

CSO LETTER CALLING FOR REVOCATION OF PATENTS ON REMDESIVIR IN INDIA

Gilead Sciences triggered global anger in 2015 with their exorbitant pricing of sofosbuvir for hepatitis C treatment, and with others in the pharmaceutical industry, have relentlessly pressured countries across the world to not use their rights under international intellectual property rules and national laws to access affordable generic medicines for their populations.

Gilead is once again cornering the market, this time over remdesivir. The US Food and Drug Administration approved it for emergency use for COVID-19 on 1 May 2020, based on which Japan also fast-tracked approval on 7 May. Current results on remdesivir show very limited value, but it is still undergoing clinical trials for COVID-19 treatment in several countries under the WHO Solidarity Clinical Trials initiative.

The company holds patents on remdesivir in several countries, including India which granted three patents on 27 September 2016, 5 September 2019 and 21 February 2020 respectively. In many developing countries, patent applications were not filed by Gilead.

However, on 12 May Gilead announced giving Voluntary Licenses to 5 generic manufacturers in India and Pakistan (Cipla Ltd., Ferozsons Laboratories, Hetero Labs Ltd., Jubilant Lifesciences and Mylan) with the condition that they can export to 127 countries listed by Gilead, excluding several middle-income developing countries especially in South America. There are no patents in many of the developing countries covered by the licenses and several of those excluded from the list.

Meanwhile, the three patents granted in India are also problematic and our analysis revealed that they violate provisions of India's Patents Act 1970.

Below is a letter to the Government of India from the Campaign for Access to Affordable Medicines, Diagnostics and Devices, India (CAMD-India) and Third World Network (India) calling for the patents to be revoked in the public interest, under section 66 of the Patents Act. The hyperlinks to the supporting documents are in the letter.

New Delhi

13th May 2020

To

Dr. Guruprasad Mohapatra
The Secretary
Department of Promotion of Industry and Internal Trade (DPIIT)
Ministry of Commerce & Industry
Email: secy-ipp@nic.in

Dear Sir

Subject: Revocation of Patent Nos. IN275967 (7068/DELNP/2010), IN319927 (1328/CHENP/2013) and IN332280 (201727012821) under sections 66 of the Patents Act, 1970

We write to bring to your notice a drug Remdesivir, which is being considered as a potential treatment for COVID-19 illness and could be an effective treatment. Remdesivir (RDV) is not approved as yet and is an investigational drug undergoing clinical trials. It is patented and manufactured by Gilead Sciences Inc. We would like to point out that RDV has been granted three patents in India viz IN 275967 (7068/DELNP/2010), IN 319927 (1328/CHENP/2013) and IN332280 (201727012821). We state that all these patents have been granted against the provisions of the Patents Act.

The first patent i.e IN275967 contains Markush claims, which does not establish and satisfy the inventive step and goes against the guidelines for granting Markush claims under the Guidelines for the Examination of Claims on Pharmaceutical Inventions. The patent claims chemical structures without evidence of their antiviral activity. Markush claims granted are vague and too broad leading to structural possibilities not contemplated by the patent specification.

The second patent i.e. IN 319927 the structure of Remdesivir is already disclosed in the Patent IN275967 and therefore has no novelty. IN'927 claims new use which is *per se* prohibited by the Act. The IN'927 patent claims nucleoside analogs that are well known to exhibit antiviral properties. For decades chemists have been developing nucleoside and its nucleoside phosphonate analogues with different modifications. The modification with nucleoside analogues having 1'-CN and 2'-OH modifications were indeed known in the context of viral or tumor suppression. Further, developing a phosphoramidate prodrug is very obvious from the existing prior arts and therefore does not satisfy the inventive step criteria under the Patents Act,1970.

Regarding the third patent IN332280, we would like to bring your attention to the communication of the Cancer Patient Aid Association (CPAA), which clearly shows the illegality in the grant of the patent. We reiterate and rely on their arguments against IN'280.

Annex I and documents attached therein explain in detail how these patents violate the provisions of the Patents Act,1970.

We submit that all the above-mentioned patents violate the provisions of the Patents Act, therefore, the existence of these patent are mischievous to the State or generally prejudicial to the public, and therefore ought to be revoked under section 66 in public interest immediately.

Sincerely

Prathibha S

Legal Researcher

On behalf of CAMD-India and Third World Network (India)

Enclosures:

1. [Annex I- Reasons for the Revocation of Remdesivir \(RDV\) patents](#)
2. [Doc 1 Colly: Description and granted claims of Indian Patent No. 275967](#)
3. [Doc-2: International search report \(ISR\) of WO 2009/132135](#)

4. [Doc-3: International Preliminary Examination Report \(IPER\) and Written Opinion of WO 2009/132135](#)
5. [Doc-4 Colly: FER and Applicant's reply to Indian Patent No. 275967](#)
6. [Doc-5: Complete Specification of WO 2009/132135 as published by PCT](#)
7. [Doc-6: Colly-FER, Applicants reply and Written submission to Indian Patent No. 319927](#)
8. [Doc-7: Complete Specification of WO2012/012776 as published by PCT](#)

Copy to:

Dr. Harsh Vardhan, Hon'ble Minister, Ministry of Health and Family Welfare

Smt. Preeti Sudan, Secretary, Ministry of Health and Family Welfare

Shri D. V. Sadananda Gowda, Hon'ble Minister, Ministry of Chemicals and Fertilizers

Shri Mansukh Mandaviya, Hon'ble Minister of State, Ministry of Chemicals and Fertilizers

Dr. P. D. Vaghela, Secretary, DOP, Ministry of Chemicals and Fertilizers

Smt. Shubhra Singh, Chairperson, NPPA, Ministry of Chemicals and Fertilizers

Shri Piyush Goyal, Hon'ble Minister, Ministry of Commerce and Industry

Dr. Anup Wadhawan, Commerce Secretary, Ministry of Commerce and Industry

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