

## IN THE HIGH COURT OF SINDH, KARACHI

Suit No. 1017 of 2011

**BEFORE:****Mr. Justice Arshad Hussain Khan****NOVEARTIS AG  
VS  
GENIX PHARMA (PRIVATE) LIMITED**

Plaintiff: Novartis AG  
Through Ms. Amna Salman, Advocate

Defendant: Genix Pharma (Private) Limited

Date of hearing: 16.08.2018

**JUDGMENT**

**ARSHAD HUSSAIN KHAN, J.** This suit was filed on 11.08.2011 against the defendant for Perpetual Injunction to restrain the defendant from committing any infringement and/or counterfeiting and/or imitation of plaintiff's right its Patent Numbers, with the following prayers:-

- a) *a decree for permanent injunction restraining the Defendant perpetually from manufacturing or making and/or importing and/packing and/or formulating and/or marketing and/or stocking for sale and/or offering for sale and/or supplying and selling, advertising or otherwise enabling others to infringe plaintiff's right and privileges in any Vildagliptin products in any form or any products containing Vildagliptin itself or its pharmaceutically acceptable salts or in combination with Metformin or any other active ingredient, or any other variation thereof in any form or in any manner and under any name whatsoever in infringement of Plaintiff's rights and privileges in relation to patent No.138896 and accepted Patent Nos.140417, 141042 and 141045;*
- b) *a decree for permanent injunction restraining the Defendant perpetually from using in any manner and selling Vildagliptin containing products per se or in combination with any other active ingredient or any colourable imitation of Plaintiff's Vildagliptin containing products in any manner or forms, process or formulations/compositions; manufacturing or making, formulating, selling, supplying, stocking, importing, exporting, offering for sale, advertising or otherwise*

*enabling others to infringe, offer for sale or use and sell Defendant`s Vildagliptin containing products in any form or in any manner and by any name whatsoever which are manufactured and/or formulated by using or adopting in any manner any step identical to or equivalent to or substantially similar to or incorporating the essential element or steps of claims the subject to or incorporating the essential element or steps of claims the subject matter of Pakistani Patent No.138896 and accepted Patent Nos.140417, 141042 and 141045.*

- c) a decree for permanent injunction restraining the Defendant perpetually from committing acts of unfair competition in relation to Plaintiff`s business of manufacturing, making, formulating, selling and supplying its Vildagliptin containing products;*
- d) a decree for permanent injunction restraining the Defendant from committing acts of misrepresenting clinical trials, studies, reports etc., conducted on Vildagliptin of Plaintiff`s origin as if those results and reports, studies etc., are those of Defendant`s Vildagliptin, which also constitutes the tort of passing off and also restraining Defendant from misrepresenting their product i.e., product of one quality, as that of the Plaintiff`s product i.e. the product of another quality;*
- e) a money decree against the Defendant for payment of Rs.100,000,000/- (rupees one hundred million only) to the Plaintiff as damages on account of partial compensation for the loss and damage for injury the goodwill and reputation of the Plaintiff;*
- f) cost of the suit may also be awarded; and*
- g) grant any such further/additional/other reliefs which this Honourable Court may deem just, fit and proper in the circumstances of the case.*

2. The case of the plaintiff as averred in the plaint is that the Plaintiff is a pharmaceutical and chemical group operating throughout the world. Its activities are focused on the service of mankind in seeking to improve both its life and its quality of life. That the plaintiff is strongly committed to research and development in an effort to identify, invent and develop, inter alia, new chemical and pharmaceutical products and compounds, including processes for their manufacture / formulations, and an amount of US \$ 6.2 billion was spent by Novartis AG., Pharmaceutical Division on research and development programs during year 2009. That amongst the completely novel invented products of substantial therapeutic importance which

has been invented, developed and patented by the plaintiff is a compound (Vildagliptin per se), its salts, its processes of manufacture and formulations/compositions now known by the International Non-Proprietary name of Vildagliptin, which is the active ingredient contained in the pharmaceutical products sold by the plaintiff. The plaintiff is proprietor in Pakistan of, amongst others, the following Pakistani Patents relating to processes for the manufacture of Vildagliptin, the product Vildagliptin per se, its pharmaceutically acceptable salts, Vildagliptin for formulations/composition and Vildagliptin product when prepared by the processes, the details of which are provided herein below:

#### Registered Patent

Patent No.	Filed	Sealed as of Dated/Granted date	Title
138896 (271/2004.	15-04-2004	16-4-2003	A PROCESS FOR THE PREPARATION OF A N-(N SUBSTITUTED GLYCYL)-2-CYANOPYRROLIDINE

#### Accepted

Patent No.	Filed	Sealed as of Dated/Acceptance date	Title
141042 (1054/99)	15-04-2004	13-12-2010	AN N-(SUBSTITUTED GLYCYL)-2-CYANOPYRROLIDINE
141045 (757/2006 Divisional	05-07-2006	Accepted on 13-12-2010	A SALT OF N(SUBSTITUTED GLYCYL)-2-CYANOPYRROLIDINE
140417 (1248/2006)	26-09-2006	Accepted on 6-1-2010	A PHARMACEUTICAL COMPOSITION COMPRISING VILDAGLIPTIN AND METFORMIN

#### Pending

Appl. No.	Filed	Priority Date	Title
39/2005	19-01-2005	20-01-2004 (US)	A DIRECT COMPRESSION COMPOSITION COMPRISING DIPEPTIDYL PEPTIDASE IV INHIBITOR (DPP-IV)
588/2006	07-06-2006	10-06-2005 US	MODIFIED RELEASE 1[(-HYDROXY-ADAMANT-1-

			YLAMDNO)- ACETYL]- PYRROLIDINE- 2(S)- CARBONITRILE FORMULATION
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That Vildagliptin products under the trademark GALVUS have been launched in Pakistan by the plaintiff through Novartis Pharma Pakistan Limited in the month of April, 2010, owing to great demand by the doctors and patients for which purpose necessary drug registration has been obtained from the Ministry of Health through Novartis Pharma Pakistan Limited, which is sole Pakistani importer, distributor and marketer of plaintiff's Vildagliptin, containing products. The plaintiff during the early part of second week of August 2011 came to know that the defendant had applied for and/or had obtained Drug Registration from the Ministry of Health for pharmaceutical products containing Vildagliptin itself or a pharmaceutically acceptable salt of Vildagliptin under trademark METVIL (containing Vildagliptin 50 mg with Metformin HCl 850 mg as well as Vildagliptin 50 mg with Metformin HCl 1000 mg), and/or Vildagliptin in combination with another active ingredient (hereinafter collectively referred to as Vildagliptin containing products unless the context would otherwise require) and was orally canvassing and announcing to the doctors and in the trade that it shall soon introduce its Vildagliptin containing products in the market under trademark METVIL (containing Vildagliptin 50mg with Metformin HCl 850 mg as well as Vildagliptin 50 mg with Metformin HCl 1000 mg) which activities of the defendant clearly infringe or threaten to infringe plaintiff's rights and privileges as detailed above relating to Vildagliptin containing products. It is also averred that the defendant, to the best of plaintiff's knowledge, has no manufacturing facilities to manufacture Vildagliptin and therefore it must be in the process of formulating and/or marketing and/or selling Vildagliptin containing products by importing same from unauthorized sources to commit infringement of plaintiff's aforesaid patent rights. It is also averred that the defendant, by importing (and/or manufacturing) or making / formulating / offering / counterfeiting / imitating plaintiff's rights and privileges in Patent Nos.13896, and accepted Patent Nos.140417, 141042 and 141045 and/or are attempting to do so as

Vildagliptin product per se and its process for manufacture and compositions, and/or Vildagliptin in combination with metformin, are protected in favour of plaintiff under Patent Nos.138896, 140417, 141042 and 141045.

3. Notices and summons were issued to the defendant but, despite the same having been received by the defendant, it has chosen not to come forward and contest the case. Consequently, this Court on 24.3.2014 declared the defendant ex-parte and subsequently the plaintiff was directed to file affidavit-in-evidence for ex-parte proof.

4. From the perusal of record, it transpires that the plaintiff on 29.03.2017 filed affidavit-in-evidence for ex-parte proof and examined Mr. Babar Waheed, authorized signatory of the plaintiff, who produced following documents.

- (i) Affidavit-in-evidence for exparte proof as Exhibit PW-1/1,
- (ii) Power of Attorney as Exhibit PW-1/2 and
- (iii) Certified copy dated 10.02.2017 of the patent Registration No. 138896 dated 25.04.2004 as Exhibit PW-1/3.

5. Learned counsel for the plaintiff at the outset submits that she does not press prayer clause relating to damages. She, however, during the course of her arguments while reiterating the contents of the plaint has contended that the inventions covered by all patents mentioned in the plaint and their complete specifications are attached to the plaint. Further contended that Vildagliptin as disclosed in patent No. 138896 and patent No. 141042 has been sold in Europe since the year 2008 under the plaintiff's trademark GALVUS whereas Vildagliptin in combination with Metformin as disclosed in accepted Patent No. 140417 is sold in Europe under trademark EUCREAS. Further contended that plaintiffs Vildagliptin containing products under GALVUS were launched in Pakistan in the month of April 2010 whereas Vildagliptin in combination with Metformin were launched in Pakistan in January 2011 under trademark GALVUS MET. It is also contended that during the second week of August, 2011, the plaintiff came to know that the defendant had applied and/or obtained Drug Registration from the Ministry of Health Pakistan (now Drug Regulatory Authority) for Vildagliptin containing products under trademark METVIL which they intended to launch. Upon having such

information the plaintiff immediately filed the present case and this court on 12.08.2011 also passed injunctive order whereby the defendant was restrained from violation the plaintiff's patent relating to Vildagliptin by manufacturing, processing or selling the drug Vildagliptin. It is also argued that the plaintiff is a registered right holder under the provisions of Patent Ordinance. Patents are duly granted by the Controller of patent (Patent Granting Authority of Pakistan) after due scrutiny and in accordance with law therefore, during the validity of aforementioned granted patents, the plaintiff enjoys exclusive rights under the provisions of Section 30 of Patent Ordinance 2000. It is also argued that under the terms of provisions of section 61 (1) (b) of the Patents Ordinance, 2000, the defendant was under obligation to disclose and to establish through evidence that the process used by the defendant to produce Vildagliptin containing products was different from process covered by the plaintiff's patents. However, the defendant's non-appearance and non-contesting the matter, despite having notice of the present case, clearly shows that the defendant has failed to discharge statutory burden under the provision. Learned counsel also referred to Section 30 of the Patents Ordinance, 2000 and submits that the said provision provides distinct rights and protection for product patents and process patents. It is also contended that both the provisions of Section 30 and 61 and relief applicable under both provisions become relevant as the plaintiff has Patents relating to Vildagliptin products per se as well as patents for process to produce Vildagliptin containing products. Lastly, argued that the stance of the plaintiff has gone un rebutted, hence the plaintiff is entitled to relieves as prayed. Learned counsel in support of her stance in the case has relied upon the following case law:

- (i) 2004 CLD 627 Messrs INTERNATIONAL INDUSTRIES LIMITED v. Messrs REHMAN TRADERS and other.
- (ii) 2004 CLD 1131 ACER, INC. v. ACER COMPUTERS
- (iii) 2004 CLD 1097 GAP, INC. (ACOMPANY ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE) through Authorized Signatory v. SHAHID CORPORATION through Shahid Maqbool (sole Proprietor) and 2 others.

- (iv) 1992 CLC 2382 GLAXO GROUP LIMITED and 2 others v. EVRON (PRIVATE) LIMITED and another
- (v) 2003 CLD 407 MERC & Co. INC. and others v. HILTON PHARMA (PVT.) LTD
- (vi) 1991 CLC Note 69 at page 52

6. I have heard the learned counsel for the plaintiff and perused the material available on record as well as the case law cited at the bar.

7. Before proceeding further, it is to be noted that a patent is a monopoly granted for a stated term to an inventor for his invention in order to encourage innovation and foster inventiveness. However, the inventor must make such disclosure of his invention as would enable a person skilled in the art to reproduce it and use it. The disclosure of the invention adds to the sum of public knowledge. Once the period of the patent has expired, any person can make use of the invention. Even prior to the knowledge and information made available it may be used by anyone if the patent is not thereby infringed. Hence, the inventor is encouraged to make it public by giving him a limited monopoly. But, the disclosure of the invention must be meaningful and proper. This disclosure is made in the specification, and what a complete specification must contain is stated in subsections (3) and (4) of section 15 of Patent Ordinance, 2000. It is, therefore, scrutinized with great care by the Patent Office, and it is only if it meets the statutory and legal requirements that it is accepted and advertised in the official Gazette in terms of Section 21 of the Patent Ordinance, 2000. It is at this stage Section 22 of the Ordinance, becomes applicable, which reads as under:

“After the acceptance of an application and until the date of sealing a patent in respect thereof, or the expiration of the time for sealing, the applicant shall have the like privileges and rights as if a patent for the invention had been sealed on the date of the acceptance of the application:

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.”

In the Ordinance 2000, the term / time for expiration of patent is given under Section 31 which reads as under :-

**“31.Term of patent.—**The term of a patent under this Ordinance shall be twenty years from the filing date.”

8. Though the present proceedings are ex-parte proceedings against the defendant and such the plea of the plaintiff has gone un-rebutted and unchallenged, yet the court being custodian of rights of litigants, is required to dispense with justice keeping in view their entitlement. As it is well settled that every Court is required to apply its mind before passing any order or judgment notwithstanding the fact that no person has appeared before it to oppose such an order or that the person who wanted to oppose was not allowed to oppose because he failed to fulfill the requirement of law. Reliance in this regard can be placed on the case of Haji ALI KHAN & COMPANY, ABBOTTABAD and 8 others v. M/s. ALLIED BANK OF PAKISTAN LIMITED, ABBOTTABAD (PLD 1995 SC 362).

9. Accordingly, I have gone through the Plaintiff's affidavit-in-ex-parte proof as well as the documents exhibited. For the sake of ready reference examination of the plaintiff's witness namely Muhammad Babar Waheed son of Abdul Waheed is reproduced as under:

“I produce affidavit in Evidence for Ex-parte Proof as Exhibit PW-1/1, I have gone through the same and relies on the contents thereof. I produce power of Attorney as Exhibit PW-1/2 (original seen and return). I produce certified copy dated 10.02.2017 of the Patent Registration No.138896 dated 25.04.2004 as Exhibit PW-1/3.”

It appears that the plaintiffs produced Certificate in respect of Patent Registration No. 138896 only and as such the presumption of genuineness/correctness is attached to the documents [Exh. PW-1/3] unless it is rebutted and or challenged. Furthermore, it transpires that the registered patent is still valid and subsisting under the law, hence the plaintiff establishes its right in respect of the patent having exhibited as PW-1/3.

10. In the instant suit, despite opportunities and notices, the defendant did not come forward to rebut the evidence or this presumption. Record also transpires that present suit was filed for

perpetual injunction and damages, however, since the learned counsel for the plaintiff during her arguments has abandoned her prayer in respect of damages, leaving the present suit only for perpetual injunction, and that relief is more or less discretionary nature.

11. In the above circumstances, the present suit is decreed in respect of prayer clause (a) to (d) only to the extent of the patent having Registration No. 138896.

JUDGE

*Karachi*  
*Dated 11.10.2018*

*Jamil\*/*