Congress of the United States
Washington, DC 20515

Foreign Competitors Welcome the Proposed Change in the U.S. Patent Law

July 24, 2007

Dear Colleague:

We want to draw your attention to an article found in one of the top newspapers in India yesterday regarding the Patent Reform Act of 2007. This article discusses how the Patent Reform Act of 2007 will allow Indian drug makers to challenge U.S. patents in an inexpensive way. **Foreign competitors welcome the proposed change in the U.S. patent law.** See reverse for the full article.

Sincerely,

Michael H. Michaud
Member of Congress

Donald A. Manzullo
Member of Congress

THE ECONOMIC TIMES

Local cos can eye patents in US

23 Jul, 2007, 0442 hrs IST,Gireesh Chandra Prasad, TNN

NEW DELHI: A Crucial bill making its way through the US Congress is set to give a new inexpensive option for Indian drug makers to attack the patents that give monopoly rights to top-selling MNC brands in the largest pharmaceutical market.

The bill passed by the judiciary committees of the House and the Senate last week, for a sweeping overhaul of the US patent system, allows an interested party to invalidate patents outside a court of law. They could approach the US Patent and Trademark Office (USPTO) for this after the patent is issued.

"The patent reform is beneficial to Indian companies as they are usually not patent holders and are often excluded from the US market by the threat from weak patents," said US-based intellectual property law firm Darby & Darby PC's Washington DC Office managing principal Dr Raj S Dave.

There will be two windows for filing petition for cancellation of a patent. The first is within 12 months of issue or reissue of the patent. The second window is available if the continued existence of patent claim is likely to cause the petitioner significant economic harm and the petitioner has received a notice from the patentee alleging infringement, said Dr Dave in reply to an ET questionnaire. It allows one to challenge a patent anytime during its life at a fraction of the cost of litigation.

"This provision will subject many existing US patents to an immediate threat of invalidation as it makes easier to show the obviousness of the invention. Seeking invalidation of patent is likely to be a part of the patent strategy that Indian generics companies may follow in the US. Companies could either make use of this provision or opt for the existing process of litigation or a mix of both depending on legal advice on a case to case basis," said Indian Pharmaceutical Alliance secretary general DG Shah. Now, requesting marketing approval for a patented drug's generic copy leads to the innovator suing the applicant.

There are some major differences between moving the patent office for revoking a patent and filing for marketing approval and risking litigation. If the patent is invalidated at the patent office, the market for the drug is open to all generics makers unlike in the second case, where the successful generics company gets a six month market monopoly. Since only the first company to successfully file para four application is entitled to the six month market monopoly, companies may not wait for the patent office's decision.

"The provision has to be used judiciously," says Ranbaxy executive director corporate affairs and global corporate communications Ramesh L Adige. "The documents and arguments a petitioner relies on for invalidation at the patent office cannot be relied upon in a court of law, as the law stands today. Therefore, losing the case at the patent office means the company needs fresh ground to challenge the patent elsewhere," he told ET. He added that the reforms are still some way off as they need to be voted in the full house and senate.

The reforms will give more flexibility and freedom for adopting the appropriate patent challenge strategy on a case to case basis, said Anoop Narayanan of Mumbai-based law firm Majmudar & Co.

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