

“VEKLURY REMDESIVIR AND IT’S IPR MANAGEMENT”

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ABSTRACT

Remdesivir injection, is the most heard injection in the times of Pandemic i.e. COVID-19. The fact which is unknown to half the world is that remdesivir is the brand name, but the truth is that the remdesivir is the chemical or medical name for the injection. It was for the first time being introduced by U.S based company known as Gilead Science Inc. for the treatment of virus caused by rodents. On the surge in COVID-19 cases, Veklury Remdesivir cleared all the human and the clinical trials for the successful treatment of novel corona virus. Since 2020, the world has been facing the shortage of Veklury remdesivir. The shortage has forced the Gilead Science Inc. to enter into an agreement with Indian and Pakistani Companies for its production. Veklury Remdesivir being the most demanded, anti-viral drug has also threat of being infringed. The Gilead Science Inc., to protect their invention has vested in various intellectual property rights and have adopted various IP management strategies.

Keywords: Anti-Viral Drug, COVID-19, Infringement, Intellectual Property Rights, IP Management, Remdesivir, Veklury.

Introduction: Veklury Remdesivir

Remdesivir is an antiviral injection which is used for the treatment of “SARS-CoV-2” i.e. the chemical name of corona virus.¹ The antiviral drug reduces the viral replication. In India, an individual with symptoms of COVID is treated with remdesivir along with the oxygen therapy, vitamins and other various supplements as per prescribed.²

The fact which is unknown to half the world is that remdesivir is the brand name, but the truth is that the remdesivir is the chemical or medical name for the injection. Remdesivir injection was first introduced and invented by the Irish company named “Gilead Sciences Inc.” by the name of “Veklury”.³ Veklury was not invented specifically for the treatment as it was invented by Gilead Science Inc. in the year 2016 for the treatment of the virus spread by animals in the society. Veklury was the first antiviral drug which was approved by the FDA (Food and Drug Administration) for the treatment of COVID-19 by issuing an

¹Rashmi Mabiyan, ROLE OF REMDESIVIR IN TREATMENT OF COVID-19, Economic Times, Healthworld.com, Reterived on 18/05/2021 from <https://health.economictimes.indiatimes.com/news/pharma/role-of-remdesivir-for-treating-of-covid-19-patients/82111739>

² REMDESIVIR INJECTION, U.S. National Library of Medicine, MedlinePlus.com, Reterived on 18/05/2021 from <https://medlineplus.gov/druginfo/meds/a620033.html>

³ David J, WHAT IS THE ROLE OF ANTI VIRAL DRUG REMDESIVIR IN CORONAVIRUS, Medscape, Reterived on 18/05/2021 from <https://www.medscape.com/answers/2500114-197451/what-is-the-role-of-the-antiviral-drug-remdesivir-in-the-treatment-of-coronavirus-disease-2019-covid-19>

emergency use authorization on 1st May, 2020 and getting final approval on 22nd October, 2020.⁴ Today, near about 50 countries are using Veklury for the treatment of the COVID-19.⁵

The most important medical remedy for the most dangerous virus has gained a lot of demand in the past two years. Due to which the Gilead Science Inc. extended their plants throughout the world, doubled the production of Veklury. In the time when the nation is crying, some people see remdesivir as the most profitable business just by infringing regardless of the elements required for its production. Gilead Sciences Inc., the owner of Veklury Remdesivir to protect their invention from infringement must have dealt and gone through the various intellectual properties for the same.

Intellectual Property Vested

Gilead Science Inc. for protecting the Veklury Remdesivir from infringement has vested in the following intellectual property rights:

2.1) PATENT

Gilead Science Inc. being the Irish based company got their invention Veklury Remdesivir patented in the U.S. Patent office. Gilead Science Inc. filed '**Patent Application No. 16/265,016**' on '**1st February, 2019**'. The Patent application got '**published on 22nd August, 2019**' with '**Patent Publication number US2019/0255085A1**.'⁶

On reading the patent application submitted by the Gilead Science Inc. in the U.S. patent office it was quite evident that the Veklury remdesivir was invented by them in the year 2016. Which makes the confusion in the minds of public why it was invented in 2016, being the antiviral of COVID-19. In the patent application it is quite clearly mentioned that this medicine was invented past in year 2016 as a treatment for the virus infected by the animals specifically Lassa virus (virus caused by the rats)⁷ and Junin virus (virus caused by intake of infected rodents secretions and excretions)⁸.

On the close analysis of the patent application, all the aspects which should be present in the patent application are being present such as background, drawings, method for treatment, prior art, definitions of certain medical terms etc.

The another question that arises here is why Gilead Science Inc. filed the patent application in 2019 being Veklury remdesivir invented in the year 2109. The reason behind the same is that till year 2019, Veklury was used for the treatment of two viruses only. With the situation of rising Covid and Veklury

⁴ Id.

⁵ ABOUT VEKLURY, Gilead Sciences Inc., Reterived in 18/05/2021 from <https://www.gilead.com/purpose/advancing-global-health/covid-19/about-veklury>

⁶ GILEAD SCIENCES INC., 'VEKLURY REMDESIVIR', PATENT NO. US2019/0255085A1, PUBLISHED ON 22ND AUGUST 2019, Google Patents, Reterived on 18/05/2021 from <https://patents.google.com/patent/US20190255085A1/en>

⁷ Jill Seladi, EVERYTHING YOU NEED TO KNOW ABOUT LASSA FEVER, Medical News Today, Reterived on 18/05/2021 from <https://www.medicalnewstoday.com/articles/306886#:~:text=Lassa%20fever%20is%20an%20acute,spleen%2C%20it%20can%20be%20fatal.>

⁸ Phillip R., JUNIN VIRUS, Science Direct, Reterived on 18/05/2021 from <https://www.sciencedirect.com/topics/neuroscience/junin-virus>

remdesivir being only the treatment for that time being started gaining the demand and it might only be the reason that company decided to get Veklury remdesivir patented.

2.2) Trademark/ Wordmark

Gilead Science Inc. got 'Veklury' registered as wordmark under The Trademarks Act, 1999. The trademark application number filed with the trademark registry is '2968002' which was published on '22nd May, 2017' in "Journal No. 1798-0" under the class 5 of trademarks i.e. pharmaceutical preparations.⁹ The filing mode of the application was international bureau with international registration No. '1236621'.

So, the Gilead Science Inc. opted out for the Patents and Trademarks as the intellectual property rights for protecting their invention Veklury Remdesivir from the infringement. With the increasing demand for the patented and trademarked, Veklury Remdesivir in the COVID pandemic, it will be very interesting to know the IP value of the Veklury Remdesivir.

Ipr Valuation

3.1) Market For The Product

The whole nation is battling with the deadly wave of COVID-19 having approximately 3 crore people effected in India.¹⁰ There has been a continues shortage of remdesivir leading to usage of other medicines or injections which makes the treatment of COVID-19 incomplete and regularly thousands of people are dying due to the shortage of remdesivir.

The increase in cases of COVID-19 has forced the producers of the remdesivir to increase its production at rapid pace. Earlier, health ministry used to have 38 lakhs vials of Remdesivir per month which have been increased simultaneously with COVID cases to 1.03 crore vials per month. But, still with crores of vials per month, we can quite evidently see the nation crying out there for the vials of the Remdesivir.¹¹ One of the reason considered for the shortage of Remdesivir is black marketing. The sellers have stocked the vials to charge the higher price from an individual who is in need and willing to pay higher price than the routine price. Also keeping in mind the current situation of the COVID-19 and daily increasing case, the Gilead Science Inc. has decided to setup 40 additional manufacturing plants. So, it is clearly evident that the market of the Remdesivir is not limited to the boundaries of one nation but, the whole world needs Remdesivir.

WORDS SPEAK

⁹ VEKLURY, TRADEMARK APPLICATION NO. 2968002, PUBLISHED ON 22 MARCH 2017, Trademarks Registry, Reterived on 18/05/2021 from <https://ipindiaonline.gov.in/eregister/eregister.aspx>

¹⁰ INFORMATION ON COVID-19 INDIA, Government of India, Ministry of Health and Family welfare.com, Reterived on 19/05/2021 from <https://www.mohfw.gov.in/>

¹¹ PB JayaKumar, INSIDE REMDESIVIR PUZZLE: LITTLE SUPPLY, Business Today, Reterived on 19/05/2021 form <https://www.businesstoday.in/sectors/pharma/covid-19-why-is-there-a-shortage-of-remdesivir/story/438153.html>

3.2) Ip Valuation Of Veklury Remdesivir

1. Market Method.

Market method of the IP valuation is in which the demand and the market covered by the product are being taken into the consideration. So, the IP valuation by market method for Veklury Remdesivir can be done by comparing the demand and market coverage in the year 2019 and 2020.

Year	Product Demand (In Dollar Billion)
2019	\$ 22.1 Billion
2020	\$ 24.4 Billion

Table 1

Source: Financial Statements of Gilead Science Inc. for the year 2019 and 2020¹²

From the above data and statistics its quite evident that the demand for Veklury Remdesivir increased to \$24.4 billion in the year 2020 which is considered to be the year in which the COVID wave was most dangerous as compared to the year 2019 in which COVID emerged was \$22.1 Billion. This represents approximately 10% increase in the sale of Veklury Remdesivir which has majority demand of the product from the United States which amounted to \$18.1 billion and then followed by Europe i.e. \$2.3 billion.

2. Income Method

¹² YEAR IN REVIEW 2020, Gilead Science Inc., Retrieved on 19/05/2021 from https://www.gilead.com/-/media/files/pdfs/yir-2020-pdfs/2020-gilead-yir_desktop.pdf?la=en&hash=D8A37C5533FE14906AFBAF121615DE76

Income method of the IP valuation is in which the approximate profits earned by the product are being taken into the consideration. So, the IP valuation by market method for Veklury Remdesivir can be done by comparing the profits in the year 2019 and 2020.

Year	Profit (In Dollar Billion)
2019	\$ 22.4 Billion
2020	\$ 24.7 Billion

Table 2

Source: Financial Statements of Gilead Science Inc. for the year 2019 and 2020¹³

With the increased sales from \$22.4 billion in 2019 to \$ 24.7 billion quite evidently shows that the Veklury had made its monopoly in the market and have made Gilead Science Inc. earn higher profits. Keeping the sales of Veklury in mind the owner and partners of the Gilead Science Inc. has tried to find the ways and methods to shorten the process of manufacturing of Veklury. Gilead Science Inc. also promised 1 million people having Veklury in United States. This clearly shows that the sales of the Veklury Remdesivir has been boosted and its IP value in the market can even be calculated for the period.

3. Other Methods:

One of the method of IP valuation is **transaction method** which takes into the consideration the actual price which is paid for the product in the market. Currently, Veklury is sold at \$552.38 per unit in United States¹⁴ and in and about Rs. 4000-5000 per unit in India. Also, it can be calculated through **Option based method** taking into consideration the share repurchases by Gilead Science Inc. of \$ 1.6 billion in the year 2020 and hold of marketable securities of value approx. \$ 7.9 billion in the year 2020.¹⁵

¹³ Id.

¹⁴ VEKLURY PRICES, Drugs.com, Reterived on 19/0/2021 from <https://www.drugs.com/price-guide/veklury>

¹⁵ YEAR IN REVIEW, Gilead Science Inc., Reterived on 19/05/2021 from https://www.gilead.com/-/media/files/pdfs/yir-2020-pdfs/2020-gilead-yir_desktop.pdf?la=en&hash=D8A37C5533FE14906AFBAF121615DE76

So, it is not wrong to state the Veklury as an intellectual property has high value today. So, the higher demands and as per the needs something needs to be done for the management of the intellectual property rights by Gilead Science Inc.

Ip Management & It's Strategies

Gilead Sciences Inc. believes that if the patent would not be there specially in the pharmaceutical sector, then it would not have made the other companies in the market to do more research and development. Intellectual property rights are believed the most favourable reason for the innovation.¹⁶ Also, in the pharmaceutical sector IP initiates the innovation across the world which gives the patients an needy access to all the medicines which they need. Gilead Science Inc. has formulated various strategies to control and manage their IP rights for Veklury Remdesivir which are as follows:

- 1. Voluntary Generic Licensing to Limited Countries:** Gilead Science Inc. have given voluntary license to the under developed and developing nations such as India. They have given license to produce the Veklury Remdesivir medicine to the limited countries as their IPR management strategy. Gilead directly works with their partners and provide them with the technology to manufacture the medicine.
- 2. Patent Pool:** Gilead Science Inc. is the part of Medicine patent pool which is a United nations initiative to promote the licensing of patented Veklury in the low income states. It is expected that when more companies will join the medicine patent pool, then the potential impact on patient access will continue to grow.
- 3. Patent Protection and Access:** The countries to which the Gilead Science Inc. has given the license to produce the Veklury Remdesivir if there the patent protection exist then the partners closely work with the local authority and the government. They ask the local authorities and the government to increase access to the company's medicine.
- 4. Partnerships:** "Ongoing cooperation between and within the private and public sectors for Remdesivir is essential to ensure that patents do work for the benefit of patients. The access programs of Gilead and the MPP demonstrate that IP and access can not only coexist, but that responsible use of IP can actually drive a significant expansion in access to Veklury Remdesivir in developing countries."¹⁷

WORDS SPEAK

¹⁶ David Weder, IP RIGHTS AND THEIR EFFECT ON INNOVATION, Academics, Mckendree.edu, Reterived on 19/05/2021 from

¹⁷ INTELLECTUAL PROPERTY MANAGEMENT AND PATIENT ACCESS, Gilead Sciences Policy Position, Gilead Science Inc., Reterived on 20/05/2021 from <https://www.gilead.com/~media/Files/pdfs/other/Intellectual%20Property%20and%20Patient%20Access101014.pdf>

Licensing & Agreement

To fight with the outbreak of novel COVID -19, Gilead Science Inc. is working hard on the Veklury Remdesivir which is the effective drug for the treatment of the COVID-19. To fulfil the demand of the Remdesivir, Gilead Science Inc. has granted and signed '**Non- Exclusive Voluntary Licensing Agreement**' with India and Pakistan and has allowed them to distribute the Remdesivir further to 127 countries.¹⁸ Non-exclusive Voluntary Licensing agreement means granting the license to more than one entity voluntarily between the patent holder and licensee. Gilead Science Inc. has entered into the agreement with the following companies:¹⁹

Company	Remdesivir Name	Trademark Details
Zydus Cadila	Remdac	Application No: 4728647 ²⁰ Application Date: 02/11/2020
Hetero Labs	Covifor	Application No: 4527437 ²¹ Application Date: 11/06/2020
Dr. Reddy	Redyx	Application No: 4540033 ²² Application Date: 22/06/2020
Cipla	Cipremi	Application No: 4740699 ²³ Application Date: 10/11/2020
Jubilant Life Science	JUBI-R	PATENT ²⁴ Application No: 202011022634

¹⁸ Aishani Singh, VOLUNTARY LICENSING AGREEMENTS FOR REMDESIVIR, Mondaq, Reterived on 20/05/2021 from <https://www.mondaq.com/india/patent/945086/voluntary-licensing-agreements-for-remdesivir>

¹⁹ EP, GILEAD SIGNS VOLUNTARY LICENSING AGREEMENT, Express Pharma, Reterived on 20/05/2021 from <https://www.expresspharma.in/gilead-signs-voluntary-licensing-agreements-with-cipla-hetero-labs-jubilant-lifesciences-mylan-for-remdesivir/>

²⁰ REMDAC, TRADEMARK APPLICATION NO. 4728647, APPLICATION ON 02/11/2020, Trademarks Registry, Reterived on 18/05/2021 from <https://ipindiaonline.gov.in/eregister/eregister.aspx>

²¹ COVIFOR, TRADEMARK APPLICATION NO. 4527437, APPLICATION ON 11/06/2020, Trademarks Registry, Reterived on 18/05/2021 from <https://ipindiaonline.gov.in/eregister/eregister.aspx>

²² REDYX, TRADEMARK APPLICATION NO. 4540033, APPLICATION ON 22/06/2020, Trademarks Registry, Reterived on 18/05/2021 from <https://ipindiaonline.gov.in/eregister/eregister.aspx>

²³ CIPREMI, TRADEMARK APPLICATION NO. 4740699, APPLICATION ON 10/11/2020, Trademarks Registry, Reterived on 18/05/2021 from <https://ipindiaonline.gov.in/eregister/eregister.aspx>

²⁴ JUBILANT LIFE SCIENCE, 'JUBI_R, PATENT NO. 202011022634, PUBLISHED ON 29th MAY 2020, Indian Patent Advanced Search System, Reterived on 20/05/2021 from <https://ipindiaservices.gov.in/PublicSearch/PublicationSearch/Search>

		Application Date: 29/05/2020 Status: Published
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Table 3

The technology has been transferred by the Gilead Science Inc. to the above named drug company for production of the Remdesivir to make them available to all the needy patients as soon as possible. These products are also declared as royalty free by the WHO till the emergency of the COVID-19 ends. These all companies were given the non-exclusive voluntary agreement for the production of the Remdesivir after Gilead Science Inc. have produced Veklury Remdesivir. So, it's important to know whether there was any prior art to the Veklury Remdesivir or not.

Prior Art

On the plain reading of all the documents that are made available by the U.S. Patent office for Veklury Remdesivir it can be concluded that there was no prior art and no objections have been raised on the patent with regards to the prior art.

But there are two patents granted in India to the Gilead Science Inc. itself which can't be said the prior art of the Veklury Remdesivir but, something same to that. *First*, is “**SUBSTITUTED CARBA-NUCLEOSIDE ANALOGS FOR ANTIVIRAL TREATMENT**” with **Patent Number:** 275967, **Application No:** 7068/DELNP/2010 and has been granted on 27/09/2016 and was filed on 22/04/2009.²⁵ *Second*, is ‘**COMPOUNDS FOR TREATING PARAMYXOVIRIDAE VIRUS INFECTIONS**’ with **Patent Number:** 319927, **Application No:** 1328/CHENP/2013 and has been granted on 05/09/2019 and was filed on 22/07/2011.²⁶ Both of these patents are the similar form of remdesivir and since they were filed by Gilead Science Inc. only which appears like the prior art to Veklury Remdesivir.

Threats And Infringement of IP

The Veklury Remdesivir has obtained a high market demand due to COVID-19 and to fulfil the demand of remdesivir they granted non-exclusive voluntary agreement to five Indian companies so that they can further supply to 127 other countries. For the many pharmaceutical industries, getting an agreement from Gilead Science Inc. would have been the dream. This has forced many companies to infringe the intellectual property rights granted to Veklury Remdesivir.

²⁵ GILEAD SCIENCE INC., ‘SUBSTITUTED CARBA-NUCLEOSIDE ANALOGS FOR ANTIVIRAL TREATMENT’, PATENT NO. 275967, GRANTED ON 27/09/2016, Indian Patent Advanced Search System, Retrieved on 20/05/2021 from <https://ipindiaservices.gov.in/PublicSearch/PublicationSearch/Search>

²⁶ GILEAD SCIENCE INC., ‘COMPOUNDS FOR TREATING PARAMYXOVIRIDAE VIRUS INFECTIONS’, PATENT NO. 319927, GRANTED ON 05/09/2019, Indian Patent Advanced Search System, Retrieved on 20/05/2021 from <https://ipindiaservices.gov.in/PublicSearch/PublicationSearch/Search>

One of the such example is when India's BDR Pharmaceuticals attempted to launch the generic version of remdesivir without even getting the non-exclusive voluntary agreement from the Gilead Science Inc. The matter was solved as BDR pharmaceutical, remdesivir was not allowed to be produced in its earlier stages by Drug Controller General of India. If the BDR pharmaceuticals remdesivir would have been sold in market then the power to file an infringement case would have been vested with Gilead Science Inc.²⁷

There have been various instances in which the pharmaceuticals companies to earn the profits have tried to infringe the IP rights of the Veklury Remdesivir and the reason behind the infringement would be non-granting of the non-exclusive voluntary license for producing the remdesivir and the greed to earn more revenue.

Cases Filed or Settled

When it comes to the Intellectual property, there is no chance that the product would be granted patent or trademark without the intervention of the courts. There are the few instances or objections raised in the case of Veklury Remdesivir intellectual property rights which are discussed as follows:

1. The NGO named Cancer Patient Aid Association has raised the objections to Department of Promotion of Industry and Internal Trade regarding the revocation of patent granted to remdesivir i.e. Patent No's: IN 275967 and IN 319927. These are the two patents granted to the Gilead Science Inc. and are the forms similar to the remdesivir. The NGO have objected that patents have failed to fulfilled the criteria of novelty and inventive step set under the Indian Patents Act.²⁸ The application of the revocation has been filed under Section 66 of The Patents Act, 1970.²⁹
2. While, the registration of the 'Veklury' as trademark in India, the objection was being raised under Section 11(1) of the Trademarks Act, 1999. The objection was raised by the proprietor 'Sanofi Ltd.' for the trademark of "VICLOR" with application no. 681445 that the mark appears to be similar. The attorneys on the behalf of Gilead Science Inc. said that the above said trademark "VICLOR" has not been used from the past 20 years and even the application for the same is not complete which makes the "VICLOR" as pending application and under section 11 the pending applications are not considered.³⁰ The contention of attorney's was allowed.³¹

²⁷ INDIA'S BDR PHARMACEUTICALS ATTEMPT TO LAUNCH REMDESIVIR, Global Data, Retrieved on 20/05/2021 from <https://www.globaldata.com/indias-bdr-pharmaceuticals-attempt-to-launch-generic-version-of-remdesivir-looks-difficult-says-globaldata/>

²⁸ NGO ASK GOVERNMENT TO REVOKE PATENTS GRANTED TO REMDESIVIR, Patents, Pharmabiz.com, Retrieved on 20/05/2021 from <http://www.pharmabiz.com/NewsDetails.aspx?aid=124196&sid=1>

²⁹ The Patents Act, 1970, Section 66

³⁰ The Trademark Act, 1999, Section 11

³¹ REPLY TO EXAMINATION REPORT FOR APPLICATION NO. 2968002, The Registry of Trademark, Retrieved on 20/05/2021 from https://ipindiaonline.gov.in/eregister/showdocument.aspx?DOCUMENT_NO=WFlaW1xdKC4oKDAoLidYWVpbXF0=

Conclusion & Suggestions

Many states in the world are reporting a shortage of Remdesivir, a Gilead-patented antiviral injection, as a result of the current Covid-19 outbreak. In June of last year, India's drug regulator licenced the drug for limited emergency use in the care of Covid-19 patients, and it is now produced and distributed by five Indian companies under a voluntary licencing arrangement with Gilead. The licence agreements signed by Gilead are reassuring in terms of production and delivery capability; however, they do not guarantee fair prices (as shown by the various price points set by different licensees) or access to the drug anywhere it is required. Also, ***it is not wrong to suggest that***, the Veklury Remdesivir should remain royalty free permanently not interim, if interim it will boost the price of the Remdesivir as the companies will take royalty as cost from consumers.

Since Gilead owns the Remdesivir patent, it has the sole right to bar third parties from bringing the drug into India without its permission under the Section 48 of The Indian Patent Act, 1970. This right, though, is not absolute. But, any individual who imports Remdesivir in compliance with the section 107 A (b) of the Indian Patents Act is not infringing on Gilead's patent rights, and Gilead has no right to prohibit such import. ***It is not wrong to suggest that***, since due to the restrictions of the patent on remdesivir the central government can amend the IPR laws, which could allow them to import remdesivir from other countries to fulfil the shortage of remdesivir in India.

Also, ***it is not wrong to suggest that*** in India the procedure for granting of patent is very long. The patent application filed by Jubilant Life Science still not have been granted the compulsory license required for patent of medicine. So, the government should make Section 92 of the act applicable which allows the government to grant patent of compulsory licensing by passing it in notification. This would help in fulfilling the shortage of remdesivir in the country.