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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Reserved on: 16th July, 2021
Pronounced on: 20th July, 2021

I.A. 7615/2021 in

\+ CS (COMM) 463/2020

MERCK SHARP AND DOHME CORP. & ANR. ... Plaintiff

Through: Mr. Pravin Anand, Ms. Tusha Malhotra and Ms. Pankhuri Malik, Advs.

versus

SMS PHARMACEUTICALS LIMITED .... Defendant

Through: Ms. Meenakshi Arora, Senior Adv. with Mr. PB Suresh, Mr. Vipin Nair, Mr. Arindam Ghosh, Mr. Sughosh Subramaniam, Ms. Chitra Vats and Mr. Agnish Aditya, Advs.

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR

J U D G M E N T

% (Video-Conferencing)

IA 7615/2021 in CS (COMM) 463/2020

1. This application, by the defendant under Order XXXIX Rule 4 of the Code of Civil Procedure, 1908 (CPC), seeks vacation/modification of the ex-parte *ad interim* order, dated 21st October, 2020 passed by this Court in the present proceedings.

The controversy in issue and order dated 21st October, 2020

The Plaint

2. Plaintiff No. 1 - Merck Sharp and Dohme Corporation (who would, for the sake of convenience, be referred to, hereinafter, as "the plaintiff") has, by the present suit, sought injunction against infringement, by the defendant, of the plaintiff's Indian Patent No. 209816 ("IN'816", in short), whereby the plaintiff's invention, Sitagliptin, an anti-diabetic drug, stands patented.

3. The date of filing of the international application under the Patent Cooperation Treaty (PCT), for Sitagliptin, by the plaintiff, was 5th July, 2002. By operation of the explanation to Section 53(1)[1] of the Patents Act, 1970 ("the Patents Act"), therefore, the patent would expire on 5th July, 2022.

4. The plaint alleges that the defendant was infringing IN'816 of the plaintiff by advertising, for sale, Sitagliptin Hydrochloride in its list of Active Pharmaceutical Ingredients (APIs) and Analytical Standards. Reliance has been placed, in the plaint, on investigations stated to have been conducted by the plaintiff in September, 2020 which, according to the plaintiff, disclosed that the defendant was

[1] **53. Term of patent. -**
(1) Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.
Explanation. -For the purposes of this sub-section, the term of patent in case of International applications filed under the Patent Cooperation Treaty designating India, shall be twenty years from the international filing date accorded under the Patent Cooperation Treaty.

exploiting Sitagliptin for commercial use. For this, the plaint cites, by way of evidence, (i) the Product List of the defendant on its website, in which Sitagliptin is reflected under the categories "APIs" and "Analytical Standards", (ii) the fact that Sitagliptin does not figure among the products under the head "Pipeline" on the defendant's website, indicating that it was currently being offered for sale, (iii) the coverage, in the category of "APIs", on the defendant's website, of Sitagliptin Hydrochloride under the head "Current Product List", (iv) the listing, by the defendant, on its webpage, of five different isomers of Sitagliptin under the head "Analytical Standards", (v) the offering, for sale, of Sitagliptin API by the defendant through its business profile on India Mart, Linkedln, TradeIndia, JustDial, Pharma Compass and PharmaAdda, (vi) the "Pre-feasibility report" and "Final Environmental Assessment Report" submitted by the defendant to the Ministry of Environment, Forest and Climate Change and the "Executive Summary Report", submitted to the Andhra Pradesh Pollution Control Board in January, 2019, in all of which it was claimed that the manufacturing capacity of defendant, for Sitagliptin API would be 10 tonnes per month, after its expansion, and (vii) Export-Import data of the defendant, which reflected that, in 2017, 2018, 2019 and 2020, the defendant had exported Sitagliptin.

5. Additionally, the plaint also relies on personal enquiries stated to have been made, by the investigator engaged by the plaintiff with the defendant. Of these, the only enquiry which may be stated to have any relevance to effecting of sales by the defendant of Sitagliptin is by way of a call to one Mr. Chandra Shaker, Assistant General Manager

of Marketing of the defendant, on 21st September, 2020. The plaint alleges that, from the said conversation, the investigator learnt that the defendant had been providing Sitagliptin API for sale in the domestic market and was willing to do so in future as well. It is further alleged that, *vide* a subsequent e-mail dated 21st September, 2020, Mr. Chandra Shaker provided the investigator the price quotation for Sitagliptin Phosphate API, which was ₹ 1 lakh per Kg.

6. On the basis of the aforesaid averments asserted in the plaint, this Court, *vide* order dated 21st October, 2020, on the very first date of hearing, observed and held thus:

> "4. Grievance of the plaintiff in the present suit is to the manufacturing and selling by the defendant of the pharmaceutical composition with the international non-propriety name Sitagliptin, for which the plaintiff has a valid and subsisting patent. Learned counsel for the plaintiff has taken this Court through the home page of the defendant's website wherein in the drugs available defendant claims that Sitagliptin is also available, despite the fact that the defendant on its website claims a disclaimer that there may be a patent in favour of third parties in respect of some of the drugs. Further, the plaintiff's investigator conducted an inquiry as to the availability of the compound Sitagliptin to which a reply was received from the defendant affirming availability of Sitagliptin Phosphate for a sum of ₹1 lakh for 1 Kg. Even on the third party website like India Mart, defendant is advertising the sale of drug Sitagliptin.
>
> 5. Considering the fact that plaintiff has a valid and subsisting patent being IN '816 for which a certificate of validity has already been granted by this Court, as also the other averments in the plaint and the documents filed therewith, this Court finds that plaintiff has made out a prima facie case in his favour and in case no ex-parte ad-interim injunction is granted the plaintiff will suffer irreparable loss. The balance of convenience also lies in favour of the plaintiff and against the defendant.

> 6. Consequently, an ex-parte ad-interim injunction is granted in favour of the plaintiff and against the defendant in terms of prayer (i) of Para 6 of IA 9671/2020."

7. The aforesaid ex-parte *ad interim* order continues to remain in force till date.

Written Statement of the defendant

8. Consequent to issuance of summons, the defendant has filed its written statement by way of response to the plaint. The written statement asserts the fact that the defendant is a 30 year old Research and Development based API Manufacturing Group, with clients spread over 70 countries. Para 4 of the written statement asserts that the defendant is involved in persistent research, so as to make pharmaceutical products available to the common man at reasonable costs. It is further asserted that the activities of the defendant are carried out in complete compliance with patent laws and their dictates.

9. The written statement further asserts that a joint venture was executed between the defendant and M/s Chemo AG Lugano ("Chemo" in short), for development and manufacturing of certain products, so that they could be launched in the market after patent terms expired. This, it is averred, was after obtaining due permissions from Governmental and Drug Control Authorities and within the parameters of patent laws. No manufacture or production of these drugs for commercial purpose was undertaken, the sole intent being to launch them in generic form at affordable price after the patents

granted in respect of the APIs in the said drugs expired. The defendant was, therefore, according to the written statement, involved in supplying Sitagliptin Hydrochloride as an API for research and development purpose after having been granted due approval, therefor, by the Drug Control Authorities.

10. The defendant has filed, with the written statement, approvals in Forms 25 and 29, issued under the Drugs and Cosmetics Act, 1940 and the rules made thereunder by the Drug Control Administration, which permits the defendant to manufacture Sitagliptin Hydrochloride, of specified quantities, for export to Switzerland, Spain, Cyprus and the U.K. One such sample certificate, dated 21st September, 2016, permitting export of 52 Kgs of Sitagliptin Hydrochloride by the defendant to Switzerland, may be reproduced thus:

"GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

L.Dis.No.964/JD/DCA/VSP/2016 **Dated : 21-09-2016**

From
M B R Prasad, M.Pharm, M.Phil, A.I.C.
Joint Director & Licensing Authority,
Drugs and Copyrights,
Drugs Control Administration,
Visakhapatnam Region,
Visakhapatnam. Andhra Pradesh

To
M/s SMS Pharmaceuticals Ltd.,
Unit-VII, Kandivalasa (V),
Poosapathirega (M),
Vizianagaram District-535204
Andhra Pradesh, India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Approval of Specific Export Permission-in Form 25 – Regarding.

Ref: 1. Your application dt. **13-09-2016**
2. Lr.No.:**43-2/HZ/2016-17/844/8992** Dt.**09-09-2016** of the Deputy Drugs Controller(I), CDSCO, Hyderabad.

With reference to your application cited, you are hereby permitted to

manufacture the following product as additional item under your Drug License in **Form-25** bearing No.**14/VZ/AP/2010/B/R Dt.25-03-2010, Valid upto 24-03-2020** for specific quantity mentioned and to be exported to the country specified.

S.No.	Name of the Product	Quantity	Country of Export
1.	SITAGLIPTIN HYDROCHLORIDE	52Kg's	SWITZERLAND

The above additional product is permitted subject to the following conditions.

1. Detailed particulars of rejects/returned goods if any shall be furnished to this office at once for the purpose of issuing necessary orders in such cases. Till such time, the goods shall not be altered/disposed of in any other manner.
2. The specification/standards asked for by the Importing Country/Firm shall be complied with while exporting the drugs.
3. The federal regulations of the importing country shall be fulfilled while exporting/supplying the drugs.
4. The batches to be exported shall undergo quality control testing at your laboratory or at destined site.

L.Disc.No.964/JD/DCA/VSP/2016 Approval of **(One)** Additional Product to **M/s SMS Pharmaceuticals Ltd., Unit-VII, Kandivalasa(V), Poosapathirega (M), Vizianagaram District**, Andhra Pradesh, India in **Form-25 bearing No.14/VZ/AP/2010/B/R/ Dt.25-03-2010, Valid up to 24-03-2020.**

5. You are required to ensure that the entire quantity of the drug(s) manufactured on the basis of the above NOC is exported and no part of it is diverted for domestic sale in India through a declaration in the form of an affidavit or Non-judicial stamp paper.
6. You are requested to submit the information pertaining to quantities of drugs manufactured and exported to the state licensing authority and Zonal Sub Zonal of CDSCO after completion of the export under this approval.
7. You shall ensure that the drug(s) manufactured on the basis of NOC given as per your Export order is exported and that no part of it is diverted for Domestic sale in India.
8. On the event of the relevant Export order being cancelled, you shall ensure physical destruction of all un-exported quantity of the drug(s) and shall submit a declaration to CDSCO, Zonal Office, Hyderabad and State Licensing Authority in the form of an affidavit on non-judicial stamp paper.
9. You shall make available for inspection of the appropriate authorities, on completion of the export orders and furnish information to this Office

regarding the actual quantities of the drugs produced, details regarding each consignment dispatched, remaining stocks of the drugs and related raw materials and intermediates in hand.
10. You shall ensure that the drug for which "NOC" has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

In case of Narcotics/Psychotropic Drugs, you are also directed to approach The Narcotic Commissioner of India, 19th The Mall Morar, Gwalior-6 so far as the revisions of the NDPS Act and the Rules are concerned in the matter.

Further you are informed that non-compliance of any the conditions mentioned above the matter will be reviewed and the licenses/permissions issued herewith are liable for Suspension/cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetics Rules. You are therefore requested to plan your production accordingly.

Yours faithfully,
Sd/-
JOINT DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION
VISAKHAPATNAM"

11. The defendant, in the written statement, claimed never to have sold Sitagliptin Hydrochloride in commercial quantities or to any clients who are using it for commercial purposes. Every sale, it is submitted, was duly licensed by the Drug Control Authorities. All exports to Spain, Switzerland, Cyprus and U.K., it is further asserted, were only for testing/research/development purposes. Domestic sales of Sitagliptin Hydrochloride were also only for the said purpose.

12. The written statement presses into service Section 107A of the Patents Act, along with the judgment of this Court in ***Bayer Corporation v. U.O.I.***[2], to contend that the activities of the defendant were permissible, as the defendant was only engaged in sale and

[2] **2019 (78) PTC 521(DB)**

export of Sitagliptin Hydrochloride for the purposes of research and development. The written statement has also dealt, point-by-point, with the various results, cited by the plaintiff as having been obtained consequent on investigation, to demonstrate that these results do not, in any way, indicate that the defendant was selling Sitagliptin Hydrochloride for commercial purposes or in commercial quantities. Section 107A of the Patents Act reads thus:

> "**107A. Certain acts not to be considered as infringement. –** For the purposes of this Act, –
>
> (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;
>
> (b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights."

13. Para 53 of the written statement draws specific attention to a disclaimer, contained on the website of the defendant, which reads thus:

> "Some of the products may have patent rights in one or more countries and any such product having an existing patent will not be offered/sold for commercial requirements. The final responsibility with respect to third party patent rights lies exclusively with the buyer."

(I may note, here, that, though the plaint also acknowledges the existence of this disclaimer, the plaintiff has alleged that the disclaimer is merely in the nature of a tactic to enable commercial

exploitation, by the defendant, of Sitagliptin Hydrochloride.)

Pleadings in the present application

14. By the present application preferred under Order XXXIX Rule 4 of the CPC, the defendant has sought modification/vacation of the *ex parte* interim order dated 21st October, 2020 (*supra*), citing in their favour Section 107A of the Patents Act. The defendant has annexed, with the application, the following communication dated 17th June, 2021, from VERBEN AG, Lugano, Switzerland to the defendant:

> **"VERBEN AG, Lugano Branch**
> Via Pelli 17
> 6900 Lugano
> Switzerland
>
> **SMS Pharmaceuticals Ltd.**
> Plot. No. 72, H. No. 8-2-334/3 & 4,
> Road No. 5. Opp. SBI Executive Enclave,
> Banjara Hills, Hyderabad,
> Telangana – 500 034
> INDIA
>
> **Letter Agreement regarding supply of Sitagliptin API for R&D purposes**
>
> As you are aware Verben AG (the "Company"), has an existing purchase order (VL- 21/00094) regarding Sitagliptin active pharmaceutical ingredient from SMS Pharmaceuticals. The ordered quantities are for the exclusive purpose of research and development activities with a view to obtaining marketing authorizations or other regulatory approval of medicinal products (the "Research Quantities").
>
> The Research Quantities will only be used for the purpose of the research and development activities which are the practical requirements for obtaining marketing authorizations. However, we have already suffered significant delay in the delivery of the Research Quantities.

If the aforementioned order for the Research Quantities is not dispatched forthwith, this order will regrettably have to be cancelled and we will need to find an alternate supplier.

Signed for and on behalf of the Company by:

Names: Mr. Stefano Vanossi and Mr. Paolo Limido

Date: 17 June 2021"

15. The defendant in its application re-asserts its stand in the written statement that the defendant was engaged in dealing with Sitagliptin Hydrochloride as an API, in non-commercial quantities, after obtaining requisite approvals from the Drug Control Authorities for research and development purposes. This is sought to be demonstrated, *inter alia*, by a comparison of the quantities permitted to be sold/exported by the Drug Control authorities, *vis-à-vis* the quantities actually sold/exported by the defendant, which is represented in a tabular form:

Sl. No.	Name of the Customer	Customer P.O and Date P.O Quantity	Licensed Quantity (In KG)	Dispatched Quantity Invoice wise	Domestic/Exported Country
2016					
1.	M/s. Chemo AG Lungo Branch	CS-16/05929-PO Dt:13.07.2016 20.00 Kg	52.0	20.0	Export
2017					
2.	Chemo AG Lungo Branch	CS-17/01912-PO Dt:06.03.2017 18.74 Kg	52	18.74	Export
3.	Chemo AG Lungo Branch	CS-16/05930-PO Date:13.07.2016 12.00 Kg	52	12	Export
4.	Chemo AG Lungo Branch	CS-16/07961-PO Date:26.09.2016 188.00 Kg	188	188	Export
5.	M/s. Verben	VL-17/00159-PO	---	32.93	Export

	S.A., Lungo Branch	Dt:26.05.2017 32.93 Kg			
2018					
6.	M/s.Chemo India Formulations Pvt Ltd	CIF-PO-1718-322R1 Date:08.03.2018 90.00 Kg	150	2	Domestic
7.	M/s.Chemo India Formulations Pvt Ltd	CIF-PO-1718-322R1 Date:08.03.2019 90.00	150	5	Domestic
2019					
8.	M/s.Chemo India Formulations Pvt Ltd	CIF-PO-1718-322R1 Date:08.03.2018 90.00 Kg	150	83	Domestic
9.	M/s. Verben S.A., Lugano Branch	VL-18/00067-PO Dated:28.02.2018 106.00 Kg	106	106	Export
10.	M/s.Chemo India Formulations Pvt Ltd	CIF-PO-1819-FD-R47 Date:27.03.2019 3.00 Kg	150	3	Domestic
11.	M/s. RA Chem Pharma Ltd	U2RM/TT18-19/177 Date:04.10.2018 78.44 Kg	215.91	73.18	Domestic
12.	M/s. Chemo AG Lugano Branch	CS-19/01867 Date:14.03.2019 1.00 Kg	1	1	Domestic
13.	M/s. RA Chem Pharma Ltd	U2RM/TT18-19/177 Date:04.10.2018 78.44 Kg	215.91	5.26	Domestic
14.	M/s. RA Chem Pharma Ltd	U2RM/TT18-19/203 Date:30.10.2018 39.22 Kg	215.91	39.22	Domestic
15.	M/s. RA Chem Pharma Ltd	U2RM/TT18-19/204 Date:30.10.2018 39.22 Kg	215.91	30.20	Domestic
16.	Chemo AG Lugano Branch	CS-19/04680-PO Dt:03.07.2019 3.50 Kg	3.50	3.50	Domestic
17.	M/s. RA Chem Pharma Ltd	U2RM/TT18-19/204 Date:30.10.2018 39.22 Kg	215.91	9.02	Domestic
18.	M/s. RA Chem Pharma Ltd	U2RM/TT18-19/205	215.91	18.12	Domestic

		Date:30.10.2018 18.12 Kg			
19.	Chemo AG Lugano Branch	CS-18/04312-PO Dt.29.05.2018 135.00 Kg	135	75	Export
2020					
20.	Chemo AG Lugano Branch	CS-19/04945-PO Date:12.07.2019 15.00 Kg	15	15	Export
21.	Chemo AG Lugano Branch	CS-18/04312-PO Dt.29.05.2018 135.00 Kg	135	25	Export
22.	M/s. Unison Pharmaceuticals Pvt Ltd	U2PORM192000 054 Dt.27.12.2019 5.00 Kg	20	5	Domestic
23.	M/s.Thame laboratories	A11010 Dt.10.03.2020 7.00 Kg	7	7	Export
24.	M/s. Unison Pharmaceuticals Pvt Ltd	U2PORM192000 054 Dt.27.12.2019 5.00 Kg	20	2	Domestic

16. The defendant has also placed reliance on the following order passed by a coordinate Bench of this Court on 27th August, 2020 in CS (COMM) 195/2020, which is also in the context of Sitagliptin. By the said order, this Court modified the earlier injunction order granted against manufacture and dealing in Sitagliptin, by allowing usage of the Sitagliptin API by the defendant for research and development purpose, subject to compliance with the directions, in that regard, contained in the judgment in ***Bayer Corporation***[2].

> "1. Mr. Pravin Anand, who appears on behalf of the plaintiffs, says that he will require further time to obtain instructions from the plaintiffs *vis-à-vis* the affidavit furnished to him on behalf of the defendant.
>
> 1.1 Mr. Anand's request is acceded to.
>
> 2. Ms. Rajeshwari, who appears on behalf of the defendant, says that in view of the stand taken by the

defendant, the interim order dated 25.06.2020, passed by this Court, be modified to the extent that the defendant be entitled to carry on research and development work *vis-à-vis* the subject API [i.e. API SITAGLIPTIN] subject to the compliance of the directions contained in the judgement of the Division Bench of this court in ***Bayer Corporation vs. Union of India and Others***, 2019 SCC OnLine Del 8209.

3. Mr. Anand says as long as the defendant complies with the directions contained in the aforesaid judgement, he would have no objection to the modification of the order dated 25.06.2020 in the aforesaid terms.

3.1 The statement of Mr. Anand is taken on record.

4. The order dated 25.06.2020 is modified to the extent, as indicated above. The defendant will use the subject API only for research and development purposes and shall also adhere to the directions contained in the ***Bayer Corporation*** case.

5. I.A. No. 4801/2020 is, accordingly, disposed of.

6. List the matter on 23.09.2020."

17. The plaintiff has filed the reply to the application of the Defendant under Order XXXIX Rule 4 CPC, in which, essentially, the assertions in the plaint have been reiterated. Emphasis has, additionally, been placed on the quantity of Sitagliptin sought to be exported by the defendant. For ready reference paras 13, 15 and 18 of the reply filed by the plaintiff, in response to the present application may be reproduced thus:

"13. Further, during the said investigation, the investigator telephonically contacted Mr. Shaker who was stated to be the Assistant General Manager of Marketing of the Defendant. Through this call, it was learnt that:

a. The Defendant has been providing Sitagliptin

API for sale in the domestic market;

b. The Defendant is willing to provide Sitagliptin API for sale even if an order for just 1KG is placed, i.e. the Defendant does not seek that a minimum quantity is purchased while offering Sitagliptin API for sale. However, the price for the product can be higher depending on the quantity ordered;

c. Mr. Shaker provided the investigator with a price quotation for its Sitagliptin Phosphate API, which is INR 1 Lakh/Kg of Sitagliptin Phosphate API.

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15. In light of the above factual matrix and evidence available, the Defendant has displayed its dishonesty by:

a. Manufacturing and producing infringing Sitagliptin API, including Sitagliptin Phosphate API and Sitagliptin Hydrochloride API, in India despite being in full knowledge of patent rights and obligations arising out of products protected by valid patents as the Defendant itself has applied for 16 patents which have all been published;

b. Advertising and Offering for sale its infringing API, including Sitagliptin Phosphate API and Sitagliptin Hydrochloride API, in India;

c. Distributing and selling infringing Sitagliptin API, including Sitagliptin Phosphate API and Sitagliptin Hydrochloride API, in India; and

d. Exporting its infringing Sitagliptin API, including Sitagliptin Phosphate API and Sitagliptin Hydrochloride API, from India.

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18. It is submitted that the above infringing activities of the Defendant have come to a halt at the moment due to the

> interim order dated October 21, 2020 and if the same was to be vacated/modified, the Defendant would resume its infringing activities and may soon even launch their infringing product in the domestic market."

18. The defendant has also filed a rejoinder to the reply, of the plaintiff, in which attention has specifically been invited to the law enunciated by the Division Bench of this Court in ***Bayer Corporation***[2]. It is emphasized, by the defendant, that Section 107A of the Patents Act does not require the defendant to be engaged in research and development activities on its own, and that the provision also permits sale of the patent in API to other entities engaged in research and development activities or for research and development purposes. This position, it is further emphasized, stands underscored by the decision in ***Bayer Corporation***[2]. The rejoinder reiterates the position that the defendant is acting in joint venture capacity with Chemo Iberica SA and Verben AG ("Chemo" and "Verben", in short) for conducting research and development for generic drugs. Chemo and Verben, it is further submitted, are group companies of the defendant. All exports, by the defendant, it is pointed out, were within the quantities permitted by the Drug Control authorities.

19. The rejoinder emphasizes the fact that the suit patent held by the plaintiff in respect of Sitagliptin is due to expire in April 2022. Urgent necessity of the API, in order to undertake research and development so as to make the generic drug available to the public at affordable costs, once the patent has expired, it is submitted, exists. The reluctance of the plaintiff to agree to the request of the defendant

which, according to the defendant, is entirely in accordance with Section 107A of the Patents Act is, it is alleged, with a view to monopolizing Sitagliptin Hydrochloride, without allowing it to be made available in generic form to the public.

Submissions at the bar

20. Mr. Pravin Anand, learned Counsel appearing for the plaintiffs, opposing the application of the defendant, advances the following submissions :

(i) Once the drug is permitted to be exported, it is impossible for the plaintiff to verify or investigate whether it is ultimately being used for research and development or is being commercially exploited. Even if the foreign entity, to whom the defendant proposes to sell Sitagliptin, were to engage in commercial exploitation thereof, and, consequently, to infringe the plaintiff's patent, the plaintiff would have no remedy against such foreign entity. Grant of the request of the defendant, would, therefore, submits Mr. Anand, afford a *carte blanche* to the defendant to infringe, with impunity, the plaintiff's suit patent, leaving the plaintiff remediless.

(ii) Exports of Sitagliptin by the defendant have been continuing since 2016, much before the patent is slated to expire in 2022. Almost 800 kg have been so exported. Such transactions could not be treated as being aimed at research and development. For this purpose, Mr. Anand relies on the judgment of the Chancery Division of the High Court of U.K. in

Merck Sharp Dohme Corpn. v. Teva Pharma B.V.[3]. .

(iii) There is no material to show that Chemo and Verben are sister concerns of the plaintiffs. They, therefore, are third party entities, located outside the jurisdiction of this Court, against whom it would be nearly impossible for the plaintiffs to proceed, in the event of infringement of the plaintiff's suit patent.

(iv) The quantity exported by the plaintiffs in the past is so large that it is not possible to accept the contention that it is meant for research and development purposes.

(v) There is no compliance, by the defendant, with the conditions laid down by the Division Bench of this Court in paras 112 and 113 of the report in ***Bayer Corporation***[2].

(vi) There have been various instances where this Court has granted permission to the defendant to export the drug for research and development, under Section 107A of the Patents Act, and the permission has been misused. In such event, it is well settled that damages are not adequate as remedy for the loss and prejudice that results to the plaintiffs.

(vii) No material has been placed on record to support the stand of the defendant that it has entered into any kind of joint

[3] **[2012] EWHC 627 (Pat)**

venture with Chemo or Verben.

21. In conclusion, Mr. Pravin Anand submits that permission to export, for research and development, cannot be granted as a matter of course under Section 107A and that, in order to be entitled to grant of such permission, the defendant has to place, on record, clear and convincing material justifying the request and vouchsafing the defendant's *bona fides*. No such material, he submits, is on record in the present case. Were this Court, on the basis of the mere assertions of the defendant, in their written statement and in their application under Order XXXIX Rule 4 of the CPC, to allow export of Sitagliptin Hydrochloride by the defendant, Mr. Anand submits that there is every likelihood of the permission being misused and of the exports being exploited for commercial purposes.

22. Ms. Meenakshi Arora, learned Senior Counsel for the defendant-applicant refutes the submission of Mr. Anand. She emphasises the fact that Section 107A of the Patents Act allows, as a matter of right, sale of the patented product for research and development purposes and clearly holds that such sale/usage would not amount to infringement of the patent. She submits that the exports being sought to be effected by her client are not to companies of dubious lineage, but to well-established entities engaged in research and development, located in Spain and Switzerland. She submits that, in para 112 of its decision in ***Bayer Corporation***[2], this Court has provided sufficient safeguards to cater to any possibility of misuse of the permission granted under Section 107A. She has also relied on

paras 117, 120 and 121 of the report in ***Bayer Corporation***[2]. She has further emphasised the fact that the quantities of Sitagliptin Hydrochloride exported by her client in the past are much less than the quantities permitted to be exported by the Drug Control Authorities, clearly indicating that the exports were not for commercial exploitation. She submits that exports, in any lesser quantities, would be commercially impractical, given the cost of shipment. She further submits that there is no requirement, either in Section 107A or in the judgment of this Court in ***Bayer Corporation***[2], that exports for research and development purposes should only be to sister concerns. Nevertheless, she reiterates her submission that Chemo, Verben and the defendant had entered into a joint venture undertaking for the purpose for research and development. She undertakes, on behalf of her client, to report, to the Court as well as the plaintiff, the quantities exported by her client, should permission be granted by this Court, as prayed. Non-grant of such permission, she submits, on the other hand, would result in making it impossible to have the generic version of Sitagliptin in place and available for use by the public even after the expiry of the suit patent in July, 2022. Additionally, it would also result in severing the contractual relationship between the defendant, Chemo and Verben.

Analysis

23. Jurisprudentially, a right conferred by a statute cannot be denied by a Court, save and except on considerations which emanate from the statute itself, or from any judicial precedents dealing with the issue. It is not permissible for a Court to withhold, from a litigant, the

magnanimity which a statute extends, merely on the ground of an apprehension of *possible* misuse, unless such apprehension is manifestly credible and real. This legal principle, in my view, is practically fossilized in law.

24. The jurisdiction of this Court to proceed against a defendant, in the Patents Act, arises only in cases where the defendant infringes the patent or commits any other misdemeanour contemplated by the Act. We are concerned, in the present case, with infringement, as the plaintiffs allege infringement, by the defendant, of IN'816. Section 107A, on its plain words, excepts, from the ambit of "infringement of patent rights", "any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product". This expression has been examined, in great detail, by the Division Bench of this Court in ***Bayer Corporation***[1], following which, in para 93 of the report, the following finding has been returned:

> "93. ... In this context, therefore, it is held that the expressions, "making, constructing, using, selling or importing patented articles solely for uses reasonably related to development and submission of information required under any law for the time being in force…… or in a country other than India that regulates the manufacturing, construction, use, sale or import of any product", consequently, has to be given a wide import. *It is, therefore, open that the sale of the article or invention for the purpose of development of information in compliance with the reasonable requirements of developing countries, solely for purposes of research or development falls*

within Section 107A."

(Emphasis supplied)

25. It is clear that Section 107A neither prohibits export of the patented invention, so long as such export is to an entity engaged in research and development or for research and development purposes, nor requires there to exist any relationship between the applicant seeking the benefit of the provision and the foreign importer, to whom the API may be exported. Indeed, though Mr. Anand had, initially, sought to contend that the benefit of Section 107A would be available only if the applicant itself were engaged in research and development, he did not press this point, as a Coordinate Single Bench of this Court, has, in ***Bayer Corporation v. UOI***[4], held otherwise. The Division Bench decision in ***Bayer Corporation***[2] has also held, after a detailed analysis, that export and sale of the patented invention, by the Section 107A applicant, is not outside the beneficial reach of the provision.

The judgment in *Bayer Corporation*[2]

26. The judgment of the Division Bench of this Court in ***Bayer Corporation***[2] arose out of WP (C) 1971/2014 (***Bayer Corporation v. U.O.I.***) and CS(COMM) 1592/2016 (***Bayer Intellectual Property GMBH v. Alembic Pharmaceutical Ltd***.), both of which were initially decided by a learned Single Judge of this Court on 8th March, 2017. The judgment of the Division Bench of this Court, and its impact on the present dispute, can properly be appreciated only if, in the first instance, the decision of the learned Single Judge is briefly noticed.

[4] Judgment dated 5th November, 2014 in CM 9687/2014 in W.P.(C) 1971/2014

Judgment, dated 8th March, 2017, of the learned Single Judge[5]

27. The learned Single Judge distilled the issue, arising before him, for consideration, in the opening paragraph of his judgment as "whether the language of Section 107A of the Patents Act, 1970 permits export from India of a patented invention, even if solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product."

28. As already noticed, the learned Single Judge adjudicated WP (C) 1971/2014 and CS (COMM) 1592/2016 by a common judgment. WP (C) 1971/2014 sought directions to the Customs authorities, to restrain exports, by M/s Natco Pharma Ltd. (NATCO) of "SORAFENAT". For the said purpose, Bayer asserted its patent IN 215758 (IN'758), which claimed a drug named "SORAFENIB". Bayer initially filed CS (OS) 1090/2011 for restraining NATCO from making, marketing or selling any drug involving "SORAFENIB" or "SORAFENIB TOSYLATE". Alleging that NATCO's "SORAFENIB" product infringed IN'758, directions, as noticed hereinabove before, were sought, to the customs authorities, to restrain such exports. NATCO applied, in the writ petition, for permission to export, to China, 1 kg of the API SORAFENIB for development/clinical study and trials. Bayer contested the application.

[5] Judgment dated 8th March, 2017 of Delhi High Court in WP(C) 1971/2014 and CS(COMM) 1592/2016

NATCO relied on Section 107A of the Patents Act. The writ petition, therefore, involved the question of whether NATCO was to be permitted to export SORAFENIB, of the aforesaid quantity, to China, for carrying on activities for research and development.

29. Bayer contended, before the learned Single Judge, that Section 107A did not permit export of patented products, even if they were APIs. NATCO contended, *per contra*, that, so long as the patented product was being exported for research and development, Section 107A was not infracted. As was contended by Mr. Anand before me, Bayer contended before the learned Single Judge that, were the prayer of NATCO to be granted, there was every possibility of the suit patent of Bayer being infringed abroad, beyond the reach of the jurisdiction of this Court. It was emphasised that this Court would have no control over the use of the exported goods. NATCO expressed its willingness not to export any patented product for commercial purposes or for any purpose not covered by Section 107A.

30. The contesting respondent in CS(COMM) 1592/2016 was Alembic Pharmaceutical Ltd. ("Alembic") and the product in question in that case was RIVAROXABAN. Alembic was manufacturing and exporting RIVAROXABAN to the European Union, regarding which IN 211300 (IN'300) was held by Bayer. Alembic contended that the exports were only for the purposes envisaged in Section 107A. It also undertook that, should, at any time in future, Alembic intend to launch RIVAROXABAN commercially, one month's advance notice would be given to Bayer. Bayer contended that Alembic had exported, on

15th December, 2016, at least 90 Kg RIVAROXABAN worth ₹ 3 crores, and that such export could not be regarded as being intended for the purposes covered by Section 107A.

31. The learned Single Judge held that Section 107A clearly provided that the acts of a non-patentee covered by the provision would not be considered as infringement. Axiomatically, therefore, the patent holder could not restrain the non-patentee from performing such acts. The purpose for which the acts were being performed, was, therefore, found to be a pre-eminent consideration in examining whether the benefit of Section 107A would, or would not, be available to the defendant.

32. After a detailed discussion, the learned Single Judge opined thus:

> "The right of manufacturers / producers of medicines and of fine chemical producers, to make, construct and sell including by way of export, a patented invention, for the purposes prescribed in Section 107A is a fundamental right protected by Article 19(1)(g) of the Constitution of India and the sale cannot be curtailed except by express law. Such a fundamental right to export patented invention for the purposes prescribed in Section 107A cannot be taken away or curtailed from mere absence of the word 'export' in Section 107A when the word selling used therein takes within its ambit selling in the course of export also."

Thereafter, the learned Single Judge further went on to observe as under:

> "45. There is thus nothing in Section 107A or elsewhere in the Patents Act for me to restrict the meaning of 'selling' in Section 107A to selling domestically or to exclude therefrom selling by way of exporting.

> 46. Once 'selling' has an element of price paid or promised to be paid and it cannot be controverted that, so long as for purposes of Section 107A, can be for profit, making and selling by way of export even if for purpose of Section 107A, by a non-patentee, of patented invention, is a occupation, trade or business carrying on whereof has under Constitution of India been conferred a status of fundamental right and which can be curtailed by law only. In the absence of any law prohibiting export of a patented invention for purposes permitted under Section 107A, no such prohibition can be inferred. Supreme Court in ***Union of India Vs. Asian Food Ltd. (2006) 13 SCC 542*** has held that a citizen of India has a fundamental right to carry out the business of export.
>
> 47. ... Thus, while under Section 48 of the Act exclusive right to make and sell patented product and to prevent infringement of the said right has been granted to the patentee, under Section 107A it is clarified that making and selling patented products solely for purposes mentioned therein is not infringement. It follows that grant of patent under the Act does not confer on the patentee right to prevent others from making and selling patented product if solely for purposes prescribed in Section 107A. These are two independent provisions, admitting of no overlap or need to read one as a proviso (and consequently narrowly) to another. Once it is found that making and selling of patented product is solely for purposes prescribed in Section 107A."

Finally, the learned Single Judge held, in para 60 of his judgment, thus:

> "I thus hold that language of Section 107A of Patents Act permits exports from India of a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product. No suit prohibiting export *per se* of a patented invention can lie."

33. Having thus held that Natco and Alembic, who were both entitled to export the concerned patented products, i.e. "SORAFENIB", "SORAFENIB TOSYLATE" and "RIVAROXABAN", for research and development purposes, the learned Single Judge held that (i) the claim of Bayer, in WP (C) 1971/2014, that the purpose for which Natco was exporting "SORAFENIB" was not covered by Section 107A, could not be decided in writ proceedings and that Bayer would necessarily have to file a suit in that regard and (ii) similarly, Bayer had necessarily to establish, in an appropriately constituted suit, that the export of "RIVAROXABAN", by Alembic, was for purposes not covered by Section 107A.

34. Following these findings, the learned Single Judge disposed of WP (C) 1971/2014 and CS (COMM) 1592/2016 thus (in para 74 of his judgment):

> "W.P.(C) No.1971/2014 and CS(COMM) No.1592/2016 are thus disposed of (a) by directing that subject to Natco and Alembic filing an affidavit by way of undertaking of their respective Director duly supported by the Resolution of the respective Board of Directors, with advance copy to the counsels for Bayer, to the effect that they, during the life of the respective patent, will not export the respective patented invention for purposes other than those specified in Section 107A of the Patents Act they would be entitled to export the patented invention for the purposes of Section 107A of the Patents Act; and (b) with liberty to Bayer to, if makes out a case of the exports effected or to be effected being for purposes other than specified in Section 107A, take appropriate proceedings therefor."

The Judgment of the Division Bench

35. Bayer assailed the aforesaid decision of the learned Single Bench before the Division Bench, by way of LPA 359/2017 and RFA (OS) (COMM) 6/2017, respectively. Both these appeals were disposed of, by the Division Bench of this Court, *vide* its judgment dated 22nd April, 2019, on which both sides, before me, rely.

36. The learned Division Bench, after recording the rival submissions advanced before it, traced the history of Section 107A, which owed its origin to Section 271(e)(1) of the United States Code Title 35 (added by "Drug Price Competition and Patent Term Restoration Act, 1984") which, in turn, was enacted to legislatively overrule the decision of the Federal Appellate Court of the U.S., in ***Roche Products Inc. v. Bolar Pharmaceutical Co.***[6]**.** The Federal Court, by the said decision, upheld the request of Roche Products Inc. ("Roche", in short) to enjoin Bolar Pharmaceutical Co. ("Bolar", in short) from taking, during the life of Roche's patent, statutory and regulatory steps necessary to market, after the patent expired, the patented drug. The Federal Appellate Court held thus:

> "Bolar may intend to perform "experiments" but unlicensed experiments conducted with a view to the adoption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use de minimis. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise

[6] **733 F.2d 858(1984)**

of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes."

37. Section 271(e)(1) of the United States Code Title 35 was enacted by the U.S. Congress in the light of the aforesaid decision of the Federal Appellate Court, to permit use of patented products in experiments for the purpose of obtaining Food and Drug Administration (FDA) approval. The exception created by this provision, from the normal scope of infringement came, therefore, to be known as "the Bolar exception".

38. The Division Bench unequivocally rejected, in para 85 of the report, the submission advanced before it, that exports were excluded from the benefit of Section 107A. It observed that the purpose of Section 107A was facilitation of research and progress in the fields covered by the patents, and that it was in the nature of "a special provision that deals with the rights of the patented invention for research purposes". Paras 92 to 94 of the report, which follow, are of particular relevance:

"**92.** This Court is of the opinion that the interpretation canvassed by Bayer is strained and artificial. *Once it is held that patented inventions can be sold for the purpose of carrying on research which fulfils the regulatory requirements of India, there cannot be any bar or an interpretation narrowing the scope of such sale. What is important is the purpose of the sale, i.e. objective of carrying on experiment, research and developing information (in the form of reports, outcomes etc.). If the purpose of the sale is to ultimately exploit the patented invention and either work upon it or "work around" or work it through research so as to be prepared to apply for the patent for approval to market it once the patent tenure ends, there can be no impairment of the patentee's rights. The natural consequence of that sale*

cannot be curtailed by a contrived interpretation to say that it is only information that can be sold or exported, not the patented invention. Likewise, the reference of another country i.e the export for reasonably complying with the laws of another country in relation to the kind of research and experimentation needed is something that cannot be dictated by interpretation of Indian law alone. It is plausible-even reasonable-that many nations may require experimentation or research to be carried on in their soil nationally so as to be able to supervise the process and then oversee the outcome. It is, therefore, not possible to dictate the behaviour and legal requirements of other nations by confining the research exception within the territory of India.

93. The natural interpretation of the expression "use" is in all its senses. *In this context, it would be necessary to recognize that in regard to various products, especially those concerning the pharmaceutical, medicinal preparations, surgical and diagnostic purposes and those relating to the agriculture or bio-chemical sector, it may be critical for a database of populations, drugs and co-relation, with disease and its relationship with characteristics that are predominantly local. National regimes might well insist that such research and experimentation in regard to those aspects be either entirely or at least in part be carried on in their territory. In this context, therefore, it is held that the expressions, "making, constructing, using, selling or importing patented articles solely for uses reasonably related to development and submission of information required under any law for the time being in force…… or in a country other than India that regulates the manufacturing, construction, use, sale or import of any product", consequently, has to be given a wide import. It is, therefore, open that the sale of the article or invention for the purpose of development of information in compliance with the reasonable requirements of developing countries, solely for purposes of research or development falls within Section 107A(a).*

94. There is one more manner of looking at the issue. *A patent owner's interests are clearly injured if the invention or the product or the method which is the subject matter of the patent is worked for purely commercial purposes and the ensuing product is offered in the market. Such products would be competitors to the patented invention and because of their*

> *copycat nature, one can reasonably expect them to be significantly lower in cost, in the marketplace. However, in the case of sale, construction or use of the patented article, either within India or outside the territory of India, the question of such injury cannot ordinarily arise if the object or purpose of that transaction is solely to experiment or research and develop information that is reasonably related to the requirements of the law (Indian or overseas). If one considers this aspect, it is clear that the fullest effect ought to be given to the research exception embodied in Section 107A(a). The objections with regard to the territoriality of patents or the strained interpretation given to the provision of construing export (i.e. the export sale) only to sale of information overseas, is unwarranted. Bayer's argument, therefore, is rejected on this aspect.*"
>
> (Emphasis supplied)

39. Following this, the Division Bench held, in para 96, that it was "therefore, clear, that the submissions with respect to impermissibility of exportation of the product cannot be accepted".

40. Thereafter, in para 106, on the aspect of the quantity and the place of research and development, the Division Bench held thus:

> "It is clear, therefore, that *neither the quantity used nor the place of research and development or information (i.e. within the country granting patent or on foreign soil) is per se conclusive that the claim to use the Bolar or research exception has to be rejected.* Instead, the conduct or action of the individual or entity making, using, constructing or selling the patented product or invention and the purpose for which it sought to be used (i.e. end use and that it should not be commercial) would be important and decisive whether the exporting or purchasing entity intends to use the patented product for commercial purposes."
>
> (Emphasis supplied)

41. Para 111 of the report reiterated this position by holding that "the volume of the patented product and its use for research and development of information cannot be prescribed by any one norm".

42. Having so opined, para 112 and 113 of the report, on which both sides before me rely, went on to hold as under:

> "**112.** The approach of the learned single judge in permitting export, without any inquiry and holding that export of 1000 or 2000 tablets constituted reasonable use, in this case, cannot be countenanced. In such case, upon the patent proprietor alleging the infringement was to institute legal proceedings to injunct the alleged exporter or seller, it is equally possible for the seller or exporter to seek a declaration or appropriate relief (including in a suit for groundless threat, if such action lies) that its overseas sales are for research and purposes covered by Section 107A. This Court is of the opinion that the inquiry and adjudication in such cases would be in regard to the following:
>
> (1) The patent granted;
>
> (2) The nature of the product or elements sought to be exported;
>
> (3) The details of the party or party importing the product, (4) The quantity sought to be exported
>
> (5) Other particulars with respect to the end use of the product, to establish that it is solely for research and development of information to regulatory authorities in the other country;
>
> (6) All particulars regarding the relevant regulations, covering the kind and scope of inquiry, including the quantities of the product (i.e the patented product or compound, API or fine chemical needed). These details must be supplied by the exporter/seller of the product to the overseas buyer. In case the defendant is not the seller, it should disclose who had purchased the product in the relevant quantities, to facilitate its impleadment in the proceedings. In the event it cannot

do so, the consequences of such result ought to be considered by the court.

(7) If the regulations are in the language of that country, an authentic English translation to facilitate a speedy resolution;

(8) Appropriate *interim order*, including undertaking by way of affidavit to compensate the plaintiff, in the event the suit were to be decreed and the extent of such monetary compensation. The affidavit should be of an authorized personnel, and kept alive during the pendency of litigation, duly authenticated by the board of director or other controlling body of the defendant-and whenever the company or entity undergoes amalgamation or transfer, suitable undertaking from the successor organization;

(9) If necessary, verification through the Indian mission (and its trade division) abroad regarding the authentication of the third party and/or its facilities abroad.

(10) If it is held by the court that the exporter is not involved in sale or export of any patented product, but a generic article, unprotected by patent law, when denying relief, suitable restitutionary relief should be awarded to the defendants in monetary terms, to preclude litigation that prevents trade or competition.

113. The above aspects are only indicative of the matters that need examination, they are in no way exhaustive and the court may consider any other matter relevant to the subject."

43. In conclusion, even while holding that that writ proceedings were not an appropriate remedy for such dispute, the Division Bench lent its imprimatur to the findings of the learned Single Judge, to a large extent, in sub-para (a) of para 121, being the penultimate paragraph of the judgment of the Division Bench, which read thus:

> "In the light of the above discussion and findings, it is held and directed as follows:
>
> > (a) Sale, use, construction of patented products (by individuals and entities that do not hold patents) in terms of Section 107A of the Act for purposes both within the country and abroad is authorized and legal provided the seller ensures that the end use and purpose of sale/export is reasonably related to research and development of information in compliance with regulations or laws of India (or the importing country), for its submission in accordance with such laws. The impugned judgment of the learned single judge and the findings recorded on this aspect are accordingly affirmed."

The ***Bayer*** takeaway

44. The position that emerges from the aforesaid decision in ***Bayer Corporation***, of the learned Single Judge and the Division Bench, is that there can be no restraint of export of a patented invention, provided such export is for research and development purposes. The Division Bench, as well as the learned Single Judge, have categorically upheld the right, conferred by Section 107A of the Patents Act, as inviolable. Even while so holding, the Division Bench in ***Bayer Corporation***[2] does require the Court, concerned with a prayer for export of a patented product for research purposes, under Section 107A, to be sensitised regarding the *bona fides* of the request and the circumstances of the case before it. The Division Bench has appreciated the concern of patent holders about possible and uncontrolled infringement of the patented product in foreign climes, were every prayer for export of the patented product to be granted as a matter of course. In arriving at this decision, the Court is required to

consider, *inter alia*, the factors enumerated in para 112 of the report, reproduced *supra.*

45. At the same time, the Bolar exception, as statutorily engrafted in Section 107A of the Patents Act, has a laudable public purpose to serve, and the Court cannot afford to defeat this purpose by adopting an unjustifiably blinkered approach. Competing and opposing considerations arise, in such cases, before the Court, which stand pithily encapsulated in ***Bayer Corporation***[2], neither of which can really be said to subserve the other (in para 112 of the report):

> "In such case, upon the patent proprietor alleging the infringement was to institute legal proceedings to injunct the alleged exporter or seller, it is equally possible for the seller or exporter to seek a declaration or appropriate relief (including in a suit for groundless threat, if such action lies) that its overseas sales are for research and purposes covered by Section 107A."

This is precisely what has happened in the instant case, save that the exporter has moved the Court for a declaration that the exports are permissible – by way of a prayer to allow the exports – and the patent proprietor, being the plaintiff before me, opposes the application.

46. Having gone through the allegations in the plaint as well as the reply to the present application of the defendant, I am unable to find any such cogent material on the basis of which the grant, to the defendant, of the benefit of Section 107A of the Patents Act can be denied. I have already opined that the Court, confronted with a request by an applicant for being extended the benefit of Section 107A, has, nonetheless, to keep the apprehensions of the patent holder in mind,

and examine whether the concerns expressed by it constitute legitimate ground to deny the prayer. In the case of the present plaintiff, and its Sitagliptin patent, I have also to bear in mind the fact that the plaintiff has itself unreservedly agreed to the extension of similar benefit to M/s Honour Lab Ltd ("HLL", in short) on 27th August, 2020, whereupon a similar application filed by HLL in CS (Comm) 195/2020 (***Merck Sharp & Dohme Corp v Honour Lab Ltd***) stands allowed. All that was required, by the plaintiff, in that case, was for HLL to comply with the directions contained in ***Bayer Corporation***[2].

47. Significantly, the *ad interim* injunction order which was originally granted by this Court in CS (Comm) 195/2020 on 25th June, 2020, and which stood vacated/modified by the order dated 27th August, 2020 consequent on the plaintiff's concession, records submissions, advanced by the plaintiff, identical to those advanced in the present case against the defendant before me, thus (in paras 4.3 to 5.2 of the order):

> "4.3 It is claimed by the plaintiffs that the defendant is attempting to supply the Active Pharmaceutical Ingredient (in short "API") SITAGLIPTIN and, thus, infringing the rights, which in here in plaintiff No. 1's patent IP No. 209816.
>
> 5. Counsel for the plaintiffs, in order to establish that the defendant is embarking on the said course, have drawn my attention to the transcripts which relates to the conversations held between the investigator appointed by the plaintiffs and the representative of the Defendant. The transcripts, which are available on record, pertained to conversations held on 01.06.2020 and 04.06.2020.
>
> 5.1 Furthermore, the counsel for the plaintiffs, have also referred me to the defendant's website, which is indicative of

> the fact that the defendant is representing to the world at large that it is in a position to supply, amongst other APIs, the API in issue i.e. API SITAGLIPTIN.
>
> 5.2 Besides this, it was also contended that though the defendant seeks to portray the API SITAGLIPTIN is being supplied for research and development purposes, it is actually being used for commercial purposes as well. For this purpose, my attention was drawn to pages 282-286 and 293-295 of the documents filed by the plaintiffs."

These factors, which were urged before me by Mr. Pravin Anand while opposing the present application, and which were also urged by the present plaintiff in CS (Comm) 195/2020 did not, however, inhibit the plaintiff from agreeing, on 27th August, 2020, to extension, to HLL, of the benefit of Section 107A of the Patents Act.

48. Denial of like benefit to the defendant in the present case is, therefore, also likely to place the defendant at a disadvantage *vis-à-vis* at least HLL.

49. In like circumstances, the Court is expected to adopt a like stance. Consistency is the very foundation of any robust legal system, as it fosters certainty in the law. A judge may err in law, but he shall not err in consistency. Passing contrary orders in cases involving similar issues and similar circumstances is bound to erode the faith of the public in the legal system. The fact that the order in the case of HLL was passed on a concession by the plaintiff, whereas no such concession is being extended in the present case, cannot justify withholding, from the present defendant, the benefit which was made available to HLL, as the order in the case of HLL becomes

enforceable, not because of the concession extended by the plaintiff, but because of the imprimatur of the Court, lent to such concession, by placing its approving judicial seal thereon.

50. The grounds urged by Mr. Pravin Anand to reject the application of the defendant, though persuasive, fail, in the ultimate analysis, to impress, especially in the light of the order passed in CS (Comm) 195/2020 *supra*. Ms Arora has placed, on record, the communication from Verben, clarifying that it was seeking to purchase the drug only for research and development purposes. There is no reason for this Court to disbelieve the said communication. Besides, it is undisputed that, since 2016, similar exports have been made, by the defendant, to Chemo and Verben, and the plaintiff has not sought to allege that any of these consignments were misused or were commercially exploited. While Mr Anand has emphasized the "huge" quantity of Sitagliptin imported by the defendant in the past, since 2016, the plaintiff does not allege that any part of such imports was commercially exploited. This, if anything, would seem to vouchsafe, rather than discredit, the *bona fides* of the defendant's intentions.

51. Ms Arora has also pointed out the fact that the exports were, in fact, made as per approvals granted by the Drug Control Authorities, and in quantities much less than those approved for export. She has invited my attention to the license granted by the Drug Control authorities in Form 29, which permits supply of 150 kg Sitagliptin Hydrochloride to Chemo "exclusively for the purpose of manufacture of the R & D formulation development/manufacture of Exhibit

batches for export Purpose for registration only". Even otherwise, in para 109 of the report, ***Bayer Corporation***[2] clearly approves the proposition that "the volume of use, sale, construction etc. of patented invention – or the quantum is itself inconclusive on the issue". This sentiment is echoed in para 111, which holds that "the volume of the patented product and its use for research and development of information cannot be prescribed by any one norm". Significantly, in ***Bayer Corporation***[5], the learned Single Judge held that 90 kg could not be regarded as a commercial quantity, when sought to be exported purportedly for research and development. This finding has not been reversed by the Division Bench. The quantity of Sitagliptin being sought to be exported by the defendant cannot, therefore, constitute a legitimate basis to deny, to it, the benefit of Section 107A.

52. Though, Mr. Pravin Anand, has drawn attention to instances in which similar permissions were granted by the Court and were misused, he, with his customary fairness, accepts that none of these instances relates to the present defendant. The mere fact that, in certain cases, the liberty granted by the Court may have been unfairly exploited, cannot, quite obviously, be a basis for the Court to deny, wholesale, such liberty when sought. Not a single invoice, whereunder Sitagliptin, or Sitagliptin Hydrochloride, was ever commercially sold by the defendant, or by its foreign buyers, has been placed on record by the plaintiff.

53. The other considerations voiced by Mr. Pravin Anand, too, cannot justify rejection of the defendant's application. I am not

convinced that the difficulty, if at all, for the plaintiff to verify whether the APIs sold by the defendant to Chemo or Verben, are being commercially exploited, can constitute a legitimate basis to deny the benefit, to the defendant, of Section 107A. No such instance of commercial exploitation has been cited by the plaintiff, despite exports, to Chemo and Verben, by the defendant, having been continuing since 2016. Ms Arora is also correct in pointing out that Section 107A does not require the existence of any relationship between the defendant and its foreign buyers. Indeed, if the argument of Mr. Pravin Anand, seeking rejection of the defendant's application on the ground that Chemo and Verben are not sister concerns of the defendant, and are located outside India, were to be accepted, all exports of patented pharmaceutical preparations, for research and development, would have to be disallowed, thereby rendering the Bolar exception effectively otiose.

54. Mr. Pravin Anand has sought to contend that the criteria enumerated in para 112 of the judgement in ***Bayer Corporation***[2] have not been fulfilled by the defendant. When one goes to these criteria, however, the submission cannot easily be accepted. The "enquiry and adjudication", in such cases, according to the decision in ***Bayer Corporation***[2], has to include the patent granted, the nature of the product or elements sought to be exported, the details of the party or parties importing the product, the quantity sought to be exported, and other particulars with respect to the end use of the product to establish that it is solely for research and development of information and regulatory authorities in the other country. These requirements

already stand satisfied by the defendant, by the disclosures contained in the written statement filed in response to the plaint and the present application. Criteria (6) and (7), in para 112 of ***Bayer Corporation***[2], require furnishing of the relevant regulations and other details "by the exporter/seller of the product *to the overseas buyer*". These details do not, therefore, concern the plaintiff. Criterion (8) in para 112 empowers the Court to pass an "appropriate interim order including undertaking by way of affidavit to compensate the plaintiff in the event the suit were to be decreed and the extent of such monetary compensation". Criteria (9) and (10) do not concern the controversy in the present case.

55. Mr Anand submits, with some chagrin, that the present defendant is actuated, not by any public spirit of research or development, but by purely commercial interests, to sell the patented drug at a profit. That, in my view, cannot be a guiding consideration, where Section 107A of the Patents Act is concerned, *provided the API is ultimately to be used for research and development*. Commercial gain, even if reaped by the defendant in the process, cannot disentitle it to the benefit of Section 107A. Charity is foreign to commerce.

56. The importance of the Bolar exception, and the public purpose behind it, stand underscored in paras 117 and 120 of the report in ***Bayer Corporation***[2], thus:

> "**117.** The history of the ***Bolar*** provision highlights that the interest in creativity and progress was not to be undermined by the seemingly wide nature of patent rights; in the context of essential products such as drugs, diagnostic aids, medical devices and other articles, the teachings in the patent necessarily do not lead to its use by the public, upon their

> lapse to the public domain. To fulfill drug acceptability standards prescribed by regulatory authorities, further tests are to be conducted. The ***Roche v. Bolar*** **[733 F.2d 858(1984)]** decision elicited immediate Congressional response and the Hutch Waxman Act was enacted, in effect, nullifying that decision. TRIPS recognised the need for ***Bolar*** like research provisions, enabling research and development in numerous ways which relieve those involved in such activities, of the charge of patent infringement. *Therefore, a constricted and narrow textual interpretation of such provisions is not called for.*
>
> *****
>
> **120.** The Bolar exemption is the global community's thought out design to ensure that the enclosure of intellectual property rights, granted to inventions, does not last beyond the term assured and that the general public is afforded with the end of the bargain which every society guarantees while sealing a patent i.e. access to the technology or invention for generations to come. But for a Bolar exemption, a third party manufacturer would not be able to start experimentation and ready a product, for its availability to the general public after the expiry of the patent term."

57. Courts must, therefore, aim at expanding, rather than constricting, the width and amplitude of the Bolar exception, which is actuated by laudable public purpose.

Conclusion

58. For all these reasons, I am of the opinion that the defendant's prayer, for being extended the benefit of Section 107A of the Patents Act, deserves to be allowed. The defendant is permitted, therefore, to export the API Sitagliptin to Chemo and Verben, as prayed. For this purpose, the defendant shall, however, file, before such export, an

affidavit, before this Court, setting out the quantities of Sitagliptin/Sitagliptin Hydrochloride being cleared and exported by the defendant. The affidavit shall also contain an undertaking that the exports are intended only for the purposes of research and development by the foreign buyers Chemo and Verben. The defendants shall remain bound by the said undertaking. The affidavit shall also undertake to comply with all the safeguards contained in the judgement of the Division Bench of this Court in ***Bayer Corporation***[2]. The defendant shall also remain bound by any further orders to be passed by this Court in that regard.

59. Consequent on receipt of the consignments by Chemo and Verben, the said buyers would also tender, to the defendant, formal undertakings, agreeing to use the imported product only for research and development purposes. These undertakings shall also be placed on record by the defendant in these proceedings.

60. The defendant shall ensure strict compliance with the decision of the Division Bench in ***Bayer Corporation***[2].

61. Subject to the above, IA 7615/2021 stands allowed. The *ex parte ad interim* injunction granted by this Court on 21st October, 2020 stands modified accordingly.

C. HARI SHANKAR, J.

JULY 20, 2021
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