

Differential Pricing & Financing of Essential Drugs
A WHO/WTO Secretariat Workshop
Norway

Antitrust/Competition Law Considerations and Trade Law Considerations
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There follows a summary outline of the antitrust/competition law cautionary warning presented on April 9 and the regular presentation presented on April 10.

- I. Introduction.
 - A. Pleased to make these presentations at the invitation of the WTO Secretariat.
 - B. Not acting as counsel to the Workshop or to the WTO but rather appearing as an invited participant and speaker.
 - C. The antitrust/competition law cautionary warning is not intended to prevent legitimate discussion of important public policy matters.
- II. The Antitrust/Competition Law Prohibition Against Agreements Among Competitors that Restrain, Limit or Impede Competition.
 - A. All major antitrust regimes condemn horizontal agreements or cartels that restrain competition.
 - B. In the United States the antitrust laws contain criminal enforcement provisions, both as to companies and individuals, and provide for private actions for treble damages filed by any party (domestic or foreign) injured by an illegal agreement.
 - C. In the United States certain horizontal arrangements are unlawful *per se* and cannot be defended regardless of the objective or motive of the agreement.
 - D. Horizontal agreements that are unlawful *per se* include agreements that fix prices or terms and conditions of sale, agreements on pricing levels, discounts and the like, agreements to allocate markets or customers,

agreements to limit output, and potentially other horizontal agreements that eliminate or restrict any significant element of competition.

- E. While transparency or “public” discussion may be helpful, it does not provide any protection for an otherwise illegal horizontal agreement. There is no requirement that an agreement be concealed or secret for it to be subject to challenge.
- F. No immunity is provided by the presence of U.S. Government officials at any meeting, even including antitrust enforcement officials.
- G. There are presently over 30 sitting grand juries in the United States investigating international cartels.
- H. In addition to increasingly record-setting criminal fines of hundreds of millions of dollars in prosecutions of international cartels, there are numerous executives serving time in United States penal institutions as a result of antitrust law guilty pleas or convictions, including a significant and growing number of European executives.
- I. In the United States, Congress can provide certain limited immunity from the antitrust laws, but this has been rarely done for a specific industry and is typically politically controversial.
- J. In sum, compliance with the antitrust laws in the United States represents a very serious and high priority matter for U.S. companies and multinational and foreign companies that do business in the United States.

III. Antitrust Compliance in Trade Association or Similar Meetings Where Competitors Are in Attendance.

- A. As a general matter, subjects relating to pricing and future marketing conduct and strategy are prohibited.
- B. In recent private antitrust litigation, trade association meetings and other gatherings of competitors have been alleged to be or characterized as “opportunities to conspire.”
- C. Accordingly, the subject matter of this Workshop on its face raises antitrust sensitive issues for the pharmaceutical companies in attendance.
- D. Given the antitrust grounds rules, it would not be productive for participants in the Workshop to submit proposals or suggestions that there be joint or collective agreements among the pharmaceutical companies or even a consensus on specific formulae, etc. The companies must make independent decisions as to what they will do or will not do in the future.

- IV. Relationship of Antitrust/Competition Laws and Intellectual Property Laws.
- A. The antitrust/competition and intellectual property laws generally share the objectives of enhancing consumer welfare and promoting innovation.
 - B. There is thus no inherent conflict between intellectual property protection and antitrust/competition law.
 - C. In the United States, there are circumstances in which the antitrust laws can limit the exercise of intellectual property rights, particularly where those rights are being abused or are being used to achieve leverage in a separate market from that covered by the intellectual property rights.
 - D. Similarly, the Federal Trade Commission has in recent years challenged agreements between pharmaceutical brand companies and generic manufacturers that allegedly restrained competition. These cases involved Abbot, Hoechst, and Schering-Plough (also Mylan Laboratories - a generic manufacturer).
- V. Possible Antidumping or Predatory Pricing Actions by Pharmaceutical Producers in Countries Which Are the Beneficiaries of Tiered or Discriminatory Pricing.
- A. The WTO Dumping Code and the antidumping laws of WTO members prohibit dumping where it causes injury to a local domestic industry.
 - B. Thus, where a pharmaceutical company sells at a lower price in a country in which there is a competing pharmaceutical producer, there can be an antidumping suit -- South Africa initiated an antidumping proceeding involving pharmaceutical products from India.
 - C. Where a country that benefits from tiered or discriminatory pricing has a predatory pricing law and a local producer, such laws may also potentially be invoked against a pharmaceutical company engaged in such pricing. Predatory pricing, at least in the United States, requires a showing of predatory intent, defined as below cost selling and capability of recoupment of the losses sustained from the below-cost selling.
 - D. The antidumping laws and the predatory pricing laws should not be of concern in connection with differential pricing in the absence of local domestic pharmaceutical companies.