IN THE HIGH COURT OF SINDH, KARACHI

Before: **Mr. Justice Sajjad Ali Shah, Chief Justice**
Mr. Justice Zulfiqar Ahmad Khan

C.P.NO.D-1040 OF 2016

M/s. Getz Pharma (Pvt.) Limited
v/s.
Federation of Pakistan and others

C.P.NO.D-1042 OF 2016
M/s. Macter International Limited
v/s.
Federation of Pakistan and others

C.P.NO.D-1043 OF 2016
M/s. CCL Pharmaceutical (Pvt.) Limited
v/s.
Federation of Pakistan and others

C.P.NO.D-1269 OF 2016
M/s. AGP (Pvt.) Limited
v/s.
Federation of Pakistan and others

C.P.NO.D-1355 OF 2016
M/s. Hilton Pharma (Pvt.) Limited
v/s.
Federation of Pakistan and others

Date of Hearing	:	25.08.2016.
Date of announcement	:	07.10.2016
Petitioner	:	Through Mr.Faisal Siddiqui, Advocate & Mr.Abdul Sattar Pirzada, Advocate
Respondents	:	Through Mr.Muhammad Aslam Butt, D.A.G.

J U D G M E N T

Zulfiqar Ahmad Khan, J.:- Through the instant petition, the petitioner has impugned Notification bearing SRO No.101(I)/2016, dated 09.02.2016, wherein Respondent No.1. in "partial modification" of clause 4(4)(i) of the Drugs Pricing Mechanism (DPM), created pursuant to Notification No.F.No.9-12/2014-DDC(P), dated 05.03.2015 issued under Section 7(c)(vii) of the Drugs Regulatory Authority of Pakistan Act, 2012 (DRAP Act), alleging that the said notification is violative of clause (i) of sub-

section (4) of Section 4 of the DPM which requires that Maximum Retail Price (MRPs) of generic substitutes of the new chemical entity is to be fixed @ 30% less than Originator brand's MRP.

Brief, but very important, facts arising out of the perusal of the case are that the instant petition relates to the breakthrough medicine generically known as Sofosbuvir (branded as Sovaldi by Gilead Sciences, Inc. USA) which is termed as a miracle medicine taken orally for the cure of Hepatitis-C, of which there are more than 13 Million sufferers in Pakistan making Pakistan rank as No.2 country in the world on account of prevalence of this deadly disease. Whereas the respondent No.1 being overall custodian of protecting rights of life of the citizens of Pakistan, respondent No.2 is the Drug Regulatory Authority, formed under the above referred DRAP Act for the purpose of providing effective coordination and enforcement of the Drugs Act, 1976 and to bring harmony in inter-provincial trade and commerce of therapeutic goods. Pursuant to Section 32 of the DRAP Act, the said law is not intended to override other laws and the provisions of the DRAP Act are in addition to and not in derogation of the provisions of the Drugs Act, 1976 and any other law for the time being in force. Also of importance is to mention the Drugs Registration Board (DRB) created pursuant to Section 7 of the Drugs Act, 1976. Section 12 of the Drugs Act, 1976 empowers the Federal Government to fix the MRP at which any drug may be sold and under section 12(3), the Federal Government is also empowered to delegate its authority. Law defines MRP as the ceiling allowing companies the leverage to sell their drugs at any price below this ceiling and does not commercially mean that the MRP is the price at which the drug would be actually sold in the market.

Pursuant to sections 4 and 41 of the Drugs Act, the Federal Government also formulated the Drugs (Licensing, Registering and Advertising) Rules, 1976, as per Rule 29 (5-A), the Registration Board of DRAP is qualified to request the Federal Government for fixation of the MRP of any drug once the said drug is approved for registration by the Registration Board. For this purpose, pursuant to sections 7, 10 and 12(3) of the Drugs Act, the Federal Government constituted the Drugs Pricing Committee (DPC) vide a notification dated 05.08.2013 and delegated its authority to fix MRP in the hands of the said DPC, resultantly the said DPC acts as the Federal Government and exercises powers of the Federal Government under section 12 of the Drugs Act, 1976.

The counsel for the Petitioner submitted that his client applied to the Registration Board for the registration of a drug under the trade mark of Sofviget (Sofosbuvir 400 mg), which, as mentioned earlier, is the breakthrough medicine having replaced the earlier treatment of Hepatitis-C, which was traditionally treated by taking 24 injection shots by the patient. Now via this medicine, for the first time, cure has been found by taking tablets of Sofosbuvir orally in the complete course treatment for three months, by taking one tablet a day. The counsel for the Petitioner contended that the application for registration of its drug as generic version of Sofosbuvir along with nine other companies' similar generic drugs were scheduled before the DPC for the fixation of MRP on 31.12.2015, which meeting was cancelled and finally took place on 15.01.2016. The counsel further contended that though pursuant to clause (i) of sub-paragraph (4) of Paragraph 4 of the DPM, price of the generics are required to be 30% less than the price accorded to the Originator

brand, which pursuant to SRO 410/(I)/2015 was set at Rs.38,000/- (for 28 tablets), MRP for the petitioner's generic version was fixed at Rs.5,868/-, which is about 15.4% of the Originator's MRP. The counsel further contended that such arbitrary fixation of the price for the generic version is in complete violation of the policy mechanism, as well as, the statement given by the Minister of State for Health Services, who had declared that generic be sold @ Rs.26,600/-. Besides what has been stated above, the counsel additionally submitted that while a number of applications for the import of Originator drug were pending before the Respondent No.2, the latter arbitrarily selected prices put forward by a company called Ferozesons Laboratories Limited ("Ferozsons") at the rate of Rs.38,000/- for 28 tablets, whereas other applicants, who offered to import the Originator formulae (even from the same supplier in the USA) at far lesser prices, were ignored. As well as though Ferozesons' prices were set vide notification dated 08.05.2015, MRP for the generics were only formulated and issued vide the impugned notification dated 09.02.2016 after the lapse of eight months giving a free ride and monopoly to Ferozesons to exploit poor patients suffering from Hepatitis-C all over the country by charging monopolistic exorbitant prices. The counsel submitted that because of this favoritism, Ferozesons which used to rank at No.24 in the list of pharmaceutical companies of Pakistan with sales of Rs.2.5 Billion reached to the position of No.9 with sales of over Rs.9 Billion with growth of 222% annually. From the accounts of the said company, Ferozesons, the counsel presented a table that showed that while Ferozesons' other products for the period January-December, 2015 were sold at total Rs.3.3 Billion, by mere sale of Sofosbuvir, the

company made a windfall of Rs.5.7 Billion at the cost of nations' poor Hepatitis-C sufferers. While Ferozesons was permitted to sell the said medicine at the rate of Rs.1,14,000/- for the full course of three months, we observe from the data available that, in our neighboring country India, the full course of three months' Sofosbuvir was available for Rs.34,000/-. The counsel for the petitioner has prayed that the impugned notification be set aside and the petitioner may be allowed to sell Sofosbuvir @ Rs.26,600/- for 28 tablets, which is 70% of the MRP of the Originator Brand.

The learned D.A.G appearing on behalf of the federation supported the impugned Notification, wherein generic price is fixed @ Rs.5,868/- for 28 tablets, contending that from the period when the Originator Brand's MRP was fixed till the date of the instant notification, global prices for Sofosbuvir dramatically fell and now such generics are available at such lower prices making it possible that MRP for the generic be fixed at Rs.5,868/- so that the said lifesaving drug can reach the masses at such low price! When posed with the question that when MRP of the Originator Brand was being fixed @ Rs.38,000/- in favour of Ferozesons on 08.05.2015, why the respondents did not consider applications from other companies, who were willing to provide the same Originator Brand from the same source but at lot lesser prices - the learned D.A.G had no answers.

During the course of arguments learned counsel for the Petitioner, who was putting his case that price of generic be brought within 70% of the Originator Brand, the Court made an observation that why not set the generic's price of Rs.5,868/- as the baseline and

let the respondent follow the formula of 30% increase in the Originator's new MRP i.e. @ Rs.7,628.4 being 30% more than the price of the generic, the counsel for the petitioner did not object to such a suggestion, however, this proposal was vehemently challenged by the representative of the Ministry of Health ("MoH"), who said that the price once set for the Originator brand cannot be arbitrarily decreased except as per the formula provided in sub-section (5) of Section 4 of the pricing mechanism, which requires that the Originator must be given four years or till the time the entry of at least three generic brands in the market whichever is later at which instant the Originator's price can be reduced @ only 10% per annum for consecutive three years, therefore, the Government is bound to continue Originator's fixation at the price of Rs.38,000/- per the mechanism provided under sub-section (5), which made us wonder as if lowering the extremely high prices offered to the Originator will frustrate the regulatory regime sought to be put in place by the mechanism, whereas, the impugned notification issued in partial modification hasn't done so already?

Originator Drug:

Since unparalleled protection is granted in the Drug Pricing Mechanism for the Originator drug, it is important that we examine how the policy defines a drug to qualify as Originator and what mechanism is available for setting price for an Originator. Term Originator brand is defined under clause (xx) of sub-paragraph (1) of paragraph 2 of the DPM to mean "*a branded drug containing a new chemical entity through research and development*". The term "new chemical entity" is not defined in the said mechanism. However para

6 of Schedule – I of DRAP Act 2012 dealing with originator biological drugs defines it to mean a *biological drug which has been licensed by the national regulatory authorities on the basis of a full registration dossier* (i.e. the approved indication(s) for use were granted on the basis of full quality, efficacy and safety data). The *regulatory authority* suggested in the foregoing is the Drug Registration Board which is set up under section 7 of the Drugs Act, 1976. Rules 26 & 29 of Drugs (Licensing, Registering and Advertising) Rules, 1976 prescribe procedure for registration of drugs which require an application for registration to be made on Form 5-D (for new molecule) and or Form 5-E (for Patent Drugs). The applicant is required to furnish such further information and material as may be required by the Registration Board for proper evaluation of the drug. For a drug, where new method of manufacture is contemplated it may not require full investigations and clinical trials except in so far as they are necessary for the purpose of establishing bio-equivalence, absorption, acceptability or other such features. Rule 29(5A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 requires the Registration Board (when it registers a new drug), to send a request to the Federal Government for the fixation of maximum price of such drug. Paragraph 4 of DPM relates to fixation of MRP for New Chemical Entities (NCE - defined to mean the new chemical entity drug that has not been registered in Pakistan) and in respect of NCE pricing, provides as under:-

> (1) MRP fixation of Originator Brand of NCE shall be based on average price of the same brand in India and Bangladesh. If the Originator Brand is available in only one of these countries, MRP shall be fixed at its par after considering the exchange rate parity.

(2) If Originator Brand of NCE has not been marketed in India or Bangladesh its maximum retail price shall be fixed equal to the lowest of the following, namely:-

(i) retail price in developing countries which regulate drug prices;

(ii) whole sale price of in UK Monthly Index of Medical Supplies or British National Formulary or Australian Pharmaceutical Benefits Scheme or New Zealand Pharmaceutical Management Agency;

(iii) MRP calculated on the basis of landed cost plus 35% markup to calculate trade price. Trade price shall be grossed up to provide for 15% retailer margin; and (iv) demanded MRP.

From the foregoing it appears that for MRP fixation of an Originator, average price of the same brand in India and Bangladesh (if the said drug is available there) has to be considered. As in the instant case, Sofosbuvir was available in these two neighboring countries, the mechanism required MRP to be fixed at par with these countries, after considering the exchange rate parity. When a question to that effect was placed before the learned DAG and the representative of the Ministry of Health, no assistance was provided. We also examine from the comments submitted in this regard by MoH, no details are provided that the procedure demanded by the said mechanism was followed.

Patents and compulsory licensing:

Probably the only statute where a scientific method of determination of new and novel compound (of drug) is provided is the Patents Ordinance, 2000 which generally regulates matters regarding patents in Pakistan. Pharmaceutical compositions (i.e. drugs) are patented in large numbers under the said law which provides an established mechanism for patenting. Once patented, section 30 of the Ordinance, grants exclusive rights to drugs:

(a) Where the subject matter of Patent is a product, the holder of valid patent may prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product; and

(b) where the subject matter of a patent is a process, the holder of a valid patent may prevent third parties not having the owner's consent from the act of using the process, and from the acts of using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

(c) The owner of the patent shall, in addition to any other rights, remedies or actions available to him have the right, subject to sub-section (4) and section 59, to institute court proceedings against any person who infringes the patent by performing, without his agreement, any of the acts referred to in subsection (2) or who performs acts which make it likely that infringement will occur.

In order to be granted a patent, a drug needs to be new and novel. It is an established practice that in order to receive an Originator status under Drug laws (as well as the pricing mechanisms established in respect of drugs), the chemical composition of the said drug has to be patented under the patent laws of the country. In the instant case, no such information is placed on record by the MoH that it considered this essential requirement before the Originator drug status was provided to Sofosbuvir. Be that as it may, even if the drug is patented, there are ample provisions available under the Patent laws for acquiring compulsory licensing to those drugs which fit the criteria set under section 58 of the Patents Ordinance, 2000 introduced into national legislation as a part of flexibilities offered by the Trade Related Intellectual Property Rights (TRIPs) Agreement, 1994 of which Pakistan is a signatory and those obtained via the Doha Declaration, 2001. Section 58 is reproduced in the following:

58. Exploitation by a Government agency or third person.- (1) Subject to sub-section (2), where -

(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or

(ii) the Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or

(iii) the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or

(iv) where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology,

the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.

(2) The Federal Government shall, before taking any decision under sub-section (2), give the owner of the patent arid any interested person an opportunity of being heard if he wishes to be heard.

(3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Federal Government authorization, as determined in the said decision, and where a decision has been taken under sub-section (1), the need to correct anti-competitive practices.

(4) A request for the Federal Government authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time:

Provided that this sub-section shall not apply in cases of –

(i) national emergency or other circumstantial urgency provided that in such cases the owner of the patent shall he informed of the decision of the Federal Government as soon as reasonably practicable;

(ii) public non-commercial use; and

(iii) anti-competitive practices determined as such by a judicial or administrative body in accordance with clause (ii) of sub-section (1).

(5) The exploitation of a patented invention in the field of semi-conductor technology shall only by authorized either for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Federal Government is satisfied that the

issuance of the non-voluntary license would remedy such practices.

(6) The authorization shall be considered on its individual merits and shall not prohibit-

(i) the conclusion of license contracts by the owner of the patent;

(ii) the continued exercise, by the owner of the patent, of his rights under section 30; or

(iii) the issuance of a non-voluntary license under section 59.

(7) Where a third person has been designated by the Federal Government, the authorization may only be transferred with the enterprise or business of the person or with the part of the enterprise or business within which the patented invention is being exploited.

(8) Where the exploitation of the invention by the Government agency or third person designated by the Federal Government is authorized under clause (i) of sub-section (1), it shall be predominantly for the supply of the market in Pakistan.

(9) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Federal Government may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(10) Upon the request of the owner of the patent, the Federal Government shall, subject to adequate protection of the legitimate interest of the persons so authorized, terminate an authorization if it is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by it has failed to comply with the terms of the decision.

(11) Notwithstanding the provisions of sub-section (10), the Federal Government shall not terminate an authorization if it is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by it justified the maintenance of the decision.

(12) An appeal shall lie to the High Court against the decisions of the Federal Government under sub-sections (1) to (9).

As in the instant case where the drug is intended to heal a large part of population of Pakistan suffering from Hepatitis-C (4.5 per cent of the population), in public interest (even if a patent was

granted to Sofosbuvir), Federal Government has ample powers to invoke section 58 of the Patents Ordinance, 2000 to grant compulsory licenses to the local pharmaceutical companies to produce the said drug at lot cheaper rates – which is not done by the respondents.

Affordable Drugs – a fundamental right:

Unlike 115 countries of the world, the Constitution of Pakistan, 1973 does not explicitly recognize the 'right to health'. However, since 'right to life' is enshrined under Article 9 of the Constitution, the said article when read with Article 14 which grants the right to 'dignity of man', in our view, gives birth to the 'right to health' as a fundamental right. Additionally, the said 'right to health' is also covered by several international human rights instruments, including the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), ratified by Pakistan on 17 April 2008, which recognizes the right of nationals to the *enjoyment of the highest attainable standard of physical and mental health*. Specific obligations are set out by General Comment 14 (a legally binding key source document seeking to develop and apply human rights principles and standards via the interpretation of the human right to health through the UN Committee on Economic, Social and Cultural Rights), under which States are bound to respect, protect, and fulfil the right to health and make good-quality services and goods available, accessible, and acceptable. ICESCR so far however provides the most comprehensive coverage of the issue. As of 1995, one hundred & thirty-two states, including Pakistan, India, and Brazil have ratified the said Covenant. Article 12.1 of the Covenant defines the right to

health from an availability and accessibility framework. In regards to 'availability', the Covenant lays out the responsibility of the State to provide essential drugs (as defined by the WHO Model Lists of Essential Medicines). Also, under the said Covenant, a State has the international obligation to *"…facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required*". The 'affordability' or economic accessibility section of the Covenant stresses that health services, whether privately or publicly owned, be made affordable for all, including the disadvantaged populations. Therefore, it is the State's obligation to ensure that its population has the financial means to access such goods as medicines. Article 12.2 (d), the right to health facilities, goods and services of the Covenant provides for *the creation of conditions which would assure to all medical service and medical attention in the event of sickness*. Article 12 also includes information on a State's obligation to provide equal health care and services; a denial of which could be considered non-overt discrimination based on wealth. Therefore, the State is not permitted to favour expensive health services that benefit a few privileged, over reasonably priced medicines and preventative medicine that improves public health broadly.

According to Edwin, Jonathan James (Access to medicines as a right to health, and the conflict between innovators and generics – November 2012, The University of British Colombia) obligations on a State to provide its people with the right to health under the said Covenant falls into three categories: respect, protect, and fulfill. The obligation to 'respect', according to him, means that a State should not interfere with a person's enjoyment of their right to health,

including the denial of health serves to marginalized populations. The obligation to 'protect' has strong implications to the access to medicines issue, as it outlines that a State must protect the guarantees made under article 12 of the Covenant by preventing third party interference. A State has the responsibility to oversee and keep in check the marketing practices of medicines by the pharmaceutical industry. The obligation to 'fulfill' holds the State responsible for implementing legislature and policies that allow its population to realize the right to health. With regards state's duty to ensure access to medicines, a State, as per Edwin, can be found in violation to the above listed obligations, if the State:

- ignores such laws while entering into bilateral or multilateral agreements with other parties (States, international organizations, multinational corporations),

- fails to regulate the actions of other parties who may infringe on the right to health of their population (i.e. failure to protect consumers and workers from practices detrimental to health),

- fails to implement national policies that ensure the right to health for all, particularly marginalized populations

Beside the said Covenant, the right to health can also be found incorporated into several other declarations as follows:

- WHO Constitution
- Article 25.1 of the Universal Declaration of Human Rights
- Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination (1965)
- Articles 11 and 12 of the Convention on the Elimination of All Forms of Discrimination against Women (1979)

• Article 24 of the Convention on the Rights of the Child (1989)

• Articles 12.1/12.2 of the International Covenant on Economic, Social and Cultural Rights (1966)

• The 1989/11 resolution to the Commission on Human Rights

• The Vienna Declaration; and

• The International Bill of Rights

The above discussion culminate to a point that access to affordable drugs has been interpreted to be part of the right to health (Blood, Plasma, and Plasma Proteins: A Unique Contribution to Modern Healthcare by José Luis Valverde, Published by IOS Press), which as per above deductions emerges as a fundamental right in the light of Articles 9 and 14 of the 1973 Constitution.

The foregoing discussion reveals that access to affordable drug, being part of 'right to life' is an obligation undertaken by the state under the Constitution, as well as, pursuant to many international covenants including ICESCR. While at the same time TRIPs agreement and Doha Declaration provided flexibility to have lifesaving drugs (at least) be reproduced through national means by invoking compulsory licensing options by the respondent (MoH) who is mandated to respect, protect, and fulfil the right to health and make good-quality services and drugs available and accessible at affordable prices.

For the aforementioned reasons, following orders are made:

1. Respondents to recognize and take steps to show that they have recognized that access to affordable medicine is a fundamental right granted and protected under Articles 9 and 14 of the Constitution of Pakistan, 1973;

2. MRP for essential drugs not to be set unless flexibilities provided under Section 58 of the Patents Ordinance, 2001 have been fully exhausted in a transparent manner;
3. SRO No.101(I)/2016, dated 09.02.2016 fixing MRP of generic substitutes of Sofosbuvir at the rate of Rs.5,868 is declared legal as appropriate procedure of price determination of the said compound in the neighboring countries was complied with and the respondent had residual authority to issue the said notification in partial modification of clause 4(4)(i) of the Notification F.No.9-12/2014-DDC(P) dated 05.03.2015; and
4. Respondents to adopt due process provided under Notification F.No.9-12/2014-DDC(P) dated 05.03.2015 and after giving opportunity of hearing, re-fix MRP of Sofosbuvir fixed under SRO 410/(I)/2015 dated 08.05.2015, without being influenced from any observation made in this Judgment, but strictly in accordance with law.

The instant petitions are accordingly dismissed.

Judge

Chief Justice