May 17, 2013

European Commission
Directorate-General for Competition
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RE: HT.2742

Dear Sir or Madam:

Intellectual Property Owners Association (IPO) thanks the European Commission for the opportunity to submit these comments with respect to the Draft Regulation on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements (Draft Regulation) and the Draft Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Technology Transfer Agreements (Draft Guidelines).

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights (IPR). IPO's membership includes more than 200 companies and more than 12,000 individuals involved in the association either through their companies or as inventors, authors, executives, or law firm members. IPO members include, for example, pharmaceutical companies, technology licensors and participants in standards setting organizations around the world. IPO members file approximately 30 percent of the patents filed in the United States Patent and Trademark Office by U.S. nationals and a significant number of EPO applications.

IPO's purposes in providing this commentary include highlighting the positive features of the Draft Regulation and Draft Guidelines, identifying areas that may be interpreted in a manner that may hinder competition or innovation, and pointing out instances where the wording of the Draft Regulation and Draft Guidelines could have unintended practical consequences for IPR owners. Our comments are as follows.

I. The Draft Guidelines Appropriately Recognize The Procompetitive Potential Of Technology Transfer Agreements.

Technology transfer agreements often result from an IPR owner's desire to monetize the results of research and development programs or other investments, by sharing a technology with others for a royalty or other consideration. This sharing of technology generally improves access to and capability to practice the relevant technology. IPO appreciates that the Commission recognizes the importance of creating and protecting incentives of IPR Owners to grant licenses. *See* Draft Guidelines Nos. 9, 17, 160.

II. Portions Of The Draft Regulation And Draft Guidelines Could Be Interpreted As Hostile To Technology Transfer Agreements.

A. Reduced Market Share Thresholds

The Draft Regulation and Guidelines suggest a reduction in the market share thresholds for certain agreements between non-competitors, *see, e.g.*, Art. 3 of the Draft Regulation, despite industry commentary that these thresholds should be increased. This proposal appears to be the result of a fear that a technology will be under-utilized by a licensee, who already owns a substitutable technology, when the licensee accepts an exclusive license and then either fails to further develop the technology or strengthens its market position by acquiring a blocking position for both technologies. *See* Draft Guidelines No. 180. However, the scenario is not likely to occur because it is normally in the best interest of a licensor to see its technology commercialized, and most license agreements – particularly exclusive licenses – contain incentives to promote that objective including penalties for non-commercialization such as loss of exclusivity or complete cancellation of the license.

Licensing technology is typically pro-competitive, regardless of whether the license is between competitors or non-competitors. The general approach of reviewing technology transfer agreements on the basis of market share of the parties instead of on the basis of the type of license will often lead to unjustified conclusions when weighing the pro- and anti-competitive effects of such agreements. This is especially true where a license agreement is non-exclusive. The licensing of technology is better reviewed on the basis of type of license rather than market share of the participants in the license. IPO respectfully suggests that limiting market shares for the licensing of technology should be confined to exclusive licenses.

B. Restrictions on Exclusive Grant-Backs for Non-Severable Improvements

According to the Draft Regulation, Article 5(1)(a), any obligation requiring a licensee to grant an exclusive license back to the licensor of the technology shall not fall within the scope of the exemption granted under Article 2. IPO believes that this restriction would unduly limit the scope of the exemption as it relates to non-severable inventions. We respectfully submit that limitations on exclusive grant-backs should continue to be treated as they had been under the previous regulation, such that severable improvements that could enhance technology generally should be carefully reviewed but that non-severable improvements should remain exempt under Article 2.

Technologies evolve and improve over time. Each license granted by a licensor relates to technology as it exists at a specific moment in time. Grant-back provisions allow the licensor to make improvement technology available to all of its licensees. Often technology improvements are not severable from the original technology, to which a licensee would not have access without a license to the original technology. The licensor of the underlying technology is usually best suited to manage the continued flow of information to new licensees, ensuring that each licensee has access to the best new

technology. In the case of non-severable improvement, restricting exclusive grant-backs will generally decrease the licensor's motivation to enter into license agreements.

IPO believes that a licensee's incentive to innovate will not be diminished by hindering the licensee's ability to independently license third parties. The revenue stream from licensing a technology improvement, where the bulk of the basic technology comes from the original licensor, would rarely provide a sufficient incentive for a licensee to commit resources to continued technology improvement. Even where a licensee has taken a license subject to an exclusive grant-back obligation on non-severable improvements, the licensee will often continue to improve the technology in order to make the technology safer for its own employees, to make its product safer for the public, or to make the process of manufacturing more efficient for itself between grant-back cycles.

C. Termination In The Event of Validity Challenges by Licensee

Article 5(1)(b) of the Draft Regulation would narrow the exemption of Article 2 for license provisions that terminate a license where the licensee challenges the validity of the patent, even where the license was taken to settle patent litigation. Currently, the exemption applies not only in situations where the license affirmatively precludes the licensee from making such a challenge, but also applies to provisions that might make it costly for the licensee to do so, such as termination of the license in the event of such a challenge. IPO believes that the applicability of the exemption should not be changed. The proposed change would allow licensees to take unfair advantage of licensors in some circumstances and would diminish the incentive to license in the first instance.

The rationale behind the exclusion from the exemption is set forth in the No. 125 of the Draft Guidelines, which states that "the licensee may be deterred from challenging the validity of the intellectual property right as it would risk the termination of the licensing agreement and thus face significant risks which go far beyond its royalty obligations." This may be correct; it ignores, however, the risk that the license will not come into being in the first instance. It also ignores the likelihood that licensors will increase the use of fully-paid up licenses, which do not expose the licensor to a validity challenge.

A prudent licensee generally has done extensive due diligence at the outset of the license. IPRs as defined in Article 1(h) are publicly known and defined rights. Thus, the licensee is usually at liberty to assess the validity of the IPRs that are transferred at the time of execution of the license agreement. Prior to incurring any "sunk costs" into building a new manufacturing plant or undertaking a new product, any prudent licensee of technology should review the technology set and gain an understanding of whether the IPRs are valid.

It appears that license agreements in settlement of litigation would be treated the same as other licenses. Without a provision precluding a validity challenge, or at least allowing the licensor to terminate the license in case of a validity challenge, an unscrupulous licensee could enter into a settlement agreement after a case began to appear weak and later make a second run at trying to invalidate the IPR without any negative consequences. Such a

situation would remove any certainty about settlement for the licensor. The likely consequence of this change would be to make IPR owners more reluctant to license the technology pro-competitively and decrease the incentive to settle litigation.

D. Removal of Passive Sales Restrictions from Exemptions

Under the current Regulation, in an agreement between competitors, a passive sales restriction is considered a hardcore restriction unless the agreement is non-reciprocal and relates to sales in an exclusive territory or to an exclusive customer group, and then only for a period of two years. This allows the licensor an opportunity to exploit its technology and licensees an appropriate level of certainty for their investment in bringing the licensed technology to market. IPO believes passive sales restrictions should continue to enjoy the exemption under Article 2.

Under Article 4 (2)(b) of the Draft Regulation, passive sales restrictions will be subject to a case-by-case basis assessment under the treaty, and only with respect to a new licensee in a territory. *See* Draft Guidelines No. 116. As a result, licensors will be severely limited in enforcing existing license agreements subject to territorial/customer exclusivity. The proposed restriction may expose licensors of existing licenses subject to these types of exclusivity agreements to claims of breach of contract without any possibility to cure. Licensors will not be able to provide meaningful protection to licensees who have invested to bring a new technology to market.

IPRs provide their owners with exclusive rights, unlike other interests a contracting party might protect under a license agreement. Removal of passive sales restrictions from exemption under Article 2 would significantly devalue IPRs, rendering them no different than other contract terms.

III. The Draft Regulation and Draft Guidelines Create Uncertainty Over Time.

The Draft Regulation and accompanying Draft Guidelines seek to provide exemptions for pro-competitive license agreements and attempt to provide greater clarity regarding the scope of such exemptions. By restricting the exemptions for "potential competitors" (as defined in Article 1(1)(n)(ii) of the Draft Regulation), however, the Draft Regulation and Draft Guidelines run the risk of creating significant uncertainty for licensors. While the Draft Regulation and Draft Guidelines would not condemn particular agreements at the time they are entered, such agreements could become subject to restrictions at some unspecified time in the future.

If a licensed technology is substantially better than the technology it replaces, a licensor who is a new entrant to a particular market or license agreement will be able to take advantage of the exemption of Article 2 of the Draft Regulation. However, during the term of the license agreement, the market share of the licensor could increase. Should that market share rise above the market-share thresholds defined in Article 3, the exemption under Article 2 would no longer apply. This gives rise to uncertainty about the carefully

negotiated technology transfer agreement that has now been in place for a period of time, which becomes subject to assessment on an individual basis. *See* Draft Guidelines, Nos. 80-83. IPO respectfully submits that the Draft Regulation and Draft Guidelines be amended to exclude the concept of "potential competitors" so that licensors and licensees may have certainty regarding the agreements that they enter.

IV. The Draft Guidelines Should Approach Enforcement With An Eye Toward Policing Anticompetitive Conduct Without Unduly Constraining Settlement of Litigation.

No. 223 of the Draft Guidelines addresses the application of Article 101(1) to settlement agreements that include a so-called "reverse payment" as one of the terms:

> *Pay-for-restriction in settlement agreements*
> (223) Settlement agreements between competitors which include a license for the technology and market concerned by the litigation but which lead to a delayed or otherwise limited ability for the licensee to launch the product on this market may under certain circumstance be caught by Article 101(1). Scrutiny is necessary in particular if the licensor provides an inducement, financially or otherwise, for the licensee to accept more restrictive settlement terms than would otherwise have been accepted based on the merits of the licensor's technology.

Draft Guidelines No. 227 likewise contains guidance regarding scrutiny of licenses including a "reverse payment." These sections effectively create a presumption of anticompetitive effect and illegality for any settlement agreement that includes a "reverse payment." This presumption overlooks that the patent itself, until held invalid in a final decision, lawfully precludes competition.

IPO does not believe that consumers are usually harmed by "reverse payment" settlements. In many instances, consumers benefit. Such settlement agreements generally promote competition because they may provide for certain and predictable market entry of a generic pharmaceutical before the generic pharmaceutical company may otherwise have been able to enter, at the expiration of a presumptively valid and enforceable patent.

The Draft Guidelines would upset the careful balance of the regulatory scheme which provides an expedited approval pathway for generic pharmaceutical manufacturers without undermining the innovator pharmaceutical developer's incentives to continue investment and development of life-saving medicines. A strong patent system encourages capital investment by innovator companies in costly and risky laboratory research and clinical trials to develop new pharmaceutical products that extend life and alleviate suffering. A collateral effect of this continuous cycle of innovation is the eventual availability of a greater number of generic products. Without the protection of a robust patent system, however, pharmaceutical products can be easily copied with little investment, interrupting the cycle of new investment in research and clinical trials for the development of new drugs.

IPO believes that current antitrust laws and guidelines are adequate to evaluate settlement agreements under a "rule of reason" analysis, under which all relevant factors are considered before determining whether a particular settlement agreement violates Article 101(1) or another competition Article. The presence of a "reverse payment" is only one of many factors to be considered, and does not alone merit the presumption that every such agreement will harm competition and consumers.

Application of Draft Guidelines No. 223 would require a detailed investigation into the subjective intent of the parties and a complex "trial within a trial" of the hypothetical validity and enforceability of the intellectual property and patent rights subject to the settlement and license agreement. For the same reasons, those parts of Draft Guidelines No. 227 that call for an inquiry into whether the state of mind of the licensor regarding the validity and enforceability of the licensed IP rights should also be revised to eliminate any suggestion that the validity and enforceability of presumptively valid intellectual property rights should be evaluated by the Commission. The Commission should instead focus on objective measures of harm to competition in determining whether any particular settlement agreement violates the principles of Article 101(1) *et seq*.

V. Inter-Jurisdictional Considerations Are Paramount for Standards

We encourage the Commission to ensure that the Draft Regulation and Draft Guidelines strive for harmonization with the rules of other major competition regulatory authorities. If adopted, the Draft Regulation and Draft Guidelines would have worldwide impact. Technology licensing occurs on a global scale. Firms must compete worldwide. If the Draft Guidelines establish positions inconsistent with those in other prominent jurisdictions, the certainty needed by firms to compete globally will be diminished.

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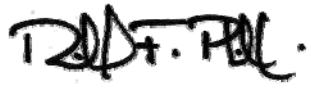
Again we thank the Commission for the opportunity to offer these comments and for its efforts to address the very difficult and complex intersection of competition law, IP law and standardization. This is an area of great interest and concern for IPO members.

Sincerely,



Richard F. Phillips
President