Civil Society Groups Strike Again:

BMS' patent bid for Hep C treatment *Daclatasvir* challenged

2 May 2015 - Stepping up efforts to counter patents on life-saving medicines, three civil society groups working to increase access to affordable, life-saving Hepatitis C (HCV) medicines, have challenged Bristol-Myers Squibb (BMS') pending patent application on Daclatasvir before the Delhi Patent Office. The pre-grant opposition has been filed by ***Hepatitis Coalition, Nagaland (HepCon), Sankalp Rehabilitation Trust (Sankalp Trust), Mumbai and Asia Pacific Network of Positive People (APN+)***, all of whom are represented by the ***Lawyers Collective***.

"BMS' patent application has no merit" said Anand Grover, Director, Lawyers Collective. "We have made out a clear case that the application lacks inventive step and does not fulfill the requirements of section 3(d), being similar to existing technology which is excluded from patentability under the law. The application ought to be rejected."

Daclatasvir, a direct acting antiviral (DAA) is a part of the class of new oral treatments to treat chronic HCV. It works to block the NS5A protein in the HCV without which the virus cannot replicate. In combination with other oral DAAs like *Sofosbuvir*, it has shown very promising treatment outcomes moving towards an all-oral, simplified and well-tolerated regimen from the current treatment regimen of painful and side-effect laden *pegylated interferon* injections.

Despite these treatment benefits that could treat and potentially cure treat millions of people living with chronic HCV, the high price of the medicine means that it might not be available for those who need it. "We know that *Daclatasvir* is selling at US $15,000per bottle in the EU. By no measure is this price affordable to the common man in India, particularly marginalized groups like People Who Inject Drugs (PWIDs) who have a high burden of HCV and also HIV co-infection" said Ketholelie Angami, of HepCon. "Along with affordability, availability of better drugs is of utmost importance" he added. Infact, a study by Andrew Hill and other researchers at the Liverpool University shows that a 12-week combination therapy with *Sofosbuvir* could cost as little as $100 - $250 a person to produce.

BMS has not been forthcoming about their pricing or access strategy on *Daclatasvir* for high burden countries like India. "We know from sources that BMS is attempting to negotiate voluntary licenses despite there being no patent on *Daclatasvir* in India, similar to what Gilead did for *Sofosbuvir*. There is no transparency about the details of these negotiations and we're very concerned about the replication by BMS of restrictive and unethical terms of Gilead type licenses." said Eldred Tellis of Sankalp Trust.

Shiba Phurailatpam, Regional Coordinator, APN+, pointed out "There is ample evidence from ARV drugs that open generic competition results in the most dramatic fall in prices. If we are to even consider scaling-up treatment with the newer DAAs there needs be several more players in the market producing drugs like *Daclatasvir*. We hope this patent opposition will help achieve just that".