Communities (CFI) in reviewing Schering-Plough Limited's (Schering-Plough) request for an annulment of the European Agency for the Evaluation of Medicinal Products' (EMEA) Decision of February 14, 2003. The EMEA Decision rejected Schering-Plough's application under EC Regulation 542/95 for a type I variation (or "minor variation") to the name of a medicinal product from "Allex 5mg oral lyophilisate" to "Allex Reditabs 5mg oral lyophilisate."

This letter contains INTA's comments in relation to the question of whether there should be a prohibition on the use of one trademark for the pharmaceutical form of a medicinal product and a second trademark for a dosage form of, or delivery devices for, that product.
INTA has not attempted to intervene before the CFI for procedural reasons. INTA would therefore be grateful if Schering-Plough would file this letter before the CFI.

1. THE INTERNATIONAL TRADEMARK ASSOCIATION

1.1 The International Trademark Association (INTA) is a 125-year-old not-for-profit organization of trademark owners and practitioners from 170 countries. INTA is dedicated to the support and advancement of trademarks and related intellectual property concepts as essential elements of commerce. Its current membership of more than 4,300 companies and firms crosses all industry lines, including manufacturers and retailers, in industries ranging from aerospace to consumer goods. INTA's membership includes more than 700 trademark owners and practitioners in the 15 Member States of the European Union (EU), including some of the largest European pharmaceutical companies such as GlaxoSmithKline, Bayer and Astra Zeneca.

1.2 An important objective of INTA is to protect the interests of the public through the proper use of trademarks. In this regard, INTA strives to advance the development of trademark and unfair competition laws and treaties throughout the world, based on the global public interest in avoiding deception and confusion. INTA has been an official nongovernmental observer to the World Intellectual Property Organization (WIPO) since 1979 and actively participates in all

trademark-related WIPO proposals. INTA has influenced WIPO trademark initiatives such as the Trademark Law Treaty and is active in other international arenas including the Asia Pacific Economic Cooperation Forum (APEC), the Association of Southeast Asian Nations (ASEAN), the European Union and the World Trade Organization (WTO). INTA's membership is varied and extensive. It is a balanced and reliable representative body and its international character brings a global approach to the issues at stake in this case.

1.3 Since 1916, INTA has acted as *amicus curiae* ("friend of the court") in the United States[1] and in other jurisdictions,[2] including Europe.[3]

1.4 INTA presents itself as a "friend of the court" in this matter. It is not a party in the instant case, but believes this case is significant to the international development of trademark law.

1.5 INTA respectfully submits this letter in the hope that it may assist the Court in reaching a decision that is in the public interest.

2. THE SCHERING-PLOUGH CASE: OVERVIEW

2.1 Schering-Plough holds a marketing authorization for certain medicinal products under the trademark "Allex." The Allex marketing authorization covers three different pharmaceutical forms: an oral lyophilisate, film-coated tablets and a syrup.

2.2 In October 2002, Schering-Plough applied to the EMEA[1] to change the name of the oral lyophilisate pharmaceutical form from "Allex 5mg oral lyophilisate" to "Allex *Reditabs* 5mg oral lyophilisate" (emphasis added).

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[1] INTA has filed *amicus* briefs before the United States Supreme Court and other Federal Courts in the following case: *Dastar Corporation v. Twentieth Century Fox Film Corporation, SFM Entertainment LLC and New Line Home Video, Inc*, 123 S. Ct. 2041 (2003); *Moseley v. V Secret Catalogue, Inc.*, 537 U.S. 418 (2003); *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23 (2001); *Wal-Mart Stores, Inc. v. Samara Bros.*, 529 U.S. 205 (2000); *College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666 (1999); *Dickinson v. Zurko*, 527 U.S. 150 (1999); *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159 (1995); *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988); *WarnerVision Entertainment Inc. v. Empire of Carolina, Inc.*, 101 F.3d 259 (2d Cir. 1996); *Preferred Risk Mut. Ins. Co. v. United States*, 86 F.3d 789 (8th Cir. 1996); and *Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556 (Fed. Cir. 1994).

[2] INTA has filed briefs and affidavits in jurisdictions outside the United States in the following cases: *Tabacalera Boquerón S.A. v. Nobleza Piccardo SACI and/or BAT and/or BAT BRANDS Limited*, Paraguayan Supreme Court (2003); *Davidoff & Cie S.A. v. N.V. Sumatra Tobacco Trading Company*, Indonesian Supreme Court (2003); *Intel v. Hanitio Luwi*, Indonesian Supreme Court (2002); *Intel v. Panggung Electronics*, Indonesian Supreme Court (2002); *Prefel v Jae Ik Choi*, Supreme Court of Korea (2002); *Ikea Inter-Systems Inc. v. Beijing Cinet Co. Ltd.*, Beijing High Court (2001); *Heublein Inc. v. Appeals Chamber of Rospatent*, Moscow City Court, Russia (1998); *Smith and Nephew v. Glen Oak*, Supreme Court of Canada (1996); *McDonald's Corporation v. DAX Properties CC and JoBurgers Drive Inn Restaurants (PTY) Limited*, Supreme Court of South Africa (Durban and Coast Local Division) (1995).

[3] INTA has filed the following *amicus* briefs before the ECJ and EFTA Court: *Paranova A/S v Merck & Co., Inc, Merck, Sharp & Dohme B.V. and MSD (Norge) A/S*, EFTA Court (2003); Praktiker *Bau- und Heimwerkermärkte AG*, ECJ (2003); *Shield Mark v. J. Kist* (2001); *Libertel Groep B.V. v. Benelux Merkenbureau* (2001); *Glaxo Wellcome Limited v. Dowelhurst Limited and Swingward Limited* (2000).

[1] Under EC Regulation 542/95 for a Type I variation (or "minor variation").

2.3 The EMEA rejected the proposed name change of the oral lyophilisate from "Allex 5mg oral lyophilisate" to "Allex Reditabs 5mg oral lyophilisate" on the basis that:[2]

- the trade name in an application for a "minor variation" should in principle be the same as that of the existing medicinal product;
- the name change would be contrary to the Commission's policy on "secondary names," and that:
  - there is no specific provision in the legislation providing that additional "invented" names or trademarks can be used to describe the pharmaceutical name of a medicinal product; and
  - the availability of a multiplicity of secondary names for different medicinal products from different companies would add to the potential for consumer confusion; and
- the name change was not rendered necessary by exceptional circumstances that may adversely affect public health.

3. IMPACT FOR INTA

3.1 In a previous letter to the Commission[3] regarding the use of different trademarks for dosage forms of medicinal products, INTA set out its view that:

- manufacturers should be entitled to use one trademark for the pharmaceutical form of a medicinal product and a second for the dosage form; and
- the use of secondary trademarks for dosage forms allows consumers to distinguish effectively between the different dosage forms of a medicinal product and reduces the risk of confusion.

3.2 The letter asked the Commission to clarify its position with regard to how it treats trademarked pharmaceutical products used in conjunction with trademark dosage forms and devices. INTA has not received a response from the Commission.

3.3 Members of INTA will be directly affected by the CFI's decision in Case T-133/03 (the Schering-Plough Case). INTA wishes to file this letter with the CFI to respectfully suggest that there should be no prohibition on the use of one trademark for the pharmaceutical form of a medicinal product and a second trademark for a dosage form of, or a delivery device for, that product. INTA's view is based on the propositions that:

(a) The absence of a statutory provision that provides for (as opposed to prohibits expressly) the use of secondary trademarks to describe the pharmaceutical form of a medicinal product should not of itself preclude the use of secondary trademarks in any way. In fact, Article 20 of the TRIPS Agreement mandates that:

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[2] See the EMEA's letter to Schering-Plough dated 14 February 2003.

[3] Dated November 25, 2002.

> *The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as the use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.*

(b) The use of a second trademark for a dosage form of, or delivery device for, a product may well present a public health advantage because of the source identifying and quality assurance purposes of a trademark.

(c) The use of an invented name for each dosage form of, or delivery device for, a product will not give rise to confusion among the relevant public, but will help distinguish between the different dosage forms of, and delivery devices for, a medicinal product and reduce the risk of confusion among members of the medical profession and the public.

4. POSSIBLE PUBLIC HEALTH ADVANTAGE

4.1 Article 54 of EC Directive 2001/83 sets out the particulars that should appear on the outer packaging of medicinal products:

> *[W]here a medicinal product is available in several pharmaceutical forms and/ or several strengths, the pharmaceutical form and/or the strength…must be included in the name of the medicinal product.*

4.2 Article 54(a) in particular acknowledges the need for medicinal product packaging to set out clearly the pharmaceutical form of a medicinal product. An important purpose of this Article is to ensure the safety, efficacy and quality of medicinal products on the market.

4.3 The use of a secondary trademark for the pharmaceutical form of, or a delivery device for, a medicinal product may ensure safety, efficacy and quality of medicinal products on the market. It could assist consumers in distinguishing more easily between the available pharmaceutical forms of a product because the packaging would include not only the scientific name of the particular pharmaceutical form, but also its invented secondary trade name.

5. THE RISK OF CONFUSION

5.1 The use of an invented name for each dosage form of, or delivery device for, a product will not give rise to confusion among the relevant public, but will help distinguish between the different dosage forms of, or delivery device for, a medicinal product and reduce the risk of confusion among members of the medical profession and the public.

5.2 Consumers are becoming increasingly sophisticated in their brand recognition. It is now commonplace for manufacturers in other industry sectors to use secondary trademarks or sub-brands in relation to their goods and services.

5.3 When members of the public purchase medicinal products, they are careful to acquire the correct medicine for their condition. It is likely, at least for their first purchase of a particular product that they study the product packaging in some detail to ensure that they buy a suitable medicine. The use of secondary trademarks can consequently assist consumers in purchasing the correct medicinal product quickly and easily. Rather than giving rise to a risk of confusion, the secondary trademark will serve to reduce that risk. The trademark will be fulfilling its fundamental role – to guarantee the origin of the goods.

6. CONCLUSION

6.1 The absence of a statutory provision that provides for (as opposed to prohibits expressly) the use of secondary trademarks to describe the pharmaceutical form of, or delivery device for, a medicinal product should not of itself preclude the use of secondary trademarks in that way. The prohibition on the use of different secondary names amounts to an unjustifiable encumbrance on the use of a trademark, contrary to Article 20 of the TRIPS Agreement.

6.2 The use of a secondary trademark for a dosage form of, or delivery device for, a medicinal product may present a public health advantage because the essence of a trademark is to serve as a source identifier and to assure quality to the public.

6.3 The use of an invented name for each dosage form of, or delivery device for, a medicinal product will not give rise to confusion among the public, but will help distinguish between the different dosage forms of, and delivery devices for, a medicinal product and reduce the risk of confusion among members of the medical profession and the public.

6.4 Consumers are becoming increasingly sophisticated in their brand recognition. It is now commonplace for manufacturers in other industry sectors to use secondary trademarks or sub-brands in relation to their goods and services. It is damaging for the pharmaceutical sector not to be able to implement similar branding strategies where there is no apparent risk to public health from doing so.

6.5 INTA therefore submits, for the reasons set out above, that there should be no prohibition on the use of one trademark for the pharmaceutical form of a medicinal product and a second trademark for a dosage form of, or delivery device for, that product.