IN THE HIGH COURT OF JUDICATURE AT MADRAS

Judgment reserved on	**25.02.2026**
Judgment pronounced on	**03.06.2026**

CORAM

THE HONOURABLE MR JUSTICE SENTHILKUMAR RAMAMOORTHY

C.S.No.282 of 2018
&
A. No.3319 & 3320 of 2025

1.NOVARTIS AG,
Lichtstrasse 35, 4056
Basel, Switzerland, Represented by its
power of attorney holder,
Mr.Atul Bade

2. NOVARTIS HEALTHCARE PVT.
LIMITED
Inspire BKC, 'G' Block, 7th Floor
BKC Main road, Bandra (East),
Mumbai-400 051
Represented by its power of attorney holder
Mr.Atul Bade
(amended as per order dated 17.02.2025 in
A.No.675 of 2025)

... Plaintiffs

Vs

VENKATA NARAYANA ACTIVE
INGREDIENTS PVT. LTD.
Venkata Narayana Towers,
III Floor, New No.60, Old No.35,
Venkatanarayana Road,
T.Nagar, Chennai-600 017
(amended as per order dated 23.11.2018
in A.No.8946 of 2018)

...Defendant

PRAYER : Amended Plaint filed under Order IV Rule 1 of Original Side Rules and Order VII Rules 1 and 2 of CPC read with Proviso 1 to Section 7 of the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015, praying to grant the following reliefs in favour of the plaintiffs and against the defendant:

(a) a decree for permanent injunction restraining the Defendant, by itself or through its directors, group company, associates, divisions, assigns in business, licensees, franchisees, agents, distributors and dealers from using, manufacturing, importing, selling, offering for sale either through website http://www.nutraforlife.com or by any other means exporting, directly or indirectly dealing in Active Pharmaceutical Ingredient (API), Pharmaceutical products, or formulation containing Vildagliptin alone or Vildagliptin in combination with any other compound or API or in any other form as may amount to infringement of Indian patent No.212815 of the Plaintiff No.1;

(b) a decree for mandatory injunction directing the Defendant till the expiry of the suit patent IN 212815 to provide details of any supply that the Defendant may make under provision of Section 107A to the plaintiffs including the quantity, details of parties, purpose of supply, country of supply etc. at least one month in advance of such supply and provide inspection of documents of such supplies or any other information in relation thereto if requested by the Plaintiff to ascertain that such supplies are indeed for purposes as permitted under Section 107A of the Patents Act, 1970;

(c) a decree for delivery up of all the stock of infringing pharmaceutical formulations, compound of combinations comprising Vildagliptin alone

and/or Vildagliptin in combination with any other compound or formulation available with the Defendant to an authorized representative of the Plaintiffs;

(d) an order for rendition of accounts of profits earned by the defendant for manufacture and sale of infringing pharmaceutical products or formulation or combination containing Vildagliptin alone or Vildagliptin in combination in any form and a decree for the amount so found due may be passed or in the alternative damages may be ascertained by the Hon'ble Court and a decree for damages as ascertained may be passed in favour of the Plaintiffs and against the Defendant;

(e) Cost of the proceedings and

(f) any further order as this Hon'ble Court may deem fit and proper in the interest of justice.

For Plaintiffs: M/s Hemant Singh
Mamta Jha
Arun C. Mohan
Shruthi Srinivasan
Aanjana Sasidharan

For Defendant: M/s T.K.Ram Kumar
Sumitha Vibhu

JUDGMENT

The suit was filed for remedies in relation to alleged infringement of the plaintiffs' patent in the active pharmaceutical ingredient (API), VILDAGLIPTIN, or in formulations containing VILDAGLIPTIN, by the defendant.

2. The first plaintiff is the proprietor of Indian Patent No.212815 (IN 212815) granted in relation to a new chemical entity with the international non-proprietary name "VILDAGLIPTIN", which is prescribed for the treatment of Type 2 Diabetes Mellitus. The patent was granted with effect from December 09, 1999.

Pleadings

3. In the plaint, the plaintiffs state that the first plaintiff launched VILDAGLIPTIN globally in the year 2007 under the trademark GALVUS and VILDAGLIPTIN with metformin hydrochloride in the year 2008 under the trademarks GALVUS MET or EUCREAS. After stating that said pharmaceutical products achieved great success all over the world, including India, the plaintiffs have set out the sales figures in India and globally for several years up to the year 2017. It is also stated that the above mentioned products are best selling pharmaceutical products of the second plaintiff, which is a subsidiary of the first plaintiff and the user of the trademarks in India.

4. The plaintiffs further state that they came to know that the defendant offered the patented product VILDAGLIPTIN for sale and

supply on its website://www.nutraforlife.com/products/vildagliptin.html. Therefore, the plaintiffs filed C.S.No.329 of 2015 on a *quia timet* basis seeking injunctive relief. The suit was decreed on July 31, 2015 on the basis of undertakings given by the defendant on July 28, 2015. By such undertakings, the defendant acknowledged the rights of the first plaintiff in the suit patent and undertook not to manufacture, sell, supply, export, import or offer for sale VILDAGLIPTIN. The plaintiffs further state that they did not press for damages in the suit on account of the undertakings.

5. The plaintiffs state that they received information in the second week of March, 2018 that the defendant had exported very large quantities of VILDAGLIPTIN API from India to Egypt during the years 2016-17. Details of such exports are set out in paragraph 7 of the plaint. In paragraph 9, the plaintiffs have stated that the importers of VILDAGLIPTIN from the defendant, namely, Inspire Pharmaceutical Company ('Inspire Pharma'), Mash Premiere ('Mash Premiere') and Eva Pharma ('Eva Pharma') have commercialised VILDAGLIPTIN and are selling the product in the Egyptian market. Therefore, the plaintiffs state that they issued lawyer's notice dated March 22, 2018 to the defendant calling upon the defendant to stop any further export of VILDAGLIPTIN to Inspire Pharma , Mash Premiere and Eva Pharma. The plaintiffs also

state that they engaged the services of an independent research firm, namely, Strategic Analysis (India) Private Limited to confirm whether the defendant had manufactured and exported VILDAGLIPTIN to the above mentioned entities. On the basis of the report dated April 23, 2018, it is stated that such manufacture and export was confirmed. The plaintiffs assert that the exports made to entities in Egypt constitute infringement of IN 212815 and have caused irreparable losses to the plaintiffs.

6. In the written statement, the defendant states that the API was supplied to Egyptian importers only for scientific research and development purposes. It also stated that IN 212815 was valid only till December 09, 2018. The defendant states that it is a common practice in the pharmaceutical industry to prepare the drug, carry out bioequivalence and stability tests so as to comply with statutory regulations in order to launch generic drugs as soon as the patent lapses. It is stated that for such research and development purposes, large quantities of API are required. It is also stated that Section 107A of the Patents Act, 1970 ('the Patents Act') permits production of patented products for such purposes. The defendant also states that it stopped producing and supplying VILDAGLIPTIN API on March 16, 2018 even prior to receipt of notice dated March 22, 2018 from the plaintiffs. It is

also stated that this is confirmed in the reports of the Advocate Commissioners. The defendant also states that all the shipping documents clearly state that the supply is only for research and development purposes, and that this is permitted under Section 107A.

7. The defendant further states that the patent should not have been granted for the API and that there was misrepresentation by the plaintiffs before the patent office; disclosures under Section 8 of the Patents Act were not made; and there was an admission that the patent is for a metabolite that falls within the exclusion under Section 3(d). In paragraph 9 of the written statement, the defendant states that importers are required to do clinical trials for each type of combination they want to introduce in the market and run trial batches of large quantities. It is also stated that three validation batches are used and that the quantity would be in hundreds of kilos. Therefore, the defendant submits that the suit is liable to be dismissed.

8. A reply statement was filed by the plaintiffs stating that the defendant is estopped from raising any issue regarding the validity of the suit patent in view of the undertakings given in C.S.No.329 of 2015. The plaintiffs also state that the defendant should have made it clear to the

buyer while supplying VILDAGLIPTIN that it should be used solely for purposes permitted under Section 107A and that any other use would amount to infringement under Section 48. It is also stated that a confirmation from the buyer should have been obtained in that regard. Based on the quantity of VILDAGLIPTIN exported by the defendant, the plaintiffs state that it is not reasonable to believe that it is for purposes permitted under Section 107A. The plaintiffs also state that the Commissioners' reports show that the defendant manufactured and exported thousands of kilograms of VILDAGLIPTIN during the period 2016-18 in response to purchase orders which do not state the purpose of purchase. The plaintiffs have set out the quantity of VILDAGLIPTIN exported to four entities in Egypt at paragraph 15 of the reply statement. Therefore, it is stated that the plaintiffs are entitled to the reliefs claimed.

Issues and evidence

9. Upon considering the pleadings, issues were initially framed on January 19, 2024. The plaintiffs filed Application No.5555/2024 to recast the issues. By allowing such application, the issues were recast as under on February 05, 2025:

"(a) Is the suit infructuous consequent to expiry of the plaintiffs

Patent No.212815?(OPD)

(b) Whether the suit patent expired on 09.12.2018, as contended by the defendant, or on 09.12.2019, as contended by the plaintiffs. (OPD & OPP)

(c) Whether the supply of Vildagliptin in API form by the defendant to Egyptian importers was only for scientific research and development purposes as declared by the importers, anticipating the expiry of plaintiffs patent No.212815, as per Section 107-A of the Patents Act or was it for commercial purposes? (OPD)

(d) Whether the supplying of Vildagliptin in API form by the defendant violates the undertaking given by the defendant in earlier proceedings? (OPP)

(e) Whether the defendant is in violation of the judgment and decree dated 31.07.2015 passed by this Court in the suit C.S.No.329 of 2015? (OPP)

(f) Whether the defendant is estopped from raising the plea of validity of the suit patent IN 212815 by way of defence under Section 107 of the Patents Act, 1970 in view of the decree dated 31.07.2015 passed on the basis of admission in undertaking dated 28.07.2015 furnished before this Court in the suit C.S.No.329 of 2015? (OPP)

(g) Whether the manufacture, stockpiling and export of Vildagliptin by the defendant amounts to infringement of the suit patent IN 212815? (OPP)

(h) Whether the manufacture and export of Vildagliptin by the defendant falls within the exceptions under Section 107-

A of the Patents Act, 1970? (OPD)

(i) Was the quantity of Vildagliptin in API form supplied to the Egyptian Importers essential for normal clinical trials for each variation of Vildagliptin or was it excessive? (OPD)

(j) Was the plaintiffs' patent No.212815 invalid on account of misrepresentation and lack of disclosure to the patent office under Section 8 of the Patents Act?(OPD)

(k) Is Vildagliptin a metabolite and therefore not patentable under Section 3(d) of the Patents Act 1970? (OPD)

(l) Whether the plaintiffs are entitled to damages and in the alternative, rendition of account, as prayed for? (OPP)

(m) To what other reliefs?"

10. The plaintiffs adduced evidence by examining Mr.Atul Anand Bade, authorized signatory, as PW1. In course of the examination-in-chief of PW1, 20 documents were exhibited as Exhibits [Ex(s)] P1 to P20. PW1 was cross-examined by learned counsel for the defendant and Ex.D1 was marked in course thereof. The defendant adduced evidence by examining Mr.Abaya Kumar Srisrimal, Director, as DW1. During the course of examination-in-chief of DW1, 14 documents were exhibited as Exs. D2 to D15. DW1 was cross-examined by learned counsel for the plaintiffs and in course thereof Exs.P21-P28 were marked. The defendant also examined Dr.Munusami Jayamani, Consultant, as DW2. He was cross-examined by learned counsel for the plaintiffs.

Counsel and Contentions:

11. Oral arguments were advanced on behalf of the plaintiffs by Mr.Hemant Singh, learned counsel, and on behalf of the defendant by Mr.T.K.Ram Kumar, learned counsel. Both parties also filed written arguments.

12. The first contention of Mr. Hemant Singh was that the earlier suit (C.S.No.329 of 2015) was decreed on July 31, 2015 on the basis of the undertakings by the defendant recognising the validity of the suit patent and the rights arising therefrom of the plaintiffs. On account of such undertakings, it is submitted that the plaintiffs did not insist on the award of damages. He then submitted that the plaintiffs came to know reliably that the defendant had exported large quantities of the API to Egypt. He also submitted that the importers in Egypt were already commercially producing and marketing VILDAGLIPTIN. Being a supply made by the defendant for commercial purposes, he contended that it does not fall within the scope of Section 107A of the Patents Act. Consequently, he submitted that it constitutes infringement under Section 48 of the Patents Act.

13. As regards the term of patent, he submitted that it is for a period of twenty years from the date of filing. After pointing out that the Patent Cooperation Treaty (PCT) application was filed on December 09, 1999, learned counsel submitted that the term of patent was up to December 09, 2019. In this regard, he relied upon Section 7(1B) read with Section 53 of the Patents Act.

14. He next contended that the earlier consent decree operates as *res judicata* and/or as issue estoppel, and that issues (f), (j) and (k) should be decided against the defendant on that basis. With regard to estoppel, learned counsel referred to and relied upon the following judgments:

(i)Raja Sri Sailendra Narayan Bhanja Deo v. State of Orissa, AIR 1956 SC 346 (Bhanja Deo);

(ii) Byram Pestonji Gariwala v. Union Bank of India (1992) 1 SCC 31 (Byram Pestonji Gariwala);

(iii)Dabur India Ltd v. Amit Jain & Another, 2009 (107) DRJ 17 (DB); and

(iv) Bristol-Myers Squibb Holdings Ireland v. Mylan Laboratories Limited, 2015 (1) ALT 4

15. He also submitted that no evidence was adduced by the defendant to prove that VILDAGLIPTIN is a metabolite. Turning to the cross-examination of DW1, he referred to the answers to questions 12 to 14 and 31 to 58 regarding supplies made by the defendant to companies in Egypt. Referring to the Advocate Commissioner's reports (Exs.P11 and P20), he pointed out that the defendant had not undertaken any due diligence with regard to the purpose for which the importers in Egypt intended to use the API.

16. With regard to the law on the interpretation of Section 107A, Mr.Hemant Singh referred to the legislative history before inviting my attention to the judgment of the Delhi High Court in *Bayer Corporation v. Union of India, 2019 (78) PTC 521 [Del] [DB] (Bayer),* particularly paragraphs 88, 93, 96,100, 102,103, 107, 111 and 119 thereof. He also relied on the judgment of the Italian Court of Cassation in *Sicor S.R.L. & Teva Pharmaceutical Industries Limited v. Boehringer Ingelheim Pharma GMBH & Co. KG*, *Civil Judgment Sec.1 No.18372 dated July 5, 2024 (Sicor/Teva Pharmaceutical)* for the proposition that Section 107-A incorporates the Bolar exception and that a person/defendant relying thereon should plead and establish that the manufacture, sale or use was solely for the purpose of obtaining marketing authorisation from the regulator concerned for sale after the patent expires. Because the

defendant completely failed to discharge this onus, he contended that sale by the defendant infringed the plaintiffs' patent.

17. As regards the contention that the plaintiffs failed to make proper disclosure, learned counsel submitted that such allegations pertain to alleged non-disclosure of prior art. According to him, it is not incumbent on a patent applicant to disclose prior art to comply with Section 8. He further submitted that all material information was provided and relied upon the answers of PW1 to questions 18-19, 23-24, 33-47 in this regard. He concluded his submissions by stating that not only damages but exemplary damages should be awarded on account of the defendant committing a breach of the undertakings given to this Court earlier.

18. Mr.T.K.Ram Kumar responded to the above contentions in the following manner. As regards C.S.No.329 of 2015, he submitted that said suit was filed on *a quia timet* basis. Therefore, he pointed out that there was no sale at that time and that said suit was decreed on the basis of the defendant's undertaking not to sell the patented product. He raised a preliminary objection that there was no pleading or evidence that the authorised signatories were duly authorised by the Board of Directors of

Novartis AG, and that the board resolution had not been exhibited. On this issue, he also referred to questions and answers 1 to 9 in the cross-examination of PW1. He also raised the contention that there was misjoinder of parties by referring to questions and answers 10 to 14 of PW1. His next contention was that the supply of API by the defendant was only for research and development purposes. He relied upon the averments in paragraph 2 of the written statement in this regard. He also pointed out that the defendant stopped production and supply after March 16, 2018. With regard to the quantity of exports, he submitted that hundreds of kilogrammes are required for research and development purposes. As regards the term of the suit patent, he submitted that the term should be reckoned from the priority date i.e. December 10, 1998, and that the patent expired in 2018.

19. With regard to non-disclosure, referring to applications made before the US Patent and Trademark Office (USPTO), learned counsel submitted that it is unclear therefrom as to which application was abandoned. Referring to WO 98/19998, learned counsel contended that the only change between said patent and IN 212815 is the substitution of the adamantyl with the hydroxy group. Referring to questions and answers 15 to 27 of PW1, he submitted that the non-disclosure of WO 98/19998 was material and resulted in the grant. According to him, the

Taiwan patent was not disclosed in Form 3 and both Exs.D13 and D14 were not disclosed. He also submitted that Ex.D6 and related provisional applications were not disclosed. Thus, he contended that the requirements of Section 8 of the Patents Act were not satisfied thereby rendering the grant invalid.

20. Referring to the First Examination Report(FER) of the Indian Patent Office (the IPO) and the reply thereto, he contended that the IPO did not examine the application carefully, including the implications of Section 3(d). Referring to paragraph 13 of the Division Bench judgment of this Court *in Novartis AG v. Union of India, 2007 4 MLJ 1153* and to *Novartis AG v. Union of India, AIR 2013 SC 1311,* he submitted that both this Court and the Hon'ble Supreme Court concluded that only therapeutic efficacy qualifies as enhanced efficacy in relation to the new form of a known pharmaceutical substance.

21. Without prejudice to the contentions on invalidity, according to learned counsel, the exports made by the defendant are squarely within the scope of Section 107A because they were made solely for research and development (R&D) purposes. In this regard, he referred to the invoice of the defendant at page 768 (Ex.P21) of Volume 2 of the

convenience volume and to the corresponding purchase order dated February 08, 2017 of Inspire Pharma (Ex.P22) at page 770 of the same volume. He also referred to the invoices issued to other entities in Egypt, all containing the qualification "for research and development purpose only". He contended that the quantities exported by the defendant were insufficient for commercial sale and that Indian law does not impose the obligation on the exporter to ensure that the buyer uses the API only for R&D purposes.

22. As regards estoppel and *res judicata*, referring to the judgment of the Supreme Court in *S.P.Chengalvaraya Naidu (dead) v. V.s. Jagannath (dead) by Lrs and Others, AIR 1994 SC 853,* he submitted that fraud vitiates the earlier consent by the defendant. He also relied upon the judgment of the Supreme Court in *Mathura Prasad Sarjoo Jaiswal and others v. Dossibai N. B.Jeejeebhoy, AIR 1971 SC 2355* and that of the Delhi High Court in *Chemtura Corporation v. Union of India, 2009 SCC OnLine Del 2634*. He concluded his submissions on *res judicata* by relying on the judgment of the Supreme Court in *Banwarilal v. Smt. Chando Devi(L.R.), AIR 1993 SC 1139*.

23. In his rejoinder, Mr.Hemant Singh submitted that coercion or fraud was not pleaded by the defendant and that the earlier judgment will therefore operate as *res judicata*. With regard to the contention that there was non-disclosure, learned counsel referred to Ex.D6, which is the correction certificate issued by the USPTO, and submitted that this certificate clarifies as to which application was pursued and which abandoned. Relying on Rule 21 of the Patent Rules, he submitted that if Rule 17.1 of the PCT Regulations are complied with, re-filing is not necessary with regard to the priority date. He reiterated that prior art need not be disclosed under Section 8. He contended that Section 8 read with Rule 12 and Form 3 makes it clear that only corresponding foreign applications are required to be disclosed. Referring to the purchase orders at pages 604 to 622 and 772 to 779 of volume-2 of the convenience volumes, he contended that there was clear violation of Section 107A by the defendant. He concluded his contentions by submitting that original notarised powers of attorney were filed and that this is sufficient as per Section 85 of the Indian Evidence Act, 1872 (the Evidence Act). He also submitted that there are no pleadings with regard to lack of authorisation.

Discussion, analysis and conclusions

Preliminary objections

24. In the written statement, the assertions in paragraphs 1 and 2 of the plaint regarding the first and second plaintiff authorising Mr.Atul Anand Bade to *inter alia* institute the suit and adduce evidence therein were denied, without specificity, as being beyond the knowledge of the defendant. In those circumstances and in the absence of a request for framing an issue on the authority of Mr.Bade, no issue was framed thereon. In the course of arguments, Mr. Ramkumar raised the objection that Mr.Bade was not duly authorised. In response, Mr. Hemant Singh contended that the powers of attorney marked as Exs. P1 and P2 satisfy the requirements of Section 85 of the Evidence Act.

25. The plaintiffs pleaded in paragraphs 1 and 2 of the plaint that Mr.Bade is the constituted attorney of the first and second plaintiff, respectively, and that he is duly authorised to verify and sign the plaint. The powers of attorney relied on this regard were filed as plaint documents. Upon examining these documents, if so intended, the defendant could and should have expressly pleaded, in the written statement, the lack of a board resolution. In such event, the specific denial could have been dealt with in the reply statement. This

preliminary objection should be dealt with by bearing the above aspect in mind.

26. The plaintiffs exhibited power of attorney dated March 09, 2016 executed in Basel, Switzerland as Ex.P1. Said power of attorney expressly records that it authorises the initiation of legal proceedings relating to IN 212815 in India. This document was executed by John Hutchison and Carl King as authorised signatories of Novartis AG. Their signatures have been attested by a notary public in Basel, Switzerland. The attestation records that they have acted for Novartis AG as proxy holders. In *United Bank of India v. Naresh Kumar and others (1996) 6 SCC 660,* the Supreme Court considered the law relating to authorisation to act for a company in legal proceedings and held as under:

> *"11. It cannot be disputed that a company like the appellant can sue and be sued in its own name. Under Order 6 Rule 14 of the Code of Civil Procedure a pleading is required to be signed by the party and its pleader, if any. As a company is a juristic entity it is obvious that some person has to sign the pleadings on behalf of the company. Order 29 Rule 1 of the Code of Civil Procedure, therefore, provides that in a suit by or against a corporation the Secretary or any Director*

or other Principal Officer of the corporation who is able to depose to the facts of the case might sign and verify on behalf of the company. Reading Order 6 Rule 14 together with Order 29 Rule 1 of the Code of Civil Procedure it would appear that even in the absence of any formal letter of authority or power of attorney having been executed a person referred to in Rule 1 of Order 29 can, by virtue of the office which he holds, sign and verify the pleadings on behalf of the corporation. In addition thereto and de hors Order 29 Rule 1 of the Code of Civil Procedure, as a company is a juristic entity, it can duly authorise any person to sign the plaint or the written statement on its behalf and this would be regarded as sufficient compliance with the provisions of Order 6 Rule 14 of the Code of Civil Procedure. A person may be expressly authorised to sign the pleadings on behalf of the company, for example by the Board of Directors passing a resolution to that effect or by a power of attorney being executed in favour of any individual. In absence thereof and in cases where pleadings have been signed by one of its officers a corporation can ratify the said action of its officer in signing the pleadings. Such ratification can be express or implied. The court can, on the basis of the evidence on record, and after taking all the circumstances of the case, specially with regard to the conduct of the trial, come

to the conclusion that the corporation had ratified the act of signing of the pleading by its officer."

27. Thus, even implied ratification has been endorsed. Especially in the context of the defendant neither pleading nor establishing that the power of attorney, along with the attestation by a notary public in Basel, Switzerland, does not meet the requirements of applicable Swiss law, I see no reason to conclude that the first plaintiff did not duly authorise the institution of the suit. The power of attorney from the second plaintiff (Ex.P2) is executed in favour of Mr. Bade by the Managing Director of the second plaintiff. Therefore, this preliminary objection is overruled.

28. Another preliminary objection regarding misjoinder of the second plaintiff was raised on the ground that the second plaintiff is not the patentee. The first plaintiff is the patentee of IN 212815 and the second plaintiff is a subsidiary in India of the first plaintiff. The second plaintiff markets the patented product in India and is, therefore, likely to be prejudiced by acts of infringement in India. Therefore, this preliminary objection is also overruled.

Issue Nos.(a) and (b)

29. Issue numbers (a) and (b) relate to the term of the suit patent, whether it has expired and whether the suit is consequently infructuous. The plaintiffs contended that the term of the suit patent runs from December 09, 1999 to December 09, 2019. On the contrary, the defendant contended that the suit patent expired on December 09, 2018. Section 53 of the Patents Act deals with the term of patent. Sub-section (1) and the Explanation thereto are relevant for present purposes and read as under:

> ***"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 (38 of 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.]*

30. As is evident from the Explanation, 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 thereunder. The PCT filing date is December 09, 1999 as reflected in the Form-3 accompanying the patent application of the first plaintiff (Ex.D1). In this connection, sub-section 1–B of Section 7 is relevant and the same is set out below:

> *"[(1-B) The filing date of an application referred to in sub-section (1-A) and its complete specification processed by the patent office as designated office or elected office shall be the international filing date accorded under the Patent Cooperation Treaty.]*

The conclusion that follows is that the suit patent expired on December 09, 2019, as contended by the plaintiffs, and not on December 09, 2018. The defendant proceeded on the misconception that the term of patent is to be computed from the priority date. This resulted in the defendant's contention that the suit patent expired on December 09, 2018.

31. The allegation of infringement in the suit is on the basis of exports made by the defendant to importers in Egypt between 2016 and 2017 while the suit patent was in force. Therefore, the claim for relief,

including by way of damages, survives the expiry of the patent. Issue Nos.(a) and (b) are disposed of in favour of the plaintiffs and against the defendant.

Issue No.(f)

32. This issue relates to whether the defendant is estopped from raising the plea of invalidity of the suit patent in view of the decree dated July 31, 2015 recording the undertakings of the defendant. In order to determine this issue, it is, therefore, necessary to examine the decree and the undertakings given by the defendant. The undertaking affidavit dated July 28, 2015 was affirmed by Mr.A.Deepak, Managing Director of the defendant. In relevant part, it reads as under:

> *"1) The Defendant unconditionally agrees and acknowledges the Plaintiff no.1 is the registered patentee of Indian Patent No. 212815.*
>
> *2) The Defendant hereby undertakes to this Hon'ble Court and to the Plaintiffs that it will not either by itself or through its directors, group company, associates, divisions, assigns in business, licensees, franchisees, agents, distributors and dealers use, manufacture, import, sell, offer for sale either through website http://www.nutraforlife.com or by any other means,*

export, directly or indirectly deal in Active Pharmaceutical Ingredient (API), pharmaceutical products, or formulation containing Vildagliptin alone or Vildagliptin in combination with any other compound or API or in any other form as may amount to infringement of Indian Patent No.212815 of the Plaintiff no.1.

3) ***The Defendant admits and accepts the rights of the Plaintiff no.1 in patent being IN 212815 and acknowledges the validity thereof.*** (emphasis added)

4) The Defendant further submits that the present dispute may be resolved in view of the undertaking given hereinabove and the suit may be decreed in terms of Para 41 of the plaint.

5) The Defendant consents that a decree may be passed between the parties in favour of the Plaintiffs and against the Defendant.

6) The above undertaking has been read over and explained to the Defendant and Defendant has agreed to this undertaking after reading & understanding all the clauses & facts and thus this undertaking is binding on the Defendant."

33. The judgment in the suit captures the remedies requested for in C.S.No.329 of 2015. Such remedies encompass a decree for: permanent injunction; delivery up of the stock of infringing formulations and compounds; rendition of accounts and profits; and costs. After reproducing the undertaking, it was concluded as under in the judgment:

"5. The learned counsel appearing for the defendant submitted that the suit may be decreed in favour of the plaintiffs and against the defendant in view of the undertaking given by the defendant and also in terms of paragraph 41 of the plaint. Paragraph 41 of the plaint reads as follows:

> *"The use, manufacture, import, export, offer for sale and sale of Vildagliptin API and/or pharmaceutical products containing Vildagliptin alone or in combination with any other compound, excipients or salts or substance, without prior permission and license/authorization from plaintiff No.1 would constitute infringement of Indian Patent No.212815 under Section 48 of The Patents Act, 1970. Additionally, the use, manufacture, import, export, offer for sale and sale of Vildagliptin in a pharmaceutical composition together with at least one pharmaceutically acceptable carrier or diluents would constitute use of the patented compound which is covered by claims 1,3,4 and 5 of the suit patent and infringement of Indian Patent No.212815 under Section 48 of the Patents Act, 1970 and is liable to be injuncted being illegitimate and unlawful under the provisions of Section 108 of the said*

Act. Vildagliptin therefore cannot be manufactured, used, offered to be sold or sold either alone or in combination with other pharmaceutically acceptable salts as a formulation without prior permission, consent or license from plaintiff No.1."

6. Considering the above stated facts and circumstances and considering the fact that the defendant has submitted to the decree as stated supra by filing an affidavit of undertaking dated 28.07.2015, the suit is decreed as prayed for. However, considering the above stated facts and circumstances, there will be no order as to costs. Consequently, the connected application is closed."

It is noticeable from paragraph 1 of the affidavit of undertaking of the defendant that the defendant unconditionally agreed and acknowledged that the first plaintiff is the registered patentee of suit patent IN 212815. At Paragraph 3, the defendant admitted and accepted the rights of the first plaintiff in the suit patent and acknowledged the validity thereof. Because the defendant consented to a decree being issued on the basis of such undertakings, it appears that the plaintiffs did not press for any other remedies, including costs.

34. Learned counsel for the defendant contended that said affidavit of undertaking was the result of suppression and fraud. In the written

statement, there is no allegation of suppression or fraud vitiating the execution of the affidavit of undertaking. In paragraph 8 thereof, there is a statement that the patent should not have been granted for the API; that there was misrepresentation before the IPO; that disclosures under Section 8 of the Patents Act were not made; and that the patent is for a metabolite, which is prohibited under Section 3(d) of the Patents Act. None of these allegations vitiate or undermine the consent decree in any manner. Instead, they relate to the grant by the IPO.

35. In *Bhanja Deo,* the Supreme Court considered a plea of estoppel by a consent decree. The Court quoted the judgment of Lord Herschell in *In re, South American and Mexican Company, Ex parte Bank of England* holding as under:

> *"The truth is, a judgment by consent is intended to put a stop to litigation between the parties just as much as is a judgment which results from the decision of the court after the matter has been fought out to the end. And I think it would be very mischievous if one were not to give a fair and reasonable interpretation to such judgments, and were to allow questions that were really involved in the action to be fought over again in a subsequent action."*

This principle was reaffirmed in *Byram Pestonji Gariwala*. Relying on *Baldevdas Shivlal* and *S.P. Chengalvaraya Naidu,* learned counsel for the defendant contended that a consent decree does not operate as *res judicata*. In particular, he contended that it was held in the latter judgment that an erroneous decision in an earlier judgment on a statutory prohibition would not operate as *res judicata*. These judgments do not advance the cause of the defendant. The consent decree in the earlier suit did not overlook a statutory prohibition. Besides, even if a consent decree does not operate as *res judicata* in terms of Section 11 of the CPC, at a minimum, an issue estoppel operates against the defendant. Therefore, I conclude that the defendant is estopped from raising the plea of invalidity of the suit patent. Issue No.(f) is disposed of on these terms.

Issue No.(k)

36. This issue relates to whether VILDAGLIPTIN is a metabolite and therefore not patentable under Section 3(d) of the Patents Act. Metabolites are small, organic molecules produced, consumed or altered during metabolic processes within a living cell or organism. After raising the plea that it was admitted by the plaintiffs that VILDAGLIPTIN is a

metabolite, the defendant failed to adduce any evidence to that effect. On the contrary, DW2, who was fielded by the defendant as an expert, responded as under to a question about the patented product:

> *"Q62: Is it correct that Vildagliptin is a new chemical entity and the name Vildagliptin is "an international non-proprietary name" (INN) awarded by WHO to the said compound?*
>
> *A:Yes."*

On perusal of the documentary and oral evidence of the defendant, I conclude that there is not a shred of evidence that VILDAGLIPTIN is a metabolite. Therefore, Issue No.(k) is decided against the defendant.

Issue No.(j)

37. This issue relates to whether the suit patent is invalid on account of misrepresentation and lack of disclosure to the patent office under Section 8 of the Patents Act. Because of the earlier conclusion that an estoppel operates against the defendant that precludes the defendant from challenging the validity of the suit patent, the adjudication of this issue has become moot. Nonetheless, in view of extensive arguments being made, this issue is dealt with.

38. An action for infringement of patent is instituted under Section 108 of the Patents Act and the defences thereto are prescribed in Section 107. Section 107 is as under:

> *"107. Defences, etc., in suits for infringement. (1) In any suit for infringement of a patent, every ground on which it may be revoked under section 64 shall be available as a ground for defence.*
>
> *(2) In any suit for infringement of a patent by the making, using or importation of any machine, apparatus or other article or by the using of any process or by the importation, use or distribution of any medicine or drug, it shall be a ground for defence that such making, using, importation or distribution is in accordance with any one or more of the conditions specified in section 47."*

39. Section 64 of the Patents Act enables a person interested or the Central Government or a counter-claimant in an infringement action to apply to revoke a patent. By virtue of Section 107(1), a defendant in an infringement action may defend such action on any of the grounds in Section 64. As discussed earlier, the defendant acknowledged the validity of the suit patent in the earlier suit and a consent decree was issued on that basis. Consequently, an issue estoppel operates against the defendant with regard to the validity of the suit patent. Besides, the defendant failed to challenge the suit patent on this ground by lodging a

pre-grant or post-grant opposition or by applying under Section 64 to revoke the grant. The defence raised on this basis should be viewed by bearing in mind these facts.

40. The defendant, nonetheless, pleaded that the grant of patent is vitiated by non-disclosure of information under Section 8, and that this is a recognised defence to an infringement action under Section 107. Section 64 (1) provides, in this regard, as under:

> *" 64. Revocation of patents – (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may be revoked on a petition of any person interested or of the Central Government or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say -*
>
> *(m) that the applicant for the patent has failed to disclose to the Controller the information required by Section 8 or has furnished information which in any material particular was false to his knowledge;"*

41. Thus, it is self-evident that the interpretation of Section 8 is central to the determination of this issue. Section 8 is set out below:

*"**8. Information and undertaking regarding foreign applications** (1) **Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention**, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, **he shall file along with his application [or subsequently [within the prescribed period as the Controller may allow]]—***

***[(a) a statement setting out detailed particulars of such application**; and]*

*(b) **an undertaking that, [up to the date of grant of patent in India], he would keep the Controller informed in writing, from time to time**, of [detailed particulars as required under] clause (a) in respect **of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause**, within the prescribed time.*

[(2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in

a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.]"

(emphasis added)

42. Section 8, as is evident from the above text, pertains to the provision of information regarding foreign applications corresponding to the Indian application. Sub-section (1) thereof imposes an obligation on an applicant for patent under the Patents Act to submit a statement setting out detailed particulars of applications made and under prosecution, at the time of filing the application before the IPO, in any country outside India in respect of the same or substantially the same invention, including applications prosecuted by any other person through whom he claims or by a person deriving title from the applicant. The above conclusion that sub-section (1) applies to applications under prosecution in a foreign country flows from the present continuous tense used in the expression "is prosecuting" in said provision. Clause (b) of sub-section (1) expands the obligation by prescribing that the patent applicant shall undertake to keep the Controller informed in writing of particulars relating to applications for substantially the same invention filed in any country outside India after the filing of the statement under Clause (a) of sub-section (1). Thus, while clause (a) of said sub-section applies to applications under prosecution at the time of lodging the

application before the IPO, clause (b) applies to foreign applications lodged subsequently. Sub-section (2) imposes a continuing obligation from the date of application till the date of grant or refusal.

43. It is clear from the text of Section 8 that the obligation relates to the provision of information relating to corresponding foreign applications, and that it is not an obligation to disclose prior arts. Learned counsel for the defendant contended that Exs.D13 and D14 were not disclosed. By comparing said exhibits with the suit patent, he contended that even the title is the same as the suit patent. In particular, he pointed out that WO 98/19998 (Ex.D13) is substantially the same. Learned counsel for the plaintiffs contended that Ex.D13 does not have an adamantyl substituent for hydroxy. He also pointed out that the First Examination Report of the European Patent Office refers to Ex.D13 as prior art and that prior art need not be disclosed under Section 8.

44. Section 8 is operationalised under Rule 12 of the Patents Rules read with Form 3. Rule 12 is set out below:

> *"12. Statement and undertaking regarding foreign applications:- (1) The statement and undertaking required to be filed by an applicant for a patent under sub-section (1) of section 8*

shall be made in Form 3.

[(1-A) The period within which the applicant shall file the statement and undertaking under sub-section (1) of section 8 shall be [six months] from the date of filing the application. Explanation.- For the purpose of this rule, the period of [six months] in case of an application corresponding to an international application in which India is designated shall be reckoned from the actual date on which the corresponding application is filed in India.]

(2) The time within which the applicant for a patent shall keep the Controller informed of the details in respect of other applications filed in any country in the undertaking to be given by him under clause (b) of sub-section (1) of section 8 shall be [six months] from the date of such filing.

[(3) When so required by the Controller under sub-section (2) of section 8, the applicant shall furnish information relating to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within [six months] from the date of such communication by the Controller.]"

Sub-rule (1) of Rule 12 prescribes that the statement and undertaking under sub-section (1) of Section 8 should be made in Form 3. Form 3 is scanned and reproduced below:

AND

THE PATENTS RULES, 2003

STATEMENT AND UNDERTAKING UNDER SECTION 8

(See section 8; rule 12)

1. Name of the applicant(s)	I/We .... hereby declare:—
2. Name, address and nationality of the joint applicant:	(*i*) that I/We have not made any application for the same/substantially the same invention outside India. OR (*ii*) that I/We who have made this application No..... dated..... alone/jointly with....., made for the same/substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:

Name of the country	Date of application	Application No.	Status of the application	Date of publication	Date of grant

3. Name and address of the assignee.	(*iii*) that the rights in the application(s) has/ have been assigned to..... .... that I/We undertake that upto the date of grant of the patent by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within six months from the date of filing of such application. Dated this.....day of.....20.....
4. To be signed by the applicant or his authorised registered patent agent.	Signature.....
5. Name of the natural person who has signed.	(.....)
	To The Controller of Patents, The Patent Office, At.....

45. On reading Section 8, Rule 12 and Form 3 conjointly, the conclusion that follows is that an applicant for grant of patent in India is under an obligation to submit a statement and undertaking disclosing particulars about corresponding applications under prosecution when the Indian application was filed or filed thereafter for the same or substantially the same invention in any country outside India. Under sub-section (2) of Section 8, this obligation continues even after the application is filed and until grant or refusal. The object of Section 8, as gleaned from text and context, is that the foreign applications corresponding to the Indian application and all material developments relating thereto should be brought to the notice of the IPO. The underlying rationale is that these developments could have a bearing on the Indian application. For instance, specific prior arts may be cited by the foreign patent office or the application may be accepted or rejected by such office. While not binding on the IPO, these developments would be relevant considerations in the adjudication of the application before the IPO.

46. The defendant's contention is that Exs. D13 and D14 qualify as foreign applications for the same or substantially the same invention. This contention is refuted by the plaintiffs by stating that D13 does not have an adamantyl substituent for hydroxy. The onus to establish that

D13 and D14 are substantially the same as the claimed invention is on the defendant. Learned counsel for the plaintiffs has pointed out that Ex.D13 was cited as prior art by the European Patent Office. Most certainly, there is no obligation on a patent applicant in India to disclose prior art and the obligation is limited to disclosing corresponding foreign applications for the same or substantially the same invention. In spite of raising the defence that the suit patent and Exs. D13 and D14 are for substantially the same product/invention, the defendant did not file the complete specification of the plaintiffs' patent. Even proceeding on the assumption that Exs.D13 and D14 would be material documents under Section 8 if they qualify as documents pertaining to substantially the same invention, without comparing the complete specification of the suit patent with the complete specification of Ex.D13 and D14, no rational conclusion can be drawn in respect of the defendant's assertion. In the absence of actionable evidence that Ex.D13 or Ex.D14 is an application for grant of patent for the same or substantially the same invention, without detracting from the earlier conclusion on issue estoppel, I conclude that Section 8 was not contravened by the plaintiffs. Issue No. (j) is disposed of in favour of the plaintiffs and against the defendant.

Issue Nos.(c) to (e) and (g) to (i):

47. These issues relate to the supply of VILDAGLIPTIN API by the defendant to Egyptian importers and whether such supply infringes the suit patent or falls within the scope of Section 107A of the Patents Act. The defendant admits and does not deny supply to Egyptian importers. The defence raised by the defendant is that such supply was only for research and development purposes and that it is protected under Section 107A. Therefore, the interpretation of Section 107A is at the heart of this dispute. Before closely analysing Section 107A, it is pertinent to consider the genesis of the provision.

Bolar provision and global precedents

48. The Bolar provision had its genesis in a case filed by Roche against Bolar Pharmaceutical Co. Inc. (Bolar) to prevent Bolar from applying for and obtaining regulatory approval during the term of Roche's patent, albeit for sale after the expiry of Roche's patent. While the District Court in the United States of America held that this did not constitute infringement, the Court of Appeals for the Federal Circuit reversed in *Roche Products, Inc. v. Bolar Pharmaceutical Co. Inc., 733 F.2d 858; MANU/USFD/0006/1984.* This resulted in the following statutory amendment by the Congress of the United States of America:

> *" 271(e)(i) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."*

49. The above provision was interpreted by the US Supreme Court in *Merck KGaA v. Integra Lifesciences Ltd. 545 U.S. 193 (2005)* in the factual context of Merck hiring a scientist to investigate compounds having the same receptor blocking capability as Integra's patented RGD peptide. Reversing the Federal Circuit judgment, the US Supreme Court held as under:

> *"as an initial matter, we think it apparent from the statutory text that 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA. This necessarily includes preclinical studies of patented*

compounds that are appropriate for submission to the FDA in the regulatory process."

50. Meanwhile, the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) entered into force. Bearing in mind *inter alia* the Bolar exception, Article 30 thereof enables parties thereto to incorporate exceptions to patent rights. Article 30 is as under:

> *" Exceptions to rights conferred*
>
> *Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

51. Canada's Patent statute incorporates the Bolar provision in Section 55.2(1), which is as under:

> *" It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."*

Rejecting the challenge that the above provision contravenes Article 30 of the TRIPS Agreement, the Dispute Settlement Panel (DSP) under TRIPS held as under:

> *" 7.45 In the Panel's view, however, Canada's regulatory review exception is a "limited exception" within the meaning of TRIPS Article 30. It is "limited" because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorised by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products."*

Legislative history of Section 107A of the Patents Act

52. The enactment of Section 107A was preceded by a Joint Parliamentary Committee Report. Clause 51 of the bill (renumbered as clause 43) annexed thereto contained the proposed amendment, which was explained as under:

" This clause seeks in insert a new Section 107-A in the principal Act, relating to certain acts which are not to be considered as infringement. This provision has been made to ensure prompt availability of products, particularly generic drugs, immediately after the expiry of the term of the patent. The amendment in this clause has been made to make a provision in consonance with the Bolar Provisions at the global level. The other amendment in this clause is correction of a typographical error."

The Notes on Clauses provided as under:

" this clause seeks to insert a new Section 107A in the Act, relating to certain acts which are not to be considered infringements. It is proposed that the act of making or using a patented product for the purpose of development and submission of information to a regulatory authority regarding marketing approval of the product shall not constitute an infringement. This provision is proposed to ensure that generic drug approval should be available in Indian market immediately after the expiry of the term of the concerned patents."

53. At that juncture, the text of Section 107A of the Bill was as under:

"107A For the purposes of this Act -

(a) Any act of making or using a patented invention

within three years before the expiry of the term of the patent by any person for the purpose of development and submission of the information to any regulatory authority responsible for the grant of marketing approval for the product of invention."

In the Statement of Objects and Reasons, it was stated as under:

" 4. Some of the salient features of the Bill are...

(h) to make a provision enabling persons other than patent holder to obtain marketing approval from the appropriate regulatory authorities within three years before the expiration of the term of the patent."

54. Thus, at the time of introduction of the Bill, the provision could be invoked not earlier than three years before the expiry of the patent concerned. When enacted, this limitation did not find place and the provision stood as under:

"***107A. For the purposes of this Act***,-

(a) any act of making, constructing, using or selling 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 or sale of any product;

(b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.".

Later, it was amended by the Patents (Amendment) Ordinance, 2004 by substituting “using, selling or importing” instead of “using or selling” and “use, sale or import” for “use or sale” in clause (a). Clause (b) was amended by substituting “who is duly authorised under the law to produce and sell or distribute the product” for “who is duly authorised by the patentee to sell or distribute the product”. The Patents (Amendment) Ordinance, 2004, was replaced by the Patents (Amendment) Bill, 2005, which culminated in the Patents (Amendment) Act, 2005.

55. Section 107A now reads as under:

“[107-A. 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.]"

Bayer

56. The Delhi High Court interpreted this provision in *Bayer*. One of the issues examined by the Court was whether the expression "selling" includes export of the product. The Court concluded that it falls within the scope of the provision. After discussing the origin of the marketing authorisation exception, the Delhi High Court considered precedents from other jurisdictions interpreting and applying analogous provisions. The Court also examined the legislative history of Section 107-A before holding, in relevant part, as under:

"88. In the present case, this court notices that Section 107A is not made subject to the other provisions of the Act-on the other hand, Section 48, which talks of the rights of a patent holder is subject to other provisions of the Act that includes Section 107A. Furthermore, Bayer's argument that Section 107A constitutes an exception,

cannot be accepted. It is an independent provision with a specific history behind it and was subject to intensive Parliamentary debate and scrutiny by a Joint Committee report. Furthermore, it was enacted in response to the TRIPS enabling provision to the member countries to evolve national legislation facilitating research and progress in fields covered by the patents. The judgments cited, all generally and invariably contended by Bayer deal with provisos embodied in the main provision that constituted exceptions to the general rule. However, in this case, the court is not called upon to interpret the proviso to Section 48, nor even an exception. Bayer's argument that Section 107A has to be read as subordinate to the main provision of Section 48 has to, therefore,fail....

89. In the light of the above discussion, the court is of the opinion that there is no question of treating Section 107A(a) as an exception to Section 48. Its history of interpretation by TRIPS the discussion in the Parliamentary Joint Committee Report, all clearly point to its being a special provision that deals with the rights of the patented invention for research purposes.

92. 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 or 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 these aspects be 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).

105. It is clear, therefore, that neither the quantity used nor the place of research 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 is 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."

Interpreting Section 107-A

57. Chapter VIII of the Patents Act deals with the grant of patents and the rights conferred thereby. Section 46 provides that the grant shall have effect throughout India. Section 47 prescribes that the grant of patent shall be subject to the conditions specified therein. Said provision reads as under:

> *" 47. Grant of patents to be subject to certain conditions – The grant of a patent under this Act shall be subject to the condition that -*
>
> *(1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use;*
>
> *(2) any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;*
>
> *(3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted may be made or used, by any person, for the purpose merely of experiment or research including the*

imparting of instructions to pupils; and

(4) in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette."

58. Section 48 prescribes the rights of patentees. Said provision is critical for the determination of this dispute and reads as under:

"48. Rights of patentees-Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee-

a) where the subject-matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

(b) where the subject-matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from

the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:"

As can be seen from the above, the rights of patentees under this provision are subject to (i) the other provisions of the Patents Act; and (b) the conditions specified in Section 47. The text of clause (a), which relates to product patents, makes it clear that a product patent confers on the patentee the exclusive right to prevent third parties from making, using or offering for sale, selling or importing that product in India without the consent of the patentee.

59. Section 47, extracted earlier, prescribes that the grant of a patent shall be subject to the conditions specified in the said provision. In effect, it is a statutorily prescribed limitation on the rights of a patentee. As discussed above, this becomes abundantly clear on a conjoint reading of Sections 47 and 48 because the rights conferred under Section 48 are made expressly subject to the conditions specified in Section 47. These conditions include not only use by the Government of a patented product or process [sub-sections (1) and (2)], but also use by any person of a patented product or process for experiment or research, including the imparting of instructions to pupils [sub-section

(3)]. Sub-section (4) applies only to patents in respect of a drug or medicine and enables use of such patented product by hospitals and the like maintained by or on behalf of the Government or notified by the Central Government in view of the public service rendered by such body.

60. Comparing and contrasting Section 47 with Section 107A, the latter provision (unlike the former) does not specify conditions that a grant of patent is, by statute, *ipso facto,* subject to. Section 107A, nonetheless, provides for permissible and non-infringing uses of a patented product. Because of the expression "subject to the other provisions contained in this Act" in Section 48, the exclusive negative rights under Section 48 to prevent activities related to the patented product or process would not extend to acts permitted by Section 107A.

61. Continuing the comparison, the scope of Section 107A is clearly not the same as sub-section (3) of Section 47, i.e. use of a patented product or process for experiment or research. Given that Section 47 formed part of the Patents Act at inception, Section 107A, which was incorporated by a later amendment, would be superfluous in that event. Therefore, Section 107A performs a different role and function.

62. The explanation of the Joint Parliamentary Committee on clause 51 (renumbered clause 43) of the Bill, the Notes on Clauses and the Statement of Objects and Reasons, all of which are extracted *supra,* throw ample light on the object and purpose of this provision, i.e. to enable persons, other than the patentee, to take necessary measures to obtain regulatory approval so as to be in a position to bring a generic product to market immediately or soon after the patent expires. Thus, it is a regulatory approval provision and not a provision permitting the use of a patented product or process for academic experiments, research and teaching. The underlying policy objective appears to be the prevention of *de facto* extension of the monopoly period of 20 years.

63. From the text of Section 107A, it follows that there are the following two pre-requisites to avail of Section 107A(1): (a) regulatory requirements should be the sole purpose of making, constructing, using, selling or importing the patented product; and (b) the use of the patented product should be reasonably related to such regulatory requirements. The expression “selling” without any qualification limiting it to sale in India and, significantly, the phrase “or in a country other than India” in sub-section (1) lead to the inference that the patented product may be sold to persons outside India provided such sale is in relation to obtaining regulatory approval in India or outside India.

64. From the perspective of Section 48, however, a qualification is in order. Section 48 confers a negative right on the patentee only in relation to infringing acts in India. Effectively, one of the acts of manufacture, use, offer for sale, sale or import should happen in India as a pre-condition for an action for infringement in India. For instance, if a product patented in India were to be sold outside India without such sale originating in India, Section 48 read with Section 108 of the Patents Act cannot be pressed into service. On the facts of this case, however, this is moot inasmuch as the defendant manufactured the products in India and the sale to the Egyptian importers originated from India.

65. Continuing with the interpretation of Section 107A, the text, curiously, indicates that this provision only applies to a product patent and not to a process patent. If the two requirements set out above in paragraph 63 were to be satisfied, use of the patented product shall be considered as non-infringing. In that regard, this provision is similar to Section 49 which specifies that the use of a patented product or process on a foreign registered vessel, aircraft or land vehicle by a person ordinarily resident in the country of registration would not infringe the patent, if the said vessel, aircraft or vehicle were to temporarily or accidentally enter India. A parallel may also be drawn with the fair use provision in Section 52 of the Copyright Act, 1957 and sub-sections (2) and (3) of Section 30 and Section 35 of the Trade Marks Act, 1999.

66. Returning to the facts, the defendant admits that it manufactured VILDAGLIPTIN API in India and exported it to purchasers in Egypt. Therefore, the patented product was made and sold by the defendant. Unless such manufacture and sale are protected by any permissible grounds under the Patents Act, there would be a contravention of the exclusive rights of the patentee under Section 48.

67. In order to exercise such rights, the patentee is entitled to seek reliefs in respect of infringement under Section 108. Section 108 falls within Chapter XVIII of the Patents Act titled “Suits concerning infringement of patents”. Said chapter consists of provisions relating to defences in a suit for infringement (Section 107) and also includes Section 107A. Section 47, which falls within chapter VIII was discussed earlier. On reading Sections 47, 107 and 107A conjointly, I find that a defendant in a suit for infringement may raise the ground that the suit patent is not valid under sub-section (1) of Section 107 or may contend that he has made, used or imported the patented product or process for on behalf of the Government or for experiment or research purposes in terms of Section 47. In addition to these defences, provision has been made to treat as non-infringing, the making, constructing, using, selling

or importing the patented invention solely for uses reasonably related to the development and submission of the information required under law in India or in any country other than India that regulates the manufacture, construction, use, sale or import of any product. It is clear that this provision applies to all products and is not confined to pharmaceutical products. It is also clear that it may be invoked at any time during the life of the patent.

68. This leads to the critical question as to the person on whom the onus lies to plead and establish the above pre-requisites. Given that Section 107A incorporates a Bolar provision, which, if not satisfied, would constitute infringing use, the provision should, in my view, be construed as an exception. The onus, consequently, lies on the defendant asserting that its use falls within the exception. To that extent, I am unable to subscribe to the view taken by the Delhi High Court in *Bayer* that it is a special provision and not an exception. This, in turn, leads to the questions: what is the nature of evidence required to satisfy the requirements of Section 107A; and whether the defendant has discharged this onus.

69. The defendant does not assert that it manufactured and exported VILDAGLIPTIN API to importers in Egypt to enable such importers to apply for regulatory approval in Egypt on its behalf. It is also not the pleaded case of the defendant that the supply/export was in relation to the defendant's application for regulatory approval in India. Instead, the case of the defendant is that it manufactured and supplied VILDAGLIPTIN API to these importers for research and development purposes as stated in the invoices. Considering that the defendant was not seeking regulatory approval in Egypt, the defendant should have adduced evidence that the importers required VILDAGLIPTIN API for regulatory purposes in Egypt. Logically, in that event, the supply by the defendant would have been preceded by a request from the Egyptian importers to supply for regulatory purposes, such as for obtaining marketing approval. In order to qualify as credible evidence, this should have been backed by documents indicating that the Egyptian regulatory authorities requested for information, such as pre-clinical or clinical trial data requiring the importation and use of VILDAGLIPTIN.

70. In *Sicor/Teva Pharmaceutical,* the Italian Court of Cassation grappled with the nature of evidence that is required to be provided by a person relying on the Bolar provision. Article 68(1)(b) (the relevant Bolar provision) provided as under:

> *" The exclusive right conferred by the patent right does not extend, whatever the subject matter of the invention:*
>
> *b) studies and experiments aimed at obtaining, also in foreign countries, a marketing authorisation for a drug and the consequent practical steps including the preparation and use of the pharmacologically active raw materials strictly necessary for this purpose."*

71. Specifically, the Court examined whether, in the context of the manufacturer of the patented API not being the generic product manufacturer and seller, a request from the generic product maker or seller to the purchaser is necessary. Answering in the affirmative and dismissing the appeal, in relevant part, it was recorded as under:

> *" Consequently, having to look at the purpose of the Bolar exception (the obtaining of a "marketing authorisation" in a more rapid time frame, compatible with those of the pharmaceutical sector), even though it may also apply to the producer of active ingredients that performs study/experimentation/production activities for the registration purposes, not its own, but of a third generic manufacturer, it is necessary, in this case, that the Bolar purpose is clear ab origine and that therefore, upstream of the activity of production and marketing of the active ingredient there is a "commissioning" relationship, by virtue of which the manufacturer is approached by the generic third party "for a study, production and delivery*

activity that is in turn lawful insofar as it is ex ante inherent to the aforesaid purpose" and the manufacturer acts "only by reason of a request supported by a declared purpose capable of exculpating its conduct expressly contemplated – as a limit of use – in the relative negotiating regulation".

72. I turn to and examine the evidence against this backdrop. The relevant purchase orders and invoices under which supply was made by the defendant were exhibited as Exs.P21 to P28. The commercial invoice dated March 31, 2017 (Ex.P21) for the sale of 200 kilogrammes of VILDAGLIPTIN records that the sale is for research and development purpose only. The supply under this invoice appears to be pursuant to purchase order dated February 08, 2017 from Inspire Pharma (Ex.P22). Said purchase order, including the attachment thereto, contains no indication that 200 kilogrammes are required for research and development purposes or are required to satisfy regulatory requirements. Likewise, the purchase order dated January 01, 2017 from Mash Premiere (Ex.P23) for the purchase of 800 kilogrammes of VILDAGLIPTIN also does not contain any indication that the goods sought to be purchased are for research and development purpose. The same is the case with the purchase order dated January 29, 2017 from Eva Pharma (Ex.P26). Another purchase order dated November 20, 2017

from Horus for Pharmaceutical Industries (Ex.P27) also follows the same pattern of containing no indication that the purchase was for purposes of meeting regulatory requirements. As in the case of other invoices, however, invoice dated March 16, 2018 from the defendant to Horus for Pharmaceutical Industries (Ex.P28) mentions that the sale is for research and development purpose only. The oral evidence of DW1 in cross-examination, particularly the answers to questions 32-53 and 59-60 corroborate the above conclusions.

73. Two Advocate Commissioners were appointed pursuant to orders issued in April 2018 by this Court. One of them, Ms. Suba Shiny, filed report dated May 10,2015 (Ex.P11) enclosing *inter alia* commercial invoices, purchase orders and certificates of origin for the periods 2016-17 and 2017-18, answers to a questionnaire and declarations by Tabuk Pharmaceuticals Manufacturing Co. Egypt (Tabuk Pharma) and Eva Pharma. The certificate dated April 24, 2018 purportedly on behalf of Tabuk Pharma is signed for Ahmed Nawar. There is no indication as to the designation of Ahmed Nawar in Tabuk Pharma or as to the authority under which the document was signed on his behalf. The quantity mentioned in the certificate is 84, probably referring to 84 kilogrammes. The certification reads: “we hereby certify that the said material has been purchased by us to get regulatory approval for development, clinical studies and Bio-equivalence studies.”

74. The certificate dated April 24, 2018 from Eva Pharma pertains to 200 kilogrammes purchased on May 2, 2017. This document contains two signatures but it is not possible to discern the designation or authority under which the signatories signed the declaration. The declaration reads: “we hereby declare that the said material has been purchased by us for reprocessing development for process validation trials.”

75. Both these certificates relate to only the quantities mentioned therein. Neither certificate is corroborated by documents from the Egyptian regulatory authority. For these reasons and those discussed in the preceding paragraphs, these documents do not inspire confidence. The other Commissioner’s report should be considered next.

76. Mr. N.U. Prasanna, Advocate Commissioner, filed report dated May 14, 2018 (Ex.P20) enclosing *inter alia* the answers of the defendant’s representative to questions and copies of documents. Question No.7 to Mr. John, Manager-Quality Assurance, and the answer thereto are set out below:

“ What steps does your company normally take to ensure

that any patented compounds manufactured, sold and/or exported under Section 107A of the Patents Act, 1970 comply with the requirements of that provision?

Answer: Some customers inform that they want Vildagliptin for trial purpose. But we do not make any due diligence as such."

77. Interestingly, these documents include applications for removal of excisable goods in Form ARE-1 under applicable Customs law. The earliest of these ARE-1 forms were submitted by the defendant in December 2014. Each form describes the goods as VILDAGLIPTIN for export to Egypt. It is pertinent to note that these applications indicate that the defendant was exporting VILDAGLIPTIN to Egypt even prior to the submission of affidavit dated July 28, 2015 in earlier C.S. No.329 of 2015. Q&A 9 to DW1, which is also pertinent, is set out below:

"Q9: Since when you are manufacturing Vildagliptin?

A: May be 2014/2015.

Thus, without disclosing the manufacture and export of VILDAGLIPTIN, the defendant undertook to this Court that it will not manufacture, sell or export VILDAGLIPTIN. The defendant also did not even subsequently seek a clarification by informing the Court that its exports are in relation

to regulatory approval. Exports to Egypt, however, appear to have continued unabated.

78. The plaintiff also filed certificate dated April 23, 2018 from IQVIA (Ex. P12). The Annexures thereto contains print-outs from the websites of *inter alia* Inspire Pharma and Eva Pharma. These documents contain details of formulations and depictions of packaging of products containing VILDAGLIPTIN. The products are undoubtedly being offered for commercial sale. While it cannot be concluded merely on the basis of Ex.P12 that the goods sold by the defendant were, in turn, sold commercially by the Egyptian importers, it establishes that these parties were already engaged in the commercial sale of formulations containing VILDAGLIPTIN. If so, they would not require regulatory approval.

79. Taking into account this evidence, the question that falls for consideration is whether the defendant has discharged the onus of establishing that the supply was for research and development purposes merely by stating so in the relevant invoices. Considering the fact that a patent confers a monopoly right on the patentee for a period of twenty years to prevent third parties from making, using, offering for sale, selling or importing the patented product or process without the consent

of such patentee, in my view, the defendant in an action for infringement is required to discharge a far heavier burden to establish that the supply falls within the scope of Section 107A.

80. Recognising that the evidence necessary to discharge such burden would depend on the facts and without intending to be exhaustive, at a minimum, the following four categories of documents should be provided by a person relying on 107A:

> *(a) Evidence that regulatory approval was sought for in relation to the patented product in India or outside India.*
>
> *(b) Evidence that the regulator requested for product-related data such as pre-clinical or clinical trial data relating to the patented product in response to the request for approval.*
>
> *(c) If the person requesting regulatory approval is not the manufacturer of the API or formulation, evidence of request for supply from the person seeking regulatory approval to the manufacturer or seller along with supporting documents as per (a) and (b) above.*
>
> *(d) Evidence that the impugned use of the patented product is reasonably related to the request for regulatory approval.*

81. In *Bayer,* the Delhi High Court had concluded that the following non-exhaustive aspects are relevant while deciding whether the matter falls within the scope of Section 107A:

> *"(1) The patent granted;*
>
> *(2) The nature of the product or elements sought to be exported;*
>
> *(3) The details of the party or parties 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 meant for 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.

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."

82. I concur fully that the above aspects should be taken note of as non-exhaustive factors or criteria to evaluate whether the sale, use, import or export by a defendant falls within the scope of Section 107A.

Indeed, in my view, by exercising generic rule-making power under Section 159(1) of the Patents Act [notwithstanding the absence of a specific clause in Section 159(2)], the Central Government should, after consulting all stakeholders, frame rules listing the documentary and other requirements for reliance on Section 107A. This would ensure that this provision is used legitimately and not abused to circumvent Section 48.

83. Circling back to the facts to record final conclusions, the evidence shows that the manufacture in India and supply from India by the defendant was of quantities equal to or in excess of 200 kilogrammes. Although the quantities exported are per se non-determinative, the report by IQVIA (Ex.P12) and the extracts from the websites of Inspire pharma, Eva Pharma and other Egyptian importers reveal that the importers were undertaking commercial sale of VILDAGLIPTIN formulations. On the basis of evidence adduced by the defendant in this case, I am unable to conclude that the manufacture and supply of VILDAGLIPTIN by the defendant was solely for research and development purposes or that the use of the patented product was reasonably related to the fulfilment of regulatory requirements in Egypt. Therefore, I conclude that the defendant's manufacture and export of VILDAGLIPTIN infringes the suit patent. These issues are decided on the above terms.

Issue No.(l)

84. This issue relates to whether the plaintiffs are entitled to damages or whether the plaintiffs are entitled to rendition of accounts. The proof affidavit of PW1 contains information culled out of the reports of the Advocate Commissioners regarding the exports of Vildagliptin API by the defendant. In the written arguments of the plaintiffs, it is stated that the supply value is Rs.34.95 crores. A decree has been requested for on that basis. This sum of Rs.34.95 crores is not mentioned in the proof affidavit. On the basis of materials placed on record, it is not possible to accurately determine the quantum of supply, turnover derived therefrom and profits made by the defendant. Therefore, the plaintiffs are entitled to rendition of accounts by the defendant and for a decree of profits on that basis.

Issue No. (m)

85. This issue relates to other reliefs. On account of the expiry of the suit patent on December 9, 2019, the relief of mandatory injunction [clause (c) of paragraph 26 of the plaint] to direct the defendant to provide advance notice of supply made up to the expiry of the suit patent has been rendered otiose. As the successful party, the plaintiffs are entitled to costs. Learned counsel for the plaintiffs has filed a statement of litigation costs on February 20, 2026. The amount claimed therein is

an aggregate sum of about Euro 282598 towards lawyer's fees, including senior counsel's fees, corresponding to about INR 2,44,61,682. Including the claim for expenses, an aggregate sum of about Euro 342940 equivalent to INR 2,96,84,944 at the exchange rate of INR 86.56 per Euro has been claimed. This cost claim cannot be properly assessed without examining the underlying documents. Considering the totality of facts and circumstances, including the conduct of the parties, the plaintiffs are entitled to reasonable costs and expenses on the basis of actual costs incurred. The Taxing Officer shall make this determination in accordance with Section 35 of the CPC, as applicable to commercial disputes under the Commercial Courts Act, and the procedure prescribed in Order IV of the High Court Fees Rules, 1956.

86. In the result, the suit is decreed in terms of reliefs claimed in clauses (a), (c) and (d) of paragraph 26 of the plaint. The relief in clause (d) shall be by rendition of accounts followed by a decree of profits. The defendant is also directed to pay costs, which shall be determined in the manner specified above. Consequently, connected applications are closed.

03.06. 2026

Neutral Citation: Yes / No
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Plaintiffs' witness:

1. Mr.Atul Anand Bade - P.W.1

Defendant's witnesses:

1. Mr.Abaya Kumar Srisrimal - D.W.1

2. Dr.Munusami Jayamani - DW2

Documents exhibited by the plaintiffs:

Exhibits	Description
Ex.P1	Series of photocopies of the Power of Attorneys in favour of Mr.Atul Bade on behalf of plaintiff no.1 and 2 dated 09.03.2016, 08.01.2018 and 29.08.2022.
Ex.P2	Certified copy of the Patent Certificate for the Patent IN 815.
Ex.P3	Certified copy of the Complete specification for the patent No. IN 212815
Ex.P4	Certified copy of the Orders of Injunction and Decrees passed by Courts in successful enforcement of the suit pattern IN 212815
Ex.P5	Series of the Marketing Authorizations dated 18.01.2008 and 21.07.2008 granted by Central Drugs Standard Control Organisation (CDSCO) for Vildagliptin and Vildagliptin Plus Metformin Hydrocholoride.
Ex.P6	Series of the certified copies of the statement of working (Form 27) filed by the plaintiff No.1 pertaining to the suit patent IN212815 for the years 2010, 2012, 2013, 2014,2015,2016,2017,2018 and 2019.
Ex.P7	Photocopy of the Undertaking filed in the suit being C.S.No.329 of 2015 dated 28.07.2015.
Ex.P8	Photocopy of the Judgment and Decree dated 31.07.2015 granted in the suit being C.S.No.329 of 2015.
Ex.P9	Photocopy of the RTI Application of the plaintiff dated 07.08.2017
Ex.P10	Photocopy of the RTI Reply dated 21.09.2017 received from

	the office of Principal Commissioner of Customs, Chennai.
Ex.P11	Advocate Commissioner Report dated 10.05.2018 of Ms.Suba Shiny along with annexures.
Ex.P12	IQVIA certificate dated 23.04.2018 and confidential IQVIA data.
Ex.P13	Certificate by way of affidavit u/s 65B Indian Evidence Act, 1972 in support of the Internet Printouts.
Ex.P14	printout of the Picture of the Inspire Pharma's product VILDAGLUSE. (Certificate u/s 65 B of LE.Act produced)
Ex.P15	printout of the Picture of the Eva Pharma's product GLIPTUS. (Certificate u/s 65 B of LE.Act produced)
Ex.P16	extracts from Inspire Pharma's Website, Eva Pharma Website and other third party Websites such as Fouda.com and Dawaya.com VILDAGLUSE and GLIPTUS and ICANDRA
Ex.P17	copy of plaintiff's legal notice dated 22.03.2018 issued to the defendant
Ex.P18	defendant's reply dated 30.03.2018 in response to the plaintiff's legal notice
Ex.P19	copy of the plaintiff's letter dated 22.03.2018 to the Chief Commissioner of Custom, Chennai.
Ex.P20	Advocate Commissioner Report dated 14.05.2018 of Mr.N.U.Pressenna
Ex.P21	Commercial Invoice No.DXP161710432 dated 31.03.2017
Ex.P22	Purchase Order of Inspire Pharmaceuticals No.2017-2559 dated 08.02.2017
Ex.P23	The Mash Premier Purchase Order No.5 dated 01.01.2017
Ex.P24	Purchase Order No.18/2018 dated 18.01.2018
Ex.P25	Purchase order dated 16th May 2017
Ex.P26	Purchase order dated 29.01.2017
Ex.P27	Purchase Order No.20277/2017 dated 20.11.2017
Ex.P28	Commercial Invoice No.DXP171830255 dated 16th March 2018

Documents exhibited by the defendant:

Ex.D1	Certified copy of Form 3 with Annexure dated 04.04.2025

Ex.D2	Printout of the "Research Exemptions in Patent Law" by Kalyan Chakravarthi. (Certificate u/s 63 (4) (c) of BSA, 2023 filed)
Ex.D3	Printout of the Guidelines for Industry for Bio-equivalence studies (Certificate u/s 63 (4) (c) of BSA, 2023 filed.
Ex.D4	certified copy of the request for National phase entry form 1 filed by the first plaintiff dated 04.06.2001.
Ex.D5	printout of the US application no.09/209, 068 dated 10.12.1998. (Certificate u/s 63 (4) (c) of BSA, 2023 filed)
Ex.D6	printout of the US patent No.6,166,063 granted to application No.09/458, 224 to the plaintiff dated 09.12.1999. (Certificate u/s 63 (4) (c) of BSA, 2023 filed).
Ex.D7	the printout of the PCT international application No.PCT/EP99/09708 filed on 09.12.1999 published dated 15.06.2000. (Certificate u/s 63 (4) (c) of BSA, 2023 filed).
Ex.D8	printout of the European Patent Published in EP137 EPI 137 635 B1 dated 09.12.1999. (Certificate u/s 63 (4) (c) of BSA, 2023 filed)
Ex.D9	the certified copy of the First Examination Report for the impugned patent dated 28.11.2005.
Ex.D10	certified copy of the Reply to the First Examination Report dated 15.11.2006.
Ex.D11	printout of the communication issued to the plaintiff by the European Patent Office dated 27.03.2003. (Certificate u/s 63 (4) (c) of BSA, 2023 filed)
Ex.D12	printout of the response submitted by the plaintiff to the EPO dated 25.06.2003 (Certificate u/s 63 (4) (c) of BSA, 2023 filed)
Ex.D13	printout of the PCT/EP 97/06125 published internationally under No. W098/19998 dated 14.05.1998. (Certificate u/s 63 (4) (c) of BSA, 2023 filed)
Ex.D14	printout of the US application No.08/746/295 dated 07.11.1996. (Certificate u/s 63 (4) (c) of BSA, 2023 filed).
Ex.D15	printout of the US Patent 6,011,155, granted to application No.08/962,168 to the plaintiff dated 04.01.2000. (Compared with certified copy

03.06.2026

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To

M/s.Totale Global Pvt. Ltd.,
Rep. By its Managing Director,
71-C, New Avadi Road,
Kilpauk, Chennai-600 010.

SENTHILKUMAR RAMAMOORTHY J.

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Pre-delivery judgment made in C.S.(Comm Div) No.282 of 2018

03.06.2026