EARLY WORKING OF PATENTS AND RESEARCH EXCEPTIONS

1. TACD supports so called "Bolar" exceptions in patent laws to permit firms to test generic drugs and prepare data required for marketing approval by regulatory agencies, prior to the expiration of a patent. This is needed to ensure that consumers benefit from the timely introduction of competition when patents expire. Health and safety regulatory measures should not be misused as a barrier against competition.

2. TACD asks the US and the EU to reject overly restrictive interpretations of anti-discrimination language in Article 27.1 of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPs). Article 27.1 should not be interpreted as requiring a "one size fits all" patent law. The language in Article 27.1, requiring that "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology," should not be interpreted as preventing countries from addressing public interest concerns in patents, when provisions to address those public interest concerns are consistent with the TRIPs framework. Article 30 of the TRIPs regarding exceptions to patent rights should be interpreted to permit countries to address public interest concerns, including those specifically related to fields of technology.

3. TACD recommends that the EU not require Central and Eastern European (CEE) countries to eliminate "Bolar" exceptions from patent laws as a condition for EU membership.