



Ref. No. 013/ITPC-India/2010

Date 06-08-2010

Mr. V. Bhaskar
Joint Secretary
Department of Industrial Policy and Promotion (DIPP)
Ministry of Commerce and Industry
Room No. 236, Udyog Bhavan
New Delhi – 110 011
Tel: 011-23063571, Fax: 23063017
Email: v.bhaskar@nic.in

Re: Patents and high cost of Hepatitis C treatment for people living with HIV/AIDS

Dear Mr. Bhaskar,

I write to you on behalf of International Treatment Preparedness Coalition ITPC – India (ITPC – India). It is a national coalition of people living with HIV, treatment activists, doctors, lawyers and academia working on increasing access to HIV/AIDS treatment and other healthcare interventions needed by affected communities based on their needs.

This is with reference to critical issues that impact the right to health and access to treatment of people living with HIV (PLHIV). We would therefore like to raise certain concerns about the impact of the product patent regime introduced in 2005 on generic production and access to affordable medicines–

Hepatitis C (HCV): We would like to draw your attention to the May 2010, 63rd World Health Assembly Resolution on viral hepatitisⁱ and the commitment India has made to address this public health problem. In India, people living with HIV are increasing being diagnosed with Hepatitis C (HCV) co-infection. As they share many of the same risk and transmission modes, the prevalence of HCV among HIV-positive individuals is higher than the general population. HCV is now widely considered to be the leading non-AIDS cause of death among HIV-positive individuals worldwideⁱⁱ.

Treatment: Appropriate management of HCV involves the treatment of chronic HCV in the absence of which in many cases, death results from cirrhosis, liver failure or liver cancer. The current treatment for HCV consists of combination therapy involving two drugs, ribavirin and pegylated interferon. For people living with HIV who are co-infected with HCV, the usual course of HCV treatment lasts for 48 weeks, with ribavirin taken daily (orally, in pill format) and pegylated interferon once a week (by injection).

Barriers to treatment: Treatment for HCV is not available under the public health programme and patients have to pay for treatment themselves. The cost of treatment includes doctor's fees, expensive diagnostics and very expensive medicines. We would like to highlight in this letter to the Ministry of Commerce and Industry the issue of access to affordable generic versions of medicines needed for HCV treatment.



**Strengthening Community
Responses to HIV Treatment
& Prevention**

On March 3, 2006, the Swiss Pharmaceutical company Hoffmann–La Roche proudly announced that – “it has become the first pharmaceutical company in India to receive a product patent under the new regime. The product patent granted to Roche's Pegasys (pegylated interferon alfa-2a) stands valid for 20 years from May 15, 1997. This necessarily means that no other company could launch a generic version of drug in India”ⁱⁱⁱ. Subsequently a patent on Pegylated interferon alfa-2b was granted to Schering-Plough Corp (now Merck & Co.) by the Indian patent office.

As a result of the product patents granted, currently, pegylated interferon is only available from these two multinational companies. The two patented formulations of pegylated interferon on the Indian market are (a) pegylated interferon alfa-2a (from F. Hoffmann–La Roche Ltd.) and (b) pegylated interferon alfa-2b manufactured by (from Schering-Plough Corp., now Merck & Co.)

<p>Pegylated interferon alfa-2a (distributor appointed by Roche is Taksal Pharma Pvt. Ltd)</p> <p>Patent Number: IN198952 Granted by the Chennai patent office</p>	<p>Price quoted by Taksal Pharma: Rs. 11,700 per injection (135 mcg) Rs. 14,700 per injection (180 mcg)</p> <p>MRP – Rs. 18,200 per injection (180 mcg)</p> <p>Distributor price - Rs.15500 per injection (180 mcg)</p> <p><i>Please note the company or their distributors refuse to give the prices in writing to patients.</i></p>
<p>Pegylated interferon alfa-2b marketed by Fulford (India) Ltd</p> <p>Patent number: IN207233 Granted by the Chennai patent office</p>	<p>Price as quoted by Fulford India: Rs. 11,492 per injection^{iv} (80 micrograms)</p> <p>MRP is approximately: Rs. 14,000</p> <p><i>Please note the company or their distributors refuse to give the prices in writing.</i></p>

Both these versions of pegylated interferon are patented and since there can be no generic production, competition is limited and neither company has much incentive to reduce its drug's price. Both pharmaceutical companies can make a substantial profit in India by selling only a relatively tiny amount each year to those patients who can pay the very high price. Access to treatment for those who most need it remains limited due to high cost of pegylated interferon. The high cost of treatment also discourages the public health system and insurance schemes in India from providing or covering costs of hepatitis C diagnostics or treatment services.

<p>For a PLHIV the cost of buying Pegylated interferon alfa-2a for 48 weeks is Rs.7,056,00 (approximately) @ Rs. 14,700 per injection (180 mcg)</p> <p>Please note that Ribavirin is off patent and</p>	<p>In addition, patients have to pay for the diagnostics and doctors fees and other drugs needed to combat the side effects of pegylated interferon</p>
---	---



**Strengthening Community
Responses to HIV Treatment
& Prevention**

Please note that Ribavirin is off patent and is generically produced. It is a low cost drug to manufacture and is offered free if the patient buys the expensive pegylated interferon injections.	
For a PLHIV the cost of buying Pegylated interferon alfa-2b Treatment for 48 weeks is Rs. 5,516,16 (approximately) @ Rs.11,492 per injection (80 mcg)	In addition, patients have to pay for the diagnostics and doctors fees and other drugs needed to combat the side effects of pegylated interferon
Please note that Ribavirin is off patent and is generically produced. It is a low cost drug to manufacture and is offered free if the patient buys the expensive pegylated interferon injections.	

However, the patents being held by two pharmaceutical companies severely limit generic competition that can reduce the prices of pegylated interferon. In the case of antiretrovirals (ARVs) – the backbone of AIDS treatment, generic production in India brought down the prices of first line AIDS treatment from 10,439 USD to 67USD.

Recommendations:

- (1) The pricing of both the companies should be monitored for collusion in pricing. In addition, the price of pegylated interferon should be regulated and if required even brought under price control.
- (2) The validity of the patents should be scrutinized. This technology of combining interferon and other biologically active proteins with PEG has been known for years prior to these patents.
- (3) **The 2010 World Health Assembly resolution on Viral hepatitis calls for member countries – “to consider, as necessary, national legislative mechanisms for the use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights in order to promote access to specific pharmaceutical products”.** Therefore, efforts should be made to overcome patent barriers for the development of a generic version of pegylated interferon by using TRIPS flexibilities. This will not only benefit Indian patients but also patients across the developing world who depend on procuring affordable generic versions of essential medicines developed in India.

Access to affordable generic versions of pegylated interferon is going to play a critical role in scaling up HCV treatment in resource poor settings in developing countries. This is equally important for people living with HIV and HCV co-infection.

We request you to ensure that generic competition of essential drugs remains possible in India. So many lives depend on it worldwide.

Thanking you in advance for your co-operation,

Warm regards,