Patent situation and registration update for sofosbuvir

Sofosbuvir (Brand named Sovaldi®) manufactured by Gilead Sciences is approved by the United States Food and Drug Administration (US FDA) for the treatment of hepatitis C virus (HCV) genotype 1,2,3,4 and the European Medicines Agency (EMA) for treatment of genotypes 1 through 6 in combination with other medicinal products. *(Please refer to table 3 below for detailed treatment indications).*

Patent areas: Overall, there are **21 different areas where patents related to sofosbuvir are being applied**.

Patent 1: Primary patent application claiming the **base compound.**

Patent 2: Claims to the sofosbuvir **prodrug** as marketed.
Where granted, both patents can serve to prevent competitors from making sofosbuvir. Patent 1 and Patent 2 are involved in pre-grant opposition and litigation cases that dispute their novelty and inventive step. Patent 1 has been rejected by the Indian patent office and Gilead has appealed the decision.

Patents 3, 4 and 13: Claims **processes to make sofosbuvir.**
Where granted, these will require competitors to design their drugs around these patents and use other production processes.

Patent 5: is a **product-by-process patent,** claiming the sofosbuvir prodrug by a process of preparation.
Where granted, it will prevent competitors from making the sofosbuvir prodrug by the process claimed or from importing sofosbuvir that was manufactured using this process.

Patents 6, 9, 10, 11, 12, 14, 15, 16, and 19: Claims **specific derivatives of sofosbuvir**.
Seeking subsequent patents on derivatives of existing drugs is a common strategy of companies (i.e., obtaining multiple patents that cover various aspects of the same product).

Patent 7: Claims sofosbuvir for **use in combination therapy** with other anti-HCV drugs (ledipasvir and PSI7851).

Patents 8 and 20: Claims are **formulation patents**, claiming the pharmaceutical dosage form (pharmaceutical composition).

Patents 17, 18, and 21: Claims **sofosbuvir and derivatives** for use in the treatment of HCV infection.

(Please refer to table 1 below for patent status in some countries in Asia).

Table 1: Status of current patent applications

Country	Status[1]	
China	Patent 1: Granted Patent 2: Rejected[2]	Patents 3, 4, 5, 7, 9, 13, 16 and 21: Applied for and pending.
India	Patent 1: Rejected and under appeal by Gilead.	Patents 2, 4, 5, 7, 8, and 16: Applied for and pending.
Indonesia	Patent 1: Granted	Patents 4, 7 and 8: Applied for and pending.
Thailand	Patents 3, and 4: Applied for and pending.	
Vietnam	Patents 3, 4, 7, 8, 13 and 16: Applied for and pending.	
Philippines	Patent 1: Granted	Patents 2, 7, 8, 9 and 13 : Applied for and pending.
Malaysia	Patents 1 and 2: Granted	Patents 5, 8 and 9: Applied for and pending.

Table 2: Asian countries included and excluded from Gilead's voluntary license for sofosbuvir

Excluded	Thailand, Malaysia, China
Included	Indonesia, India, Vietnam, Philippines, Nepal

Table 3: Status of sofosbuvir registration in Asian countries

China	No information available
India	Approved in January 2015, generic versions available
Indonesia	Pre-submission filed in February 2015 by Mitra pharma Gilead's local partner in Indonesia
Malaysia	No Information available
Philippines	Filed in July 2014
Thailand	Filed in June 2014
Vietnam	Pending submission

[1] References are from a working paper of the World Health Organisation on the patent situation of key products for treatment of HCV prepared by Thomson Reuters in March 2015. This shows the situation of patent applications at that time. It is advised that advocates contact local intellectual property lawyers for further updated information.

[2] http://www.reuters.com/article/2015/06/19/gilead-sciences-sovaldi-patents-idUSL1N0Z42MT20150619

Patent situation and registration update for Ledipasvir

Ledipasvir is manufactured by Gilead Sciences and is approved by the United States Food and Drug Administration (US FDA). The co-formulation of Ledipasvir and Sofosbuvir, brand named Harvoni®, has been approved for the treatment of genotype 1 hepatitis C virus (HCV) infection. *(Please refer to table 3 below for detailed treatment indication).*

Patent areas: Overall, there are **5 different areas where patents related to ledipasvir are being applied**.

Patent 1: Primary patent application claiming the **base compound.**
Where granted, this patent can serve to prevent competitors from making ledipasvir.

Patents 2 and 3: Claims process to make ledipasvir.
Where granted, these will require competitors to design their drugs around this patent and use other production processes.

Patents 4 and 5: Claims combinations of different HCV drugs with ledipasvir and their formulation.

(Please refer to table 1 below for patent status in some countries in Asia).

Table 1: Patent application and status:

Country	Status of various patent applications[1]	
China	Patent 1: Granted	Patents 2 and 5: Applied for and pending
India	Patent 1: Applied for and pending	No information available on any other patent applications
Indonesia	Patent 1: Applied for and pending	No information available on any patent applications.
Thailand	No information available on any patent applications.	
Vietnam	Patent 1: Filed and status unknown	No information available on any other patent applications.
Philippines	No information available on any patent applications.	
Malaysia	No information available on any patent applications.	

Table 2: Asian countries included and excluded from Gilead's voluntary license for sofosbuvir

Excluded	Thailand, Malaysia, China
Included	Indonesia, India, Vietnam, Philippines, Nepal

Table 3: Status of ledipasvir registration in Asian countries

China	No information available
India	Pending submission
Indonesia	Pending submission
Malaysia	No Information available
Philippines	Filed in July 2015
Thailand	Filed in May 2015
Vietnam	Pending submission

[1] References are from a working paper of the World Health Organisation on the patent situation of key products for treatment of HCV prepared by Thomson Reuters in October 2014. This shows the situation of patent applications at that time. It is advised that advocates contact local intellectual property lawyers for further updated information.

Patent situation for Daclatasvir

Daclatasvir, manufactured by Bristol Myers Squibb (BMS) and brand named Dalklinza, has been approved by the European Commission for marketing in all European Union countries. This is approved for the treatment of genotype 1, 2, 3 and 4 hepatitis C Virus (HCV) infection in combination with other medicinal products. *(Please refer to table 2 below for detailed treatment indication).*

Patent areas: Overall, there are **8 different areas where patents related to daclatasvir are being applied**.

Patent 1: Primary patent application claiming the **base compound.**
Where granted, this patent can serve to prevent competitors from making daclatasvir.

Patent 2: Claims process to make daclatasvir.
Where granted, will require competitors to design around this patent and use other production processes.

Patent 3: Claims specific derivatives of daclatasvir.
Seeking subsequent patents on derivatives of existing drugs is a common strategy of companies (i.e., obtaining multiple patents that cover various aspects of the same product).

Patent 4: Claims patent on the formulation- the pharmaceutical dosage form (pharmaceutical composition).

Patents 5, 7 and 8: Claims patent for the use of daclatasvir in combination therapy with other HCV protease inhibitors.

Patents 6: Claims **patent for the** screening of NS5A-targeting compounds to inhibit HCV replication.

(Please refer to table 1 below for patent status in some countries in Asia).

Table 1: Status of current patent applications

Country	Status[1]	
China	Patent 1 and 4: Granted	Patents 2, 3, 5 and 7: Applied for and pending
India	Patent 1, 2, 3, 4, and 5: Applied for and pending	
Indonesia	Patent 1 is not filed.	No information available on any other patent applications.
Thailand	Patents 1 and 5: Applied for and pending.	
Vietnam	Patent 1 is not filed.	Patent 5 is applied and status unknown.
Philippines	Patent 1 is not filed.	Patent 5 is applied and status unknown.
Malaysia	Patent 1 is not filed.	No information available on any other patent applications.

[1] References are from a working paper of the World Health Organisation on the patent situation of key products for treatment of hepatitis C prepared by Thomson Reuters in October 2014. This shows the situation of patent applications at that time. It is advised that advocates contact local intellectual property lawyers for further updated information.