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

% **Date of decision: 8th March, 2017.**

\+ **W.P.(C) 1971/2014**

BAYER CORPORATION ..... Petitioner

Through: Mr. Sudhir Chandra, Sr. Adv. with Mr. Sanjay Kumar, Ms. Arpita Sawhney and Mr. Arun Kumar Jana, Advs.

Versus

UNION OF INDIA & ORS ..... Respondents

Through: Mr. Ripu Daman Bhardwaj, CGSC with Mr. T.P. Singh, Adv. for R-1 & 6.
Mr. Prashant Tyati and Mr. P. Venkat Reddy, Advs. for R-7.
Mr. Anand Grover, Sr. Adv. with Ms. Rajeshwari, Ms. Aparna Gaur, Mr. Tahir A.J. and Mr. Gajendra, Advs. for R-5.

AND

\+ **CS(COMM) No.1592/2016**

BAYER INTELLECTUAL PROPERTY GMBH & ANR ....Plaintiffs

Through: Mr. Pravin Anand, Ms. Archana Shanker, Mr. Aditya Gupta and Mr. Utkarsh Srivastava, Advs.

Versus

ALEMBIC PHARMACEUTICALS LTD. ..... Defendant

Through: Ms. Prathiba M. Singh, Sr. Adv. with Ms. Saya Chaudhary Kapur, Mr. Vivek Ranjan, Mr. Robin, Ms. Sutapa Jana and Mr. Devanshu Khanna, Advs.

CORAM:
HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

1. The question for adjudication in both the proceedings is, whether the language of Section 107A of the Patents Act, 1970 permits export from India of a patented invention, even if solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.

2. W.P.(C) No.1971/2014 was filed seeking a mandamus to the Customs Authorities to seize the consignments for export containing products covered by Compulsory Licence including 'SORAFENAT' manufactured by respondent No.5 therein Natco Pharma Limited (Natco) and further seeking a direction to all the Customs Ports to not allow exports thereof.

3. It was the plea of the petitioner Bayer Corporation (Bayer) in W.P.(C) No.1971/2014 (i) that Bayer had filed CS(OS) No.1090/2011 for restraining Natco from making, importing, selling, offering for sale 'SORAFENIB', 'SORAFENIB TOSYLATE' or any other drug comprising 'SORAFENIB', 'SORAFENIB TOSYLATE' or any generic version of 'SORAFENIB', 'SORAFENIB TOSYLATE' or any other product subject matter of Bayer's Patent No.215758; (ii) that Natco, during the pendency of the suit approached the Patent Office for grant of Compulsory Licence against the said patent; (iii) that the Controller of Patents vide order dated 9th March,

2012 granted Compulsory Licence in Patent No.215758 under Section 84 of the Patents Act to Natco on the terms and conditions contained therein; (iv) that one of the said terms was that the Compulsory Licence was "solely for the purposes of making, using, offering to sell and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the territory of India"; (v) that Natco was however manufacturing the product covered by the Compulsory Licence for export outside India; (vi) that the export by Natco was contrary to the terms of Compulsory Licence and amounted to infringement of the patent within the meaning of Section 48 of the Patents Act.

4. Notice of W.P.(C) No.1971/2014 was issued and vide order dated 26th March, 2014 therein, the Customs Authorities were directed to ensure that no consignment from India containing 'SORAFENAT' covered by Compulsory Licence was exported; however liberty was given to Natco to apply to the Court for permission to export the drug as and when it obtained permission from the Drug Controlling Authority for clinical purposes. Subsequently, on 23rd May, 2014, Natco pointed out that in fact it has already been granted a drug licence and with the consent of the counsel for Bayer, Natco was permitted to export the drug SORAFENIB TOSYLATE' not exceeding 15 gm for development / clinical studies and trials. Natco again applied for permission to export 1 Kg. of Active Pharmaceutical Ingredient (API) SORAFENIB to China for the purposes of conducting development / clinical studies and trials. The said application was contested by Bayer.

5. Natco filed a counter affidavit in the writ petition *inter alia* pleading (a) that Natco had not exported any products subject matter of Compulsory

Licence; the exports of which instances were given by Bayer were by third parties without notice, consent and knowledge of Natco; (b) that under the scheme of the Drugs and Cosmetics Act, 1940 (Drugs Act) permission is routinely granted for export of API to various countries upon compliance of certain conditions; there are similar provisions in the western countries as well including Europe; (c) that the Patents Act also provides that export of a patented product for generation or submission of regulatory permission is not an act of infringement; (d) that the export for which permission was sought by Natco from Court was also for regulatory purposes; (e) that such exports are not at all covered by the Compulsory Licence; (f) that the activity of conducting studies for regulatory approval is squarely covered under Section 107A of the Patents Act; (g) that Natco had never exported the finished product 'SORAFENAT' to any party outside India for commercial purpose.

6. Bayer, in its rejoinder to the counter affidavit aforesaid pleaded (i) that Section 107A of the Patents Act has no application as the acts contemplated thereunder, of making, constructing, using, selling or importing a patented invention, are to be performed within the territory of India and the information from such activity can be submitted with the regulatory authorities either in India or with the countries other than India; (ii) that Section 107A of the Act does not contemplate export of product *per se* but is limited to information generated within the territory of India; and, (iii) that export of a product covered by Compulsory Licence under the garb of Section 107A of the Act is abuse of the process of law.

7. Vide detailed order dated 5th November, 2014, Natco was permitted export of SORAFENIB for carrying on activities for obtaining regulatory

approvals within the meaning of Section 107A of the Act. Bayer preferred LPA No.804/2014 against the said order and which was disposed of by expediting the hearing of the writ petition and by prohibiting export till the decision of the writ petition. The hearing of the writ petition commenced on 7th September, 2015 and concluded on 8th July, 2016, when orders were reserved.

8. It was the contention of the senior counsel for Bayer in W.P.(C) No.1971/2014 (a) that the rights if any of Natco under Section 107A of the Act stood surrendered on Natco obtaining Compulsory Licence and thereafter Natco was governed only by the terms of the Compulsory Licence; (b) that such giving up of statutory rights under Section 107A of the Act flows from Section 84(4) of the Patents Act; (c) that the word 'selling' in Section 107A of the Patents Act means 'selling in India only' and does not include export; (d) that the words "or in a country other than India" in Section 107A relate to "the law for the time being in force"; (e) that Section 107A of the Act uses the word 'import' and from absence of the word 'export' therefrom, the only logical conclusion is of exports of patented invention being outside the ambit of Section 107A of the Act; (f) that the patented invention can be used only in India for conducting trials and the information generated from the said trials can be furnished to the concerned authorities in a country other than India; (g) that the word 'buying' in Section 107A of the Act would have included the word 'import' also; however from the fact that besides using the word 'buying', the word 'importing' has also been used, it follows that buying did not include import—similarly, selling will not include export; (h) that only Bayer as patentee has exclusive right to export, not only the finished product which

comprises of API plus excipients but also the APIs *per se*; (i) attention was invited to Rule 122B(1)(a) and to Rule 122B(2) and to Schedule Y Appendix I of the Drugs and Cosmetics Rules, 1945 (Drugs Rules) to contend that the licence for approval to manufacture new drug granted thereunder is for the purposes of carrying out trials in India only and not for carrying out trials outside India; (j) that Section 107A of the Act, owing to its history, is called the 'Bolar Provision' and is only to enable the activities mentioned in Section 107A of the Act within India and not for exports; (k) that Section 107A of the Act was not enacted for seeking approval to manufacture a new drug in other countries; (l) that the purpose of Section 107A is to allow manufacturers other than the patentee to manufacture and market the patented drug immediately after the patent expires; (m) to read the word 'export' in Section 107A would amount to making laws for other countries; (n) clinical trials can be carried out in India for obtaining permission to sell in countries other than India – it is for this reason only that the words "or in a country other than India" find mention in Section 107A; (o) though export of patented products by a person other than the patentee is also prohibited under Section 48 of the Patents Act but the need to mention the word 'export' was not felt as without making the patented product in India, the question of exporting the same does not arise – thus the use of the word 'export' therein would have been redundant (I had at that stage enquired from the senior counsel for Bayer that on the same parity of reasoning, without making, no selling would have been possible, but the word 'selling' has nevertheless been used in Section 48); (p) the law relating to patents is a territorial law and governs territorial rights and cannot have any extra territorial operation; (q) the exports depend upon whether another country allows entry of the

goods or not; (r) on the same parity of reasoning, the activities permitted in Section 107A also have to be read as permitted in India and not outside India; (s) the purport of Section 107A is not to enable other countries / foreigners to obtain market approval in their own countries; and, (t) it is not the case of Natco that Natco wants marketing approval for itself in the countries to which it is wanting to export the API.

9. The senior counsel for Natco argued i) that the exports intended by Natco are only for research and development purposes and to obtain the drug regulatory approvals in the countries to which exports are intended; ii) the component of the drug which has the healing / curative powers is the API; however API cannot be consumed directly; other ingredients have to be added to API to enable the API to reach the target organ; such other ingredients are called excipients / formulation; iii) Natco has Compulsory Licence for manufacturing API of the product of which Bayer claims patent and for marketing the drug by combining the said API with excipient/formulation; iv) that the drug regulatory regime of China requires clinical trials to be conducted in China and do not recognize clinical trials conducted in India; v) Natco is not intending export of the product covered by the Compulsory Licence for commercial purposes; vi) attention was invited to the relevant extracts of the rules of China Food and Drug Administration; vii) before a new drug is granted marketing approval, the drug regulatory authorities have to test its safety, efficacy and therapeutic value by requiring clinical trials to be undertaken; viii) however once a marketing approval has been granted, another manufacturer of the same drug (called the producer of generic drug) can obtain marketing approval of the same without being required to conduct any clinical trials and only by

satisfying the Drug Controlling Authority of its bio-equivalence and bio-availability; ix) Indian pharmaceutical industry is the largest exporter of generic drugs; x) the Indian generic industry is the biggest supplier of medicines to the developing world; xi) research and development activity with respect even to patented drugs, for submission of data to the Drug Regulatory Authority, is not infringement; xii) Natco, even before obtaining the Compulsory Licence had done the bio-equivalence and bio-availability tests and there was no objection from Bayer thereto; xiii) it is for this reason only that Natco, immediately after obtaining the Compulsory Licence, was able to introduce the drug in the Indian market; xiv) it is not as if without the Compulsory Licence Natco could not have developed the API of the patented drug for the purposes mentioned in Section 107A; xv) Section 48 of the Patents Act is subject to other provisions of the Act; xvi) Section 107A is not an exception to Section 48; xvii) Section 107A, during the validity of patent also, permits generation of data required by the laws of other countries for obtaining approval for manufacture, use and sale of products; xviii) if the laws of any other country require making and use of the patented invention in that country, for the purpose of granting the requisite approvals, to hold that Section 107A prohibits export of API to that country would amount to restricting the scope of Section 107A; xix) similarly, Section 84 of the Patents Act dealing with grant of Compulsory Licence is also an exception to Section 48; xx) the wide ambit of Section 107A is evident from the use of the words 'reasonably related to the development and submission of information....' instead of the words "actually related to the development and submission of information required.....'; xxi) the rights of Natco under Section 107A are independent of the Compulsory Licence and Natco, from

the grant of Compulsory Licence, has not been placed in any more advantageous position vis-a-vis its activities under Section 107A; xxii) that different ethnic populations have different DNA which reacts differently to same drugs – that is why the need for conducting local trials; xxiii) selling includes export; reliance was placed on para 8 of ***State of Travancore-Cochin Vs. The Bombay Co. Ltd.*** AIR 1952 SC 366; xxiv) it is not the allegation of Bayer also that the exports intended by Natco are for commercial purpose; xxv) reliance was placed on para no.8 of ***Padma Ben Banushali Vs. Yogendra Rathore*** (2006) 12 SCC 138 to contend that Sections 107A, 48 and 84 have to be ready harmoniously; xxvi) the laws of USA allow export of patented products to another country for research and development; xxvii) reliance was placed on ***Intermedics INC Vs. Ventritex Co. Inc*** 991 F.2d 808; xxviii) reference in this regard was made to Section 84(6) and attention was invited to the marketing approval dated 13th May, 2011 and to the application dated 28th July, 2011 for Compulsory Licence; xxix) Compulsory Licence, though statutory, is a contract and statutory provisions as Section 107A cannot be contracted out of; xxx) reference was made to Sections 90 and 93 of the Patents Act to contend that grant of Compulsory Licence cannot be in negation of the rights under Section 107A; xxxi) reliance was placed on the **Panel Report of the World Trade Organization in Canada-Patent Protection of Pharmaceutical Products, on the complaint by the European Communities and their member states**; xxxii) for India to continue exporting generic medicines, it is essential that the requisite drug regulatory provisions in the destination countries are applied for and obtained well before the expiry of the patents; it is only thereafter that India will be able to export the generic medicine to

those countries; to hold that the word 'export' cannot be read in Section 107A would be a barrier to such trade; xxxiii) to hold that export is not permitted would make the words 'or in a country other than India" in Section 107A redundant and otiose; xxxiv) that Natco is willing to subject itself to appropriate conditions to satisfy Bayer that exports intended are not for commercial purposes; xxxv) the process of obtaining marketing approvals takes minimum two years time; and, xxxvi) if it were to be held that person other than the patentee, for the purpose of development and research also cannot manufacture a patented product and obtain marketing approvals thereof, it would amount to extending the life of a patent from the maximum of 20 years to 22 or more years inasmuch as if the process for obtaining marketing approvals was to begin only after the expiry of the patent, the process would consume another two or more years conferring exclusivity on the patentee beyond the term of the patent.

10. The senior counsel for Bayer, in rejoinder, argued a) that the subject patent is valid till the year 2020; b) the Chinese drug regulatory authorities permit trials and marketing approvals to be applied only two years prior to the expiry of the patent – thus the exports by Natco to China cannot be to obtain approval; c) even otherwise, the Chinese entity to whom Natco is wanting to export, if requires the patented product for the purpose of obtaining approvals, can purchase it from Bayer in China; d) not reading the word 'export' in Section 107A would not sound the death knell for the Indian generic industry – it can seek approvals from the Drug Regulatory Authorities in India and can on the basis of data / information generated from trials / tests in India, also apply for marketing approval in a foreign country; e) it is not necessary that every generic drug producer should have the

capability to produce the API; f) there are 'fine chemical producers', who, though have ability to produce API in small scale, are unable to manufacture on a larger scale; such fine chemical producers only produce API and sell the same to the manufacturers / producers of generic drugs; it is for this reason only that Section 107A uses the word 'selling; g) to allow patented products to be exported can lead to infringement of patent abroad and over which infringement this Court would have no jurisdiction though the action within India would have led to such infringement; h) section 107A is an exception to Section 48 but only for the benefit of the Indian manufacturers and not for the benefit of the foreign manufacturers; it is for this reason only that the word 'export' has been deliberately omitted from Section 107A; i) reliance was placed on **judgment dated 23rd October, 2013 of the Supreme Court of Poland in reference No.IV CSK 92/2013**; j) though Natco claims that its exports are for research and development purpose but once export is effected, this Court would have no control over the use of the exported goods in foreign jurisdiction; k) the **Panel Report of the World Trade Organization** supra was only concerned with whether the Canadian legislation equivalent to Section 107A having the world 'selling' was violative of Articles 27,28 and 30 of the TRIPS Agreement and held that it is not; and, l) only the Courts in Singapore have held exports for research and development purpose to be permissible as Singapore being a small country having no facility for trials / large scale manufacture.

11. The senior counsel for the Natco in sur-rejoinder argued; i) that Section 48 has to yield to Section 107A and Section 84; ii) section 107A permits making and selling of patented product for profit, as long as it is for the purpose prescribed therein; iii) it is not essential for other generic

manufacturers of drugs to be also a producer of fine chemicals or APIs; iv) if the Chinese laws do not permit tests to be carried out before two years of the expiry of the patent, naturally they would not be carried out but the same is not a bar to exports; v) that the interpretation of Section 107A cannot change from country to country, depending upon whether that country's regulatory regime permits trials and tests to be carried out in India or not; vi) if it is found by Bayer that API exported from India has been misused, Bayer can always institute a suit in China restraining infringement; and, vii) that Natco is willing to give an undertaking not to export for commercial purposes or for any purpose other than those mentioned in Section 107A.

12. CS(COMM) No.1592/2016 has been filed by Bayer Intellectual Property GmbH and Bayer Pharmaceuticals Ltd. (both, also Bayer) to injunct Alembic Pharmaceuticals Ltd. (Alembic) from making, selling, distributing, advertising, exporting, offering for sale and in any manner directly or indirectly dealing in 'RIVAROXABAN' and any product that infringes Bayer's patent IN 211300 and for ancillary reliefs pleading i) that the subject patent is registered in the name of Bayer and is titled "OXAZOLIDINONES AND THEIR USE"; ii) that Alembic is manufacturing and exporting RIVAROXABAN to the European Union; iii) that Alembic has made multiple Drug Master File submissions to the United States Food and Drug Administration in the United States of America for the drug RIVAROXABAN; iv) that a drug Master File is a submission to the United States Food and Drug Administration that is used to provide confidential detailed information about the facilities, processes and articles used in the manufacturing, processing, packaging and storing of one or more human drugs; v) that Alembic has also filed a patent application for grant of a patent

over the process of manufacturing of RIVAROXABAN; that the said application of Alembic specifically refers to Bayer's patent and states that RIVAROXABAN is disclosed by Bayer's patent; and, vi) that Alembic is thus infringing Bayer's patent.

13. CS(COMM) No.1592/2016 came up before the Court on 14th December, 2016 when Alembic stated that the exports being effected by Alembic were within the meaning of Section 107A only. Thereafter, on 15th December, 2016, a categorical statement was made by Alembic that Alembic till then had not commercially launched the drug RIVAROXABAN and had only exported the drug within the meaning of Section 107A and that Alembic, if at any time in future intends to launch the drug RIVAROXABAN, will give one month's notice to Bayer to enable Bayer to avail of its remedies. It was the contention of Bayer on that date that Alembic exported at least 90 Kg. RIVAROXABAN worth Rs.3 crores and export of such quantity could not be within the meaning of Section 107A.

14. Attention of the counsels in CS(COMM) No.1592/2016, on 15th December, 2016, was drawn to W.P.(C) No.1971/2014 aforesaid in which judgment had been reserved; in the circumstances, since only legal question of interpretation of Section 107A of Patents Act was to be decided, need to call for written statement was not felt and binding Alembic to its statement aforesaid and with direction that Alembic thereafter will not effect any export without giving 15 days notice to the plaintiff, hearing of arguments in addition to those already addressed in the writ petition, was commenced. As a result thereof, the decision of the application subsequently filed by Alembic for effecting exports to Brazil and Palestine was adjourned. Arguments were concluded on 14th February, 2017 and judgment reserved.

15. The counsel for Bayer in CS(COMM) No.1592/2016 has argued i) that as per ***Roche Products, Inc. Vs. Bolar Pharmaceutical Co.*** 572 F. Supp. 255 (E.D.N.Y. 1983), even experimentation, research and development in the patented product was prohibited as the same would have eventually led to commercial exploitation; ii) the Hatch Waxman Act, 1984 amended the Patents Act of USA to undo ***Roche Products, Inc. Vs. Bolar Pharmaceutical Co.*** supra; iii) that was the origin of Section 107A of the Patents Act; iv) the purport of Section 107A and of Bolar Provisions in Patent Laws of countries is to prevent the maximum life of the patent from being extended, as experimentation, research, development and obtaining of marketing approval takes minimum two years time and during which patentee, notwithstanding expiry of patent, enjoys exclusivity/monopoly; v) reliance was placed on the Minutes of the Joint Parliamentary Committee constituted to amend the Patents Act of India; vi) Section 107A came into existence in the Patents Act for the first time in the year 2002 and it was amended in the year 2003; the word 'export / exporting' was consciously not added thereto; vii) research, development and trials / tests conducted in India and data / information generated can be used to obtain approvals abroad; viii) there is no need to carry out any tests outside India; ix) Section 107A permits only export of data and not patented invention; x) that even if it is held that under Section 107A the patented invention can be exported for the purposes prescribed therein, some controls need to be imposed to ensure that once the API goes outside the jurisdiction of this Court, it is not misused for commercial purpose.

16. Per contra, the senior counsel for Alembic argued a) that export is included in the word 'sale'; b) the successive amendments during the

insertion of Section 107A in the Patents Act show an intention of the legislature to give it expansive meaning; reliance was placed on the minutes and deliberations of the Joint Parliamentary Committee in this regard; c) Section 107A by its very language travels beyond the domestic market; d) reliance was placed on para 12 of ***State of Orissa Vs. Joginder Patjoshi*** (2004) 9 SCC 278 to contend that where the language is clear, it cannot be interpreted in any other way; e) merely because reading the language of Section 107A so would include 'exports' and which may lead to misuse, is no ground to interpret the language of Section 107A differently; f) if there is misuse, then Bayer can bring another action establishing the same; g) Supreme Court, to prevent Indians from being used as guinea pigs, has banned clinical trials in India for obtaining drugs approval abroad; h) that different countries have different requirements for clinical trials; some countries require trial on lakhs of people and which requires API in large quantity; i) reference was made to the statutory provisions of USA, Europe, UK, Germany, Australia, New Zealand; j) India has not imposed any limitations as some of the other countries have done; k) Alembic cannot be directed to disclose the persons to whom it is exporting, as Bayer is the competitor of Alembic in this regard.

17. I have considered the rival contentions and have also perused the written submissions.

18. The Indian Legislature, by enacting Patents Act, having codified the law relating to patents and having vide Section 107A thereof laid down that any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to 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 shall not be considered as infringement of patent right, the question, whether a non-patentee, thereunder can 'export' a patented invention for use, reasonably related to development and submission of information required under any law in a country other than India that regulates the manufacture, construction, use, sale of such products, is in the realm of statutory interpretation. Statutory interpretation is the process by which the Courts seek to ascertain the meaning of the Legislature through the medium of authoritative forms in which it is expressed (Salmond: Jurisprudence 11th Edition page 152). Though academicians have differentiated between interpretation of a statute and construction of a statute but in Courts, no difference between the two has been recognised (Justice G.P. Singh: Principles of Statutory Interpretation, 13th Edition (2012) page 2).

19. A statute, like the Patents Act is, being an edict of the Legislature, the best medium for interpretation thereof is the words of a statute. Supreme Court in ***Guru Jambheshwar University Vs. Dharam Pal*** (2007) 2 SCC 265 has reiterated that the words of a statute are first understood in their natural, ordinary or popular sense and phrases and sentences are construed according to their grammatical meaning, unless that leads to some absurdity or there is something in the context or in the object of the statute to suggest to the contrary. The true way is to take the words as the Legislature has given them and to take the meaning which the words naturally imply, unless where construction of those words is, either by the preamble or by the context of the words in question, controlled or altered. The golden rule is that the words of a statute must *prima facie* be given their ordinary meaning and

natural and ordinary meaning of the words should not be departed from, unless it can be shown that the legal context in which the words are used requires a different meaning. In ***Hiralal Ratanlal Vs. STO*** (1973) 1 SCC 216 reiterated in ***Raghunath Rai Bareja Vs. Punjab National Bank*** (2007) 2 SCC 230 it has been held that the first and the foremost principle of interpretation of a statute in every system of interpretation is the literal rule of interpretation and the other rules of interpretation i.e. the mischief rule, purposive interpretation etc. can only be resorted to when the plain words of a statute are ambiguous or lead to no intelligible results or if read literally would nullify the very object of the statute. Where the words of a statute are absolutely clear and unambiguous, recourse cannot be had to the principles of interpretation other than the literal rule. The language employed in a statute is the determinative factor of the legislative intent. The Legislature is presumed to have made no mistake. The presumption is that it intended to say what it has said.

20. I thus proceed to reproduce herein below Section 107A of the Patents Act:

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

21. Though Section 107A prescribes the "acts which are not to be considered as infringement of patent rights" but there is no provision in the Patents Act prescribing as to what is infringement of patent rights or what acts constitute infringement of patent rights. However, Section 48 reproduced herein below:

> *"**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.",*

while prescribing the rights of patentee prescribes the rights, which on conferment of patent, vest exclusively in the patentee. Axiomatically, exercise of any of those rights by a non-patentee would be infringement of patent. Thus, the acts of a non-patentee, of making, using, offering for sale, selling patented products would be infringement of patent and the patentee is entitled to approach the Courts to prevent the non-patentee from doing the said acts.

22. However Section 107A provides that the acts of a non-patentee of making, using, selling a patented product for the purposes prescribe therein shall not be considered as infringement. Axiomatically, the patentee cannot prevent non-patentee from doing them.

23. The acts of "making", "using", "selling" or "importing" referred to in Section 107A are the same as mentioned in Section 48. But for Section

107A, the acts of making, constructing, using, selling or importing of a patented invention, even if for the purposes prescribed in Section 107A would have constituted infringement of the patent. The additional word "constructing" in Section 107A and the additional words "offering for sale" in Section 48 which are not to be found in the other, for the present purposes have no relevance. It is thus 'the purpose for which the said acts are done' which distinguishes, whether the acts constitute infringement of patent or not. If the said purpose is within the confines of Section 107A, the acts so done would not constitute infringement and the patentee cannot prevent a non-patentee from doing them. However, if the purpose of doing the acts of making, using, selling or importing a patented invention is not solely for the purposes prescribed in Section 107A, the said acts would constitute infringement of patent and patentee can prevent non-patentee from doing them.

24. The counsels are *ad idem* on the spirit of / basis for Section 107A. The manufacture and sale of pharmaceutical products is regulated by law in nearly all countries and which laws prohibit manufacture and sale of pharmaceutical products without obtaining prior approvals and obtaining which approvals. The process of development and of obtaining manufacturing, marketing and selling such approvals takes a minimum of two years' time. If the process of development of a patented invention and of obtaining manufacturing and marketing approval thereof were to be commenced after the expiry of the term of the patent, it would result in the patentee, notwithstanding the term of his patent having expired, enjoying the exclusive right to manufacture and sell and market the product till anyone else develops the patented invention and obtains approvals for manufacturing

and marketing / selling thereof. It was thus deemed necessary to allow the acts of making, using, selling a patented invention, even during the life of the patent but solely for uses reasonably related to the development and submission of information required under the law for obtaining approval. In this way, a non-patentee can be ready to manufacture and market pharmaceutical products from the very moment of expiry of term of patent.

25. A person with no background of pharmaceutical industry would wonder why Section 107A would use the word 'selling'; it would ordinarily be presumed that it is only a person capable of manufacturing patented invention after the expiry of the term of the patent who would be interested in making or constructing or developing the same and in obtaining approvals for commencing the manufacture and marketing the same on expiry of the term of the patent. However the counsels inform that the manufacturers and marketers of pharmaceutical products are not always themselves the developers of such pharmaceutical product. Pharmaceutical product, as a consumer knows, in the form of medicines for oral or injectable consumption comprise of (a) API; and, (b) formulation / excipients, with the API having curative ability and the formulation / excipient being in the nature of carrier of API to the targeted organ. The invented product qua which patent is granted is generally the API. API may not always be developed / constructed by the manufacturer / producer and marketer of pharmaceutical products. There are others, known as Fine Chemical Producers, who make and develop the API component of the medicine and obtain approvals therefor and sell and supply the same to the manufacturers / producers of medicines / pharmaceutical products. Alternatively, such Fine Chemical Producers may develop and construct the API and sell the same to the

manufacturers / producers of medicines for the said manufacturers / producers of medicines to obtain approvals under the applicable laws for manufacturing and marketing thereof. Hence the need for the word 'selling' in Section 107A. Thus, sale by a non-patentee of a pharmaceutical product solely for the purposes prescribed in Section 107A would also not be infringement and cannot be prevented.

26. The counsels for Bayer could not controvert that such selling of patented invention, even if for profit, as long as solely for the purposes prescribed in Section 107A, is not infringement and cannot be prevented.

27. The point of difference between Bayer and Natco / Alembic is qua selling outside India. While Bayer contends that the word 'selling' in Section 107A is confined to within the territory of India and selling of patented invention outside India even if for purposes specified in Section 107A would constitute infringement which can be prevented by patentee, the contention of the senior counsels for Natco / Alembic is that use of the word 'selling' under Section 107A is without any such restriction of being within India only and would include selling outside India also, so long as solely for the purposes prescribed in Section 107A.

28. The counsels for Bayer, to explain why Section 107A refers to the purpose of development and submission of information required under law in a country other than India that regulates manufacture, construction, use and sale of pharmaceutical products, if selling referred to in Section 107A was to be within the confines of India contend that the information generated in India and required under law of a country other than India to be submitted for obtaining approval for manufacture and marketing of any pharmaceutical product in that country can be submitted without the sale of patented

invention outside the country. According to them, transfer from India to any other country can be only of information gathered / collected in India and required to be submitted under the laws of any other country for obtaining approvals for manufacture and sale of pharmaceutical products in that country.

29. According to me, to uphold what Bayer contends, would be contrary to the natural / literal / textual interpretation of Section 107A of the Patents Act. To ascribe natural / literal / textual meaning to the language of Section 107A of the Patents Act, I proceed to dissect clause (a) thereof as under:

(i) Any act of making, constructing, using, selling or importing a patented invention

(ii) solely for uses reasonably related to 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

(iii) shall not be considered as infringement of patent rights

30. It becomes immediately evident that 'selling' permitted by Section 107A is of 'a patented invention' i.e. a 'product' and not of 'information'. The word 'information' is in the context of 'required to be submitted to any authority under any law of India or of a country other than India regulating the manufacture and marketing of any product'. Section 107A, as per its natural / literal / textual meaning requires selling of a patented invention solely for submission of information required under any law for the time being in force in a country other than India that regulates the manufacture, construction, use and sale of any product, to be not considered as infringement of patent right. The counsels for Bayer are unable to dispute

that Section 107A envisages development and submission of information required under any law of a country other than India for obtaining approvals for manufacture and marketing of pharmaceutical products in that country. However contend that development of the information, required to be submitted in a country other than India, by making, using and constructing and selling of patented invention in India only. Significantly, the counsels for Bayer, qua 'selling' within India, admit can be of patented invention i.e. of the product, by Fine Chemical Producers of India to manufacture or producers of pharmaceutical products in India and do not insist, should be of information only. However when it comes to 'selling' outside India, they insist cannot be of patented invention or product and can be of information only. I am unable to read such dichotomy in the language of Section 107A. It is not found to distinguish between making, constructing, using, selling for submission of information required under law in India and under the law of a country other than India.

31. I am also unable to accept the contention of Bayer that, use of the word 'selling' refers to 'selling' within India only.

32. 'Sale', in Black's Law Dictionary, 10th Edition, is defined as transfer of property or title having the elements of i) parties competent to contract; ii) mutual assent; iii) a thing capable of being transacted; and, iv) a price in money paid or promised to be paid**.** Thus, use of the word 'sale'/'selling' entails transfer of property or title in a thing and does not contain any territorial limitations viz. of being within the country or State.

33. What immediately comes to mind is the use of the expression "sale in the course of export of goods out of the territory of India" in Article 286 of the Constitution of India while prohibiting the States from making law

imposing or authorizing imposition of a tax on the sale or purchase of goods. Thus, 'sale', entailing transfer of goods out of territory of India, though would also qualify as 'export' but nevertheless remain a sale.

34. Export is defined in Black's Law Dictionary supra as the process of transporting products or services to another country, to send or carry abroad, to transport merchandise from one country to another in the course of trade or to carry out or convey goods by sea. A Constitution Bench of the Supreme Court in ***Burmah Shell Oil Storage and Distributing Company of India Ltd. Vs. Commercial Tax Officer*** AIR 1961 SC 315 held that though export often involves a commercial transaction but not necessarily. Per contra, 'sale' as noticed above, is for a price and would always qualify as a commercial transaction. It thus follows that while sale by way of export would remain a sale but all exports may not be by way of sale.

35. The words 'sale'/ 'selling' thus, as per their literal / natural / textual meaning are without any geographical limitations and in Section 107A are not to be understood as 'within India' only and if such sale / selling were to involve transfer of the patented invention / product to a country other than India though would also qualify as export / exporting but would not cease to be sale / selling.

36. I must however admit that it is not as if statutes never refer to the word 'export' or that 'sale' always includes 'export'. I have already noticed Article 286 of the Constitution above, making a distinction between sale of goods, sale of good in the course of export and sale of goods outside the State. Different statutes depending on their purport and context use 'sale' and 'export'. The next thing thus to be considered is, whether there is anything in Section 107A or elsewhere in the Patents Act which requires

'selling', in the absence of the word 'exporting' to be interpreted as excluding 'selling by way of export'.

37. As far as Section 107A is concerned, use therein of the words 'law for the time being in a country other than India' is evidence of, obtaining regulatory approvals in countries other than India being contemplated by the legislature. With such contemplation, the legislature provided that certain acts mentioned in Section 107A, required to be done for the purpose of obtaining such approval, would not be considered as infringement of patent rights. One of such acts is of selling of patented invention. The plain meaning of Section 107A is that selling of patented invention for obtaining regulatory approval in country other than India would entail transfer of patented invention i.e. product from India to that country. There is nothing in the language of Section 107A to suggest that only the information generated / collected in India could be transported out of India and not the patented invention. Information generated in India, unless accepted under the law of any other country for granting regulatory approvals for manufacture, sale and import in that country, would be of no use. There is nothing in the language of Section 107A to indicate that the legislature applied itself that the regulatory laws of countries other than India would accept the information generated and collected in India. The counsels for Bayer during the hearing also could not demonstrate that information collected / generated in India would be acceptable for grant of regulatory approvals for manufacture and sale of drugs in other countries. Even otherwise, the interpretation of laws of India cannot be dependent on foreign laws. I have not found any provision elsewhere in the Patents Act requiring the word 'selling' in Section 107A to be restricted to 'within India' only.

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

38. The counsels for Bayer, in the written submissions, have cited Sections 84(7), 90(1), 92A of Patents Act to contend that the same expressly use the word 'export', indicating that wherever the legislature contemplated export, has provided so.

39. I am unable to agree. The words 'export' or 'exporting' are not mentioned therein in addition to the words 'sale' or 'selling' for it to be inferred that the words 'sale' / 'selling' when used in other provisions without the words 'export' or 'exporting' mean 'sale' or 'selling' except by way of export. Those provisions deal only with 'export' of patented products / process and naturally had to use the words 'export' or 'exporting'. The inference sought to be drawn therefrom does not follow.

40. Interestingly, the word 'export' is missing also from Section 48 of the Act. I had enquired from the counsels for Bayer, whether in the absence thereof it has to be held that a patentee has no exclusive right to export the patented product and / or to prevent another from exporting the patented product.

41. The counsels for Bayer contended that there is no need for the word

'export' in Section 48 because export is not possible by a non-patentee without making the patented product in India and exclusive right whereof is in the patentee.

42. Export however need not necessarily follow the act of making. The maker and the exporter of the patented product can be different. The non-patentee maker of the patented product can always, without sale, transfer the product to another who may export the same. Though I agree with the counsels for Bayer that export of patented product is also the exclusive right of patentee and covered by Section 48, but for the reason of the same being covered in sale / offering for sale and export in the course of sale being sale.

43. I may notice that Sections 48 as well as 107A also do not have the word 'buying'. The need, in Section 48, for conferring a right in the patentee to prevent others from buying the patented product from non patentee was not felt because once making and selling by non-patentee is prevented, the occasion for buying from non-patentee would not arise. However the need in Section 48 for preventing importing into India for the purpose of making, using, offering for sale, selling the product in India was felt because import could be without an element of making and selling in India. Similarly, need for the word 'importing' in Section 107A was felt to allow import of patented invention solely for the purposes mentioned therein. Section 107A is thus envisaging import into India of a patented invention solely for development and submission of information for obtaining regulatory approvals. I highlight, it is not referring to import of information but to import of patented invention. Once Section 107A permits import into India of a patented invention, there is no reason to read selling as excluding exports. Not only so Section 107A envisages obtaining regulatory approval

in countries other than India not only for manufacturing and sale of any product in that country but also for import into that country of any product. The laws of other countries may provide development and submission of information one kind qua grant of approvals for manufacture and sale in that country of any product and development and submission of information of different kind qua grant of approval for import into that country of any product. While for latter submission of information and development in country of origin of goods may suffice, it may not for former.

44. From the aforesaid it also follows that presence of word 'import' and absence of the word 'export' in Section 107A does not lead to any inference of the word 'selling' therein being exclusive of in the course of export. While the need for 'exporting' was not felt due to presence of the word 'selling', the need for the word 'importing' in Section 48 was necessary to preserve exclusive right of patentee and in Section 107A to allow import for purposes prescribed therein.

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

46. Once 'selling' has an element of price paid or promised to be paid and it cannot be controverted that, so long as for purposes of Section 107A, can be for profit, making and selling by way of export even if for purpose of Section 107A, by a non-patentee, of patented invention, is a occupation, trade or business carrying on whereof has under Constitution of India been conferred a status of fundamental right and which can be curtailed by law only. In the absence of any law prohibiting export of a patented invention for purposes permitted under Section 107A, no such prohibition can be

inferred. Supreme Court in ***Union of India Vs. Asian Food Ltd.*** (2006) 13 SCC 542 has held that a citizen of India has a fundamental right to carry out the business of export.

47. Undoubtedly, none can have a fundamental right to trade in what by law as the Patents Act is the exclusive right of another. However while Section 48 on the one hand confers exclusive right to make and sell patented product on the patentee, coupled with the right to prevent others from infringing such exclusive right, Section 107A provides that making and selling solely for purposes prescribed therein is not infringement. There is no reason to read and interpret Section 107A as a proviso to Section 48, as is the contention of counsels for Bayer. The legislature also, in the year 2002, when incorporating Section 107A in the Patents Act for the first time, did not choose to incorporate it as a proviso to Section 48 or even in Chapter VIII titled "Grant of patents and rights conferred thereby" of the Act but rather chose to place it in Chapter XVIII titled "Suits concerning infringement of patents", alongside Section 107 titled "Defences etc. in suits for infringement" and to adopt the language in Section 107A, of acts mentioned therein not constituting infringement i.e. exclusive right to do those acts not vesting in the patentee. Thus, while under Section 48 of the Act exclusive right to make and sell patented product and to prevent infringement of the said right has been granted to the patentee, under Section 107A it is clarified that making and selling patented products solely for purposes mentioned therein is not infringement. It follows that grant of patent under the Act does not confer on the patentee right to prevent others from making and selling patented product if solely for purposes prescribed in Section 107A. These are two independent provisions, admitting of no overlap or need to read one

as a proviso (and consequently narrowly) to another. Once it is found that making and selling of patented product is solely for purposes prescribed in Section 107A, the legislature prohibits treating or considering same as infringement of patent.

48. Supreme Court, in ***Nand Kishore Mehra Vs. Sushil Mehra*** (1995) 4 SCC 572, dealing with Sections 3(1) and 3(3) of the Benami Transactions (Prohibition) Act, 1988 which prohibits a person from entering into any benami transaction, Section 3(2) which permits a person to enter into a benami transaction of purchase of property in the name of his wife or unmarried daughter and Section 4 of the said Act which prohibits a person from enforcing rights in a property held benami, held that to hold that a person who is permitted to purchase a property benami in the name of his wife or unmarried daughter cannot enforce his rights in the property would amount to holding that the Statute which allows creation of rights by a benami transaction also prohibits enforcement of such rights, a contradiction which can never be attributed to a Statute. Similarly here, to hold that inspite of the legislature having declared the actions listed in Section 107A to be not amounting to infringement, the same have to be viewed putting on the blinkers of being infringement, would amount to holding that the Patents Act which allows actions listed in Section 107A to be done without the same constituting infringement cannot be done to the extent permitted by the language of Section 107A. The rights conferred on non-patentees under Section 107A are to be interpreted following the same rules as the rights of a patentee and are not to be read narrowly or strictly so as to reduce the ambit of Section 107A, as is the rule of interpretation of statutes in relation to provisos or exceptions. Thus, Section 48 on the one hand and

Section 107A on the other hand are to be read as any two provisions of a statute. Reliance by the senior counsels for Natco/Alembic in this regard on ***Padma Ben Banushali Vs. Yogendra Rathore*** (2006) 12 SCC 138 holding that both the statutory provisions should be allowed to operate without rendering either of them otiose, is apposite.

49. I will next consider the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the foreign reports/ judgments cited.

50. India as a party to the TRIPS Agreement has agreed to give effect to the provisions thereof without being obliged to implement in its law more extensive protection than is required by the TRIPS Agreement, provided that such protection does not contravene the provisions of the TRIPS Agreement. Else, India is free to determine the appropriate method of implementing the provisions of the TRIPS Agreement within its own legal system and practice (Article I Clause 1 of the TRIPS Agreement). The objective of the TRIPS Agreement, as per Article 7 thereof, is protection and enforcement of intellectual property rights, to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations. Per Clause 1 of Article 8 of the TRIPS Agreement, member countries, in formulating and amending their laws and regulations, have discretion to adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the TRIPS Agreement. Section 5 of the

TRIPS Agreement commencing from Article 27, deals with Patents, with Article 28 providing the rights conferred by the patent and Article 30 providing exceptions to the rights conferred. Article 30 entitles the member countries to provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking into account the legitimate interest of third parties. Article 31 of the TRIPS Agreement, while providing that the laws of member countries may allow use of patented product / process for certain purpose, vide Clause (f) provides that such use should be predominantly for the supply of the domestic market of the member country authorizing such use. It is the contention of counsels for Bayer on the basis thereof, that the use permitted by Section 107A thus has to be for selling to the domestic market only and not for selling by way of export.

51. The aforesaid contention of the counsels for Bayer misses the essential point, that Section 107A is not carving out an exception to the exclusive right conferred by grant of a patent. The exclusive right conferred by the grant of patent, of selling, offering for sale and thereby profiteering and earning from the patent is only during the term of the patent. Section 107A, though permits sale of a patented product during the term of the patent but only for the purpose of obtaining regulatory approvals for manufacturing and marketing the patented product after the expiry of the term of the patent. The purchaser/s of a patented product for such a purpose would be few and negligible in comparison to the consumers of the patented product. Else there is nothing in the provisions of the TRIPS Agreement noticed by me above, to suggest that reading the word 'selling' in Section 107A as

including by way of export, would be in violation of the TRIPS Agreement. TRIPS Agreement specifically vests discretion in the member countries to in their laws adopt measures necessary to promote public interest in sectors of vital importance to their socio-economic development. Even if it were to be held that clause (f) of Article 31 thereof allows domestic operation only of Bolar provision, the legislature was entitled thereunder to, if of the view that considering the extent of the Indian Generic Industry, export for purposes of Section 107A should be permitted, to do so.

52. In the light of the latitude under the TRIPS Agreement to member countries, it matters not that the Bolar provision in the Singapore Patents Act, 1994 in Section 66(2)(h) thereof requires ensuring that the patented product sold for the purposes of obtaining approvals is not used or sold otherwise in Singapore or is exported not outside Singapore. The legislatures of all member countries of TRIPS Agreement are not expected to adopt the same language. Section 107A of our Patents Act conveys the same by using the words 'solely for the purposes of .....' For the same reason, the rationale in the **Panel Report submitted to the Disputes Settlement Body under the World Trade Organization on a complaint filed by European Communities and their States against Canada** and in the **judgment supra of the Polish Supreme Court**, would be of no avail while interpreting Section 107A.

53. That brings me to the star argument of the counsels for Bayer that once the patented invention is permitted to be sold by way of export, even if solely for the purposes prescribed in Section 107A, this Court would lose jurisdiction to enforce use thereof for the said purposes.

54. It is the settled principle that a natural / literal / textual interpretation

not permitting of any ambiguity is not to be discarded for the possibility of misuse thereof. As far back as in ***A. Thangal Kunju Musaliar Vs. M. Venkatachalam Potti*** AIR 1956 SC 246, it was held that it must be presumed unless the contrary is proved that administration and application of a particular law would be done 'not with an evil eye and unequal hand'. In the context of challenge to the *vires* of a statute, in ***Sushil Kumar Sharma Vs. Union of India*** (2005) 6 SCC 281, it was held to be well settled that a mere possibility of abuse of a provision of law does not *per se* invalidate a legislation and that merely because power may be abused is no ground for denying the existence of power. It was also held that while interpreting a provision, the Court only interprets the law and cannot legislate it; if a provision of law is misused and subjected to the abuse of the process of law, it is for the legislature to amend, modify or repeal it if deemed necessary. Merely because no provisions are stated to exist in laws relating to export of pharmaceutical products, for ensuring that API exported is used in the destination country for the purposes for which it has been exported, does not allow me to interpret Section 107A as not permitting export thereof even if the purpose declared for export is the purpose permitted. A bench of nine Judges of the Supreme Court in ***Mafatlal Industries Ltd. Vs. Union of India*** (1997) 5 SCC 536 held, that mere possibility of abuse of a provision cannot be a ground for holding the provision to be unreasonable.

55. There is another aspect of the matter.

56. Patents Act is concerned with the protection of the rights of the patentees in India only and not outside India. Neither our legislature nor this Court can impose any conditions on the use of the goods exported once they reach the destination country or ensure that such goods continue to comply

with the laws in India. The use of the goods in the foreign country would be subject to the laws of that country and cannot be regulated by laws of India or orders of Courts of India. Supreme Court in ***Drug Action Forum Vs. Union of India*** (1997) 9 SCC 609 permitted export of drugs banned in India but not in certain foreign countries. Similarly, in ***Food Industries Vs. Suwert & Dholakia (P) Ltd.*** 1982 CriLJ 1707 the High Court of Kerala held that the provisions of Prevention of Food Adulteration Act, 1954 are not applicable to foods meant for exports. The High Court of Bombay also in ***State of Maharashtra Vs. Ghanshyam K. Zaveri*** 2001 (2) MhLJ 506 held that the provisions of Drugs Act are applicable in India and contravention thereof qua drugs meant for export is not actionable. Even if it were to be believed that the patented invention once exported from this Country for the purposes prescribed in Section 107A may be used for other purposes, it is for the patentee to enforce its rights if any in that country. The laws of this country are only concerned with the sale by way of export from this country being for the purposes prescribed. As long as the sale by way of export is declared to be for purposes of Section 107A and there is nothing to suggest that it is otherwise, no fetters can be imposed.

57. Merit is also not found in the contention of counsels for Bayer that the need for patented invention for purposes of Section 107A can be met by purchasing it from the patentee. Section 107A having permitted non-patentees to make and sell patented invention for said purposes, the patentee cannot defeat them by offering to sell itself.

58. I have also considered how it is to be determined whether the export is to be for the purposes of Section 107A or otherwise. It is the contention of the counsels for Bayer that the quantities being exported are beyond that

which are required for the purpose of Section 107A and exports are being effected to countries which permit approval to be applied for only two years before expiry of patent. The counsels for Natco / Alembic controvert, contending that laws of different countries have different requirements. They also state that though the laws of some countries may provide for regulatory approvals to be applied for only a short time before expiry of patent but development work can be and has to be begun earlier. The counsels for Bayer has gone to the extent of contending that the burden of proving that the exports are for the purpose prescribed in Section 107A has to be on the exporter.

59. This Court cannot proceed to interpret the laws of the countries of intended export to determine whether the export intended in a given case is for the purposes prescribed in Section 107A. All exports by a non-patentee of a patented invention are deemed to be for the said purpose and only if proved to be otherwise, can make the exporter liable for consequences thereof in an appropriate legal proceeding.

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

61. W.P.(C) No.1971/2014 however has an additional issue for adjudication.

62. Natco has been granted a Compulsory License under Section 84 of the Patents Act with respect to the patented invention and which is subject to the

condition as prescribed in Section 90(1)(vii) of the Act as under:

> "The license is granted solely for the purpose of making, using, offering to sell and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the Territory of India."

63. It is the contention of Bayer that Natco, by virtue of the aforesaid condition, is not entitled to exercise the rights under Section 107A, even if were to be held as inclusive of export and as has been held by me hereinabove.

64. The senior counsel for the Natco in opposition argued that the rights in Section 107A are statutory rights available to all non patentees and Natco, for the reason of having been granted the Compulsory License under Section 84 of the Patents Act, cannot be deprived of the said statutory rights. It was further contended that Compulsory License though statutory, nevertheless is a license i.e. a contract and law does not permit contracting out of statutory rights.

65. During the hearing, I enquired from the counsels whether the ability of Natco to make, construct and sell by way of export the patented invention even if for the purposes of obtaining regulatory approvals under the law of any country other than India, was attributable to Natco having been granted Compulsory Licence.

66. The senior counsel for Bayer contended that Bayer was definitely at an advantage as the manufacturing and marketing of the said drug was under the Compulsory Licence.

67. Per contra, the senior counsel for Natco contended that the ability of Natco to sell by way of export the patented invention for the purposes specified in Section 107A had no connection with the grant of Compulsory

Licence to Natco. Attention was invited to Section 84(6) of the Patents Act requiring the Controller to, while considering application for grant of Compulsory Licence, take into account the ability of the applicant to work the invention to the public advantage. It was contended that it was the case of Bayer itself that Natco was infringing its patent and for which purpose Bayer had filed a suit against Natco. It was further informed that Natco, before applying for Compulsory Licence, had already made and constructed the patented invention and was in a state of readiness to work the invention to public advantage and in fact started marketing the subject drug immediately for the grant of Compulsory Licence. It is thus argued that grant of Compulsory Licence has nothing to do with the ability of Natco to sell by way of export the patented invention. It was reiterated that Natco was able to do so and had licence therefor even prior to the grant of Compulsory Licence.

68. I have considered the rival contentions and agree with the senior counsel for Natco that a grantee of Compulsory Licence cannot be deprived of his rights under Section 107A of the Act. The condition of Compulsory Licence to which attention is drawn is for making, using, and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the territory of India. However the purpose of sale under Section 107A is different and is only for obtaining the regulatory approvals under the laws of India or in a country other than India. Thus, the grant of Compulsory Licence would not come in the way of Natco exercising its rights under Section 107A as a non-patentee.

69. I thus hold that Natco as a non-patentee cannot be deprived of making, constructing and selling by way of export a patented invention for purposes

specified in Section 107A for the reason of having been granted the Compulsory Licence.

70. The next question which arises is the orders to be passed in W.P.(C) No.1971/2014 and in CS(COMM) No.1592/2016.

71. Both Natco and Alembic have denied exporting patented invention subject matter of the respective proceedings for purposes other than Section 107A of the Patents Act. They have further, without prejudice to their rights and contentions stated that they do not in future also intend to export the patented invention subject matter of the respective proceedings for purpose other than Section 107A.

72. The claim if any of Bayer in W.P.(C) No.1971/2014 of Natco having exported patented invention for purposes other than specified in Section 107A cannot be adjudicated in writ proceedings and Bayer will have to file a suit therefor.

73. CS(COMM) No.1592/2016 also has been filed on the premise of Alembic being not permitted to *per se* export the patented invention. If it is the claim of Bayer qua the patented invention subject matter of CS(COMM) No.1592/2016 that any exports by Alembic have been for purposes other than specified in Section 107A, Bayer will have to specially make out that case in a appropriately constituted suit.

74. W.P.(C) No.1971/2014 and CS(COMM) No.1592/2016 are thus disposed of (a) by directing that subject to Natco and Alembic filing an affidavit by way of undertaking of their respective Director duly supported by the Resolution of the respective Board of Directors, with advance copy to the counsels for Bayer, to the effect that they, during the life of the respective patent, will not export the respective patented invention for

purposes other than those specified in Section 107A of the Patents Act they would be entitled to export the patented invention for the purposes of Section 107A of the Patents Act; and (b) with liberty to Bayer to, if makes out a case of the exports effected or to be effected being for purposes other than specified in Section 107A, take appropriate proceedings therefor.

75. The parties are left to bear their own costs.

76. Decree sheet in CS(COMM) No.1592/2016 be prepared.

RAJIV SAHAI ENDLAW, J.

MARCH 08, 2017
'bs/gsr'/pp