



(By e-mail to IP.Policy@uspto.gov)

United States Patent and Trademark Office
Attn: Elizabeth Shaw

Re: Prior User Rights

8 November, 2011

Dear Ms. Shaw,

On behalf of Hospira, Inc., I write in response to the United States Patent and Trademark Office's Notice of Public Hearing and Request for Comments on the Study of Prior User Rights (the "Notice"). *See* 76 Fed. Reg. 62,388 (Oct. 7, 2011). This letter provides Hospira's written comments to some of the topics and questions in the Notice.

Hospira is a global specialty pharmaceutical and medication delivery company. It conducts operations worldwide, including in the United States, Canada, Latin America, and South America; Europe, the Middle East and Africa; and Asia, Japan and Australia. Hospira is the global leader in generic injectable pharmaceuticals, and it is one of the top global providers of medication management systems, such as infusion pumps, related software and services, dedicated administration sets, gravity administration sets, and other device products. In addition, Hospira maintains a market leadership position in biosimilars in Europe.

In Hospira's view, the addition of a prior user right into the patent laws of the United States is a positive development, particularly given the change to a first-to-file system through the America Invents Act. The change brings United States patent law into conformity with those of other major countries. In fact, many of the major markets in which Hospira operates provides for some sort of prior user right as a defense to patent infringement.

In Australia, a prior user defense is available under Section 119 of the Patents Act 1990 (Cth), and it provides a personal right to continue making or using a product, method or process as claimed in a patent, when such product, method or process was established before the filing date of the patent in question. Under Section 119(4), the prior user right is transferable.

Similarly, Canadian law grants an immunity to those who acquired patented subject matter before the priority date of a claimed invention. *See* Patent Act § 56(1). The immunity comes into play when a person other than the patentee has purchased, constructed or acquired the subject matter of a claimed invention before the claim date (usually the priority or filing date) of an issued patent. It enables that person to continue to use and sell the specific articles, machine, manufacture or composition purchased, constructed or acquired without liability for patent infringement.

In Japan, Section 79 of the Patent Law also provides for a prior user right. If a person has conducted business that included working the invention, or has made preparations for doing so, before the priority date of the patent and without knowing of the contents of the invention, that person obtains a non-exclusive license under the patent, limited to their working or preparations at the time of the filing date.

Likewise, many of the major countries of Europe provide for a prior user right. French law establishes a "prior personal possession right." Art. L 613-7 IPC ("Any person who, within the territory in which this Book applies, at the filing date or priority date of a patent was, in good faith, in possession of the



invention which is the subject matter of the patent shall enjoy a personal right to work that invention despite the existence of the patent.”). In Germany, Section 12 of the Patent Act establishes a defense to infringement to those who had used an invention before its priority date in Germany. In Italy, Article 68 of the Code of Industrial Property (CIP) states that the exclusive rights granted by a patent do not extend to “prior users of the invention” to the extent of the pre-use. In the Netherlands, Article 55 of the Dutch Patents Act gives potential infringers a right based on non-public prior use. And in the United Kingdom, Section 64 of the Patents Act 1977 provides a defense to infringement—termed a “statutory license”—whereby a person may continue doing an act that began before the priority date of the patent.

In Hospira’s experience, which includes litigating patent infringement disputes in many of these foreign jurisdictions as well as others, prior user rights are an important—and fair—part of the defensive arsenal. In a first to file system, the patentee may in fact not be the true innovator, but rather the first to make it to the patent office. While such a system is sensible and provides many benefits, without prior user rights it could do great harm in certain instances and even stifle competition. For example, alleged lost profits damages awarded to a patentee could exceed the actual profits of a legitimate prior user—a user who may in fact be the true innovator.

As the global leader in generic injectable pharmaceuticals, prior user rights can be particularly important to Hospira in protecting its established products and processes against claims by producers of branded products whose business models include serially seeking and obtaining later-expiring patents on different aspects of pharmaceutical products—a practice known as “evergreening.” Often these later expiring patents are of no inventive value—perhaps minor improvements, or perhaps processes that were not “public” but were used by others. In the pharmaceutical context, such patents may be used to block generic competition. Without prior user rights available to those legitimately using later-patented technology, competition may be stifled and generic products delayed market entry or removed from the market for significant periods of time, all of which ultimately harms the public. The same applies where other generic companies apply for patents on similar “inventions”. Again, the result is decreased competition and increased healthcare costs.

The changes introduced by the America Invents Act like the addition of a prior user right, brings United States patent law in line with that of other jurisdictions throughout the world. This provides companies like Hospira, who operate globally with an improved opportunity for its products as there is increased consistency and predictability to the rules which will be applied across many countries. Given the change from a first-to-invent to a first-to-file system, prior user rights are particularly important to protecting the pre-existing rights of global companies like Hospira. In our experience, prior user rights promote innovation and competition—they do not stifle it, as some have argued. Thus, Hospira strongly supports the inclusion of a prior user right provision in the America Invents Act and believes that the new provision should, as in other countries, apply to all inventions, whether products, processes or methods.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Leah Taylor".

Leah Taylor

VP, Intellectual Property

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