The Generic Pharmaceutical Association responds to the United States Patent and Trademark Office (USPTO)'s requests for comments on issues relating to patent law harmonization. See 72 Fed. Reg. 24566 (2007).

Generic Pharmaceutical Association ("GPhA") is a trade association devoted to making affordable, high-quality generic drugs available to patients and providers. GPhA's members include manufacturers and distributors of finished generic drug products and bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA has a critical interest in ensuring that the public has timely and reliable access to generic drugs.

The GPhA is an active participant in the ongoing patent reform process in Congress, starting with the Patent Reform Act of 2005 and through the Patent Reform Act of 2007 ("2007 Act") , S.1145, currently being considered by Congress. S. 1145 covers almost every issue identified by the USPTO in the Request for Comments, either expressly, or by implication.

USPTO Issue	S. 1145
(1) Priority of Invention	Section 3, new 102(a)(2)
(2) Prior Art Effective Date of U.S. Application	Section 3, new 102(a)(2)
(3) Scope of Prior Art (effect of Published Patent Applications	Section 3
(4) Grace Period	Section 3, new 35 USC 102(a)(1)(a)
(5) Geographical Limitations in the Definition of Prior Art	Section 3, new 35 USC 102(a)
(6) Loss of Right Provisions	(non-statutory)
(7) Experimental Use Exception to Prior Art	(non-statutory)
(8) Prior User Rights	Section 5(b) (35 USC 273)
(9) Assignee Filing	Section 4

USPTO Issue	S. 1145
(10) Eighteen Month Publication of Patent Applications	Section 9(a)

The timing of the USPTO's request for comments is unfortunate. The USPTO has been an active participant in the drafting and negotiations which have led to the current bill. There is much activity in Congress to pass a bill this session.

We believe that the USPTO should allow the legislative process to continue and be engaged in that process without the distraction of the harmonization negotiations. The USPTO's participation in harmonization talks before Congress completes that legislative process would be an unwarranted diversion of the USPTO's resources and potentially confusing to the other countries participating in those talks.

Moreover, the USPTO may find itself bombarded by special interest groups dissatisfied with the legislative process. The Executive Branch should not use the B+ group as a way to promote a treaty that may have the effect of constraining Congress' consideration of a wide range of patent law policy issues. The Constitution gives to Congress the power to enact patent laws and thereby set patent policy. The harmonization negotiations run the risk of intruding on Congress' prerogatives in this regard.

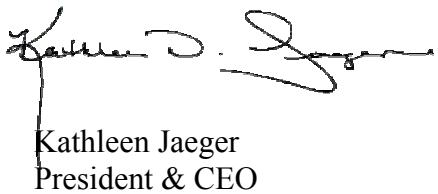
If and to the extent that the B+ process goes forward, it should be a transparent one. GPhA understand that drafts are being circulated that have not been made available to the general public - let alone interested constituents such as GPhA. The GPhA regards "harmonization" as a useful goal in some circumstances, and not in others. Increasing transparency in USPTO negotiations is consistent with one of the recommendations of the report prepared by the Federal Trade Commission (FTC) 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy"[1] which states that "Increased interaction appears desirable to foster better understanding and communication between the patent and competition communities." In addition, to the extent that harmonization allows consistent world-wide filing practices, it may also be of some benefit.

However, where "harmonization" is used in an attempt to conform U.S. national patent policy with those of other countries, it provides no benefit in itself, and may interfere with Congress' responsibility to set patent policy. Thus, if Congress determines the United States should continue to impose a duty of candor in dealing with their patent offices on pain of unenforceability, that judgment should trump any desire to "harmonize" our laws with those of countries that have made a different policy determination. Certainly, any consideration of harmonization should await the completion of the legislative process.

[1]" A report by the Federal Trade Commission" October 2003

To the extent that the USPTO continues to participate in patent harmonization negotiations with the B+ group, GPhA respectfully request the opportunity to provide additional comments as those negotiations continue and congressional action proceeds.

Sincerely,



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