

THE HIGH COURT OF DELHI AT NEW DELHI

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Judgment delivered on: 05.11.2014

+ **CM 9687/2014 in W.P.(C) 1971/2014**

BAYER CORPORATION

..... Petitioner

versus

UNION OF INDIA & ORS

..... Respondents

Advocates who appeared in this case:

For the Petitioner : Mr Sudhir Chandra, Sr. Advocate with
Mr Sanjay Kumar, Ms Arpita Sawhney
and Mr Arun Kumar.

For the Respondents : Mr Riput Daman S. Bhardwaj, CGSC
and Mr T.P. Singh for UOI.
Mr Mukesh Anand with Ms Sonia Sharma,
Mr V.C. Jha for R-2 to 4 Customs Department.

CORAM:

HON'BLE MR. JUSTICE VIBHU BAKHRU

JUDGMENT

VIBHU BAKHRU, J

1. This is an application filed on behalf of respondent no.5 (hereafter referred to as 'NPL') *inter alia* praying for permission to export 1 kg. of Active Pharmaceutical Ingredient (hereafter 'API') Sorafenib for the purposes of conducting development/clinical studies and trials. The said application was necessitated because of an interim order dated 26.03.2014 passed by this Court whereby respondent nos. 1 to 4 were directed to ensure that no consignment from India containing 'Sorafenat' covered by compulsory license be exported.

2. The controversy to be addressed is whether, the export of API by the applicant would fall within the affirmative defense to infringement of the non-applicant's patent as available by virtue of section 107A of the Patents Act, 1970 (hereafter the 'Act').

3. Briefly stated the relevant facts for considering the controversy are that the petitioner (hereafter referred to as 'Bayer') was granted a patent for a pharmaceutical product titled "Carboxyaryl Substituted Diphenyl Ureas" under the Indian Patent No.215758, for a period of 20 years from 12.01.2000. 'Sorafenib tosylate' is a compound, which is sold by Bayer under the brand name 'Nexavar'. The said product is used for treatment of patients with advanced stages of kidney and liver cancer. The said drug is stated to be a life extending drug, which extends the life of a patient by four to five years in case of kidney cancer and six to eight months in case of liver cancer.

4. Bayer alleged that NPL was manufacturing and dealing with a product which was covered under the said patent and accordingly filed a civil suit [i.e. CS(OS) No.1090/2011] for restraining NPL from launching, making, using, offering for sale, selling and importing Sorafenib/Sorafenib tosylate or any product comprising of the said ingredient or any generic version of Sorafenib/Sorafenib tosylate or any other product covered by the patent granted to Bayer.

5. NPL applied for and was granted a compulsory license on 09.03.2012 to manufacture pharmaceutical products, which were covered under the Bayer's Patent No. 215758. The Controller of Patents, Mumbai

found that reasonable requirement of public with respect to the product in question had not been satisfied and that the drug in question was not made available to public at reasonable affordable price. Accordingly, the Drug Controller granted the compulsory license to NPL for manufacturing the pharmaceutical product covered under the Patent No. 215758 held by Bayer on certain terms and conditions including that the license be used *“solely for the purpose of making, using, offering for sale and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the territory of India”*.

6. NPL has been manufacturing a product under the brand name ‘Sorafenat’ by virtue of the said compulsory license. However, as indicated above, NPL is not permitted to export the same.

7. After the grant of compulsory license as aforesaid, Bayer moved applications before the Patent Office, Mumbai seeking termination/revocation/cancellation of the compulsory license granted to NPL. Bayer also, allegedly, received information that ‘Sorafenat’ which was manufactured by NPL was being exported outside India by NPL in violation of the terms of the compulsory license. This prompted Bayer to approach this Court, by way of the present writ petition, seeking directions to respondent nos.1 to 4 to confiscate and seize consignment for export containing the product covered under the compulsory license granted to NPL. The above captioned writ petition was listed on 26.03.2014 and this Court passed an interim order directing respondent nos.1 to 4 to ensure that no consignment containing Sorafenat covered by the compulsory license is exported.

8. By the present application, NPL is seeking permission for exporting 1 kg. of the Active Pharmaceutical Ingredient (API) Sorafenib for the purposes of conducting development/clinical studies and trials, to a Chinese Pharmaceutical Company namely Hisun Pharmaceutical Co. Ltd. (hereafter 'HPCL'). NPL has also produced a certificate from 'HPCL' indicating that the said company required 1 kg. of Sorafenib tosylate for the purposes of *formulation R&D purpose and the sample was not intended for any commercial purpose*. An affidavit has been filed on behalf of NPL stating that 1 kg. of API of the product in question is required for R&D purposes and for preparation of a trial batch of generic version. It is asserted that for seeking regulatory approval "Bio-availability, Bio-equivalence and stability studies" are required to be conducted and as per the Chinese Rules and Regulations, samples from three consecutive batches of production are required. And, each batch would require 1 to 2 kgs of the API.

Submissions

9. The learned counsel for NPL submitted that the sample size of 1 kg. was required for conducting regulatory studies in China and notwithstanding the terms of license, the export of the API Sorafenib was exempt by virtue of Section 107A of the Patents Act, 1970 (hereafter 'the Act').

10. Mr Sudhir Chandra, learned senior counsel for Bayer controverted the submissions made on behalf of NPL and stressed that the regulatory approvals were being sought by the Chinese Company, HPCL, and not by NPL. He contended that, therefore in essence, the export of 1 kg. of API in

question is simply a commercial transaction in the nature of trade and the use by HPCL would not colour the transaction. He further stressed that the export in question was neither permitted in terms of compulsory license nor would fall within the scope of Section 107A of the Act; use by a third party for development purposes would not entitle NPL to infringe Bayer's patent. He submitted that since NPL was not conducting any developmental studies, the export of patented API to HPCL for the purposes of that company could not be construed to be solely for uses related to development and submission of information required by any regulatory authority. In support of his contention, the learned senior counsel relied upon the decision of the Supreme Court of the Republic of Poland in the case of *A.P Inc. v. P. Pharmaceutical*, decided on 23.10.2013 (hereafter '*Polpharma*').

11. It was further contended on behalf of the Bayer that Section 107A of the Act did not permit export of patentee's product as the word "export" was absent in Section 107A of the Act.

12. The learned counsel for the NPL controverted the contentions urged on behalf of the Bayer and contended that the language of Section 107A of the Act clearly exempted sale of any product for uses related to development and submission of information required by law in force in India or in any other country from the ambit of patent infringement. And, therefore, the scope of Section 107A of the Act could not be restricted for regulatory purposes within India. He further referred to similar provisions in Canadian Law and U.S. Law to contend that Section 107A of the Act was similar to relevant provision of the patent law in Canada and it was

much wider than a relevant legal provision in Poland or in United States of America.

13. The learned counsel further relied upon *Intermedics, Inc. v. Ventritex Co.*: 1993 U.S. App. LEXIS 3620 to contend that even in United States of America, the sale of patented product to another party for its intended use for submission of data to FDA to obtain regulatory approvals, was not found to be an infringement of patentees rights.

Analysis and conclusion

14. The facts that the products sought to be exported by NPL is for the purposes of enabling HPCL to conduct bio-equivalence and bio-availability studies for obtaining regulatory approvals in China has not been disputed. I am also inclined to accept that the product sought to be exported by the petitioner is not for commercial purposes as, admittedly, the said products would be barely sufficient to make 1000 to 2000 tablets which is approximately a single trial batch as required by the Chinese Regulatory Authorities. The guidelines issued by the Chinese Regulatory Authorities also indicate that the test drug for bio-availability and bio-equivalence studies must originate from a batch of at least 10,000 dosage units and the consignment in question is stated to be for the purposes of bio-availability and bio-equivalence studies for production of generic version(s).

15. Thus, in the given circumstances, the only question that needs to be addressed is whether the provisions of Section 107A of the Act would cover export of patented product for use by an overseas importer to conduct studies and generate data for seeking regulatory approvals in that country.

16. The question whether a patentee's exclusive rights with respect to a patented drugs extends to preventing further research and development by competitors for seeking regulatory approvals has been much debated in United States and this exception to assertion of a patent is commonly known as "*Bolar Exemption*". The use of patented inventions by companies to make generic versions for submission to the Food and Drug Administration Authorities in USA was common and, apparently, this experimental use was usually not contested as an infringement of the patent in the past. However, in 1983, this issue - whether use of a patent drug for development and an experimental purpose would constitute infringement of patent – was stoutly contested before United States Eastern District Court of New York in **Roche Products v. Bolar Pharmaceutical: 733 F.2d 858 (Fed. Cir. 1984)**; Bolar Pharmaceuticals sought to perform studies required by the US Regulatory Authorities (FDA) for producing generic versions of Roche's patented API Flurazepam which was used in manufacturing of sleeping pills sold by Roche Products Inc. under the brand name "Dalmane". The U.S. District Court rejected the action of infringement against Bolar Pharmaceuticals Co. as the patented API was not being used for commercial purposes but for obtaining FDA approvals. However, the Court of Appeals for the Federal Circuit reversed the decision of the District Court and held that "*competitor's use of patented ingredient to perform test necessary for it to obtain approval of the FDA for its version of the sleeping pill once the patent expired was a prohibit use*". At about the same time (i.e. in September 1984) US enacted "*the Drug Price Competition and Patent Term Restoration Act of 1984*" which was commonly called as the Hatch – Waxman Act. The said Act carved out an

exception to the patentee's rights in respect of use of the patentee's product for development and experimental use and this exception has been generally referred to as the *Bolar Exception*.

17. The statutory text of the Bolar Exemption; 35 US Code 271(e)(1), reads as under:-

“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into 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.”

18. Reasonable exceptions to the protection of patents are also permitted under the agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter 'TRIPS Agreement') which is administered by World Trade Organization (hereafter 'WTO'). Article 30 of the TRIPS Agreement enables providing a safe harbor for certain activities, which may otherwise offend patent rights. The said article reads as under:-

“Article 30

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.”

19. India joined the TRIPS agreement and pursuant thereto the Patent Act, 1970 was amended to *inter alia* introduce an exception to the rights conferred by a patent. The safe harbor exception was first contemplated under clause 51 of the Patents (Second Amendment) Bill, 1999, which provided for introduction of Section 107A in the Act. Section 107A as proposed under the said Bill reads 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 grant marketing approval for the product of invention;

(b) importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product,

shall not considered as an infringement of patent rights.”

20. Significantly the text of section 107A of the Act, as introduced by section 44 of the Patents (Amendment) Act, 2002, was materially different from the one proposed under the 1999 Bill. The said section as brought in force for the first time in 2002, reads as under:-

“107A. Certain acts not to be considered as infringement -
For the purposes of this Act,-

(a) any act of making, constructing, using or selling a patented invention solely for uses reasonable 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 authorized by the patentee to sell or distribute the product,

shall not be considered as an infringement of patent rights.”

21. As is apparent, confining availability of the exception to a specified time period, that is, three years prior to expiry of the patent, as was proposed in the 1999 Bill, was not accepted; section 107A as enacted did not confine the safe harbour exception to any specified period. Notably, the safe harbour provision was also widened to include ‘constructing’ or ‘selling’ a patented invention and the language of the provision was changed to expressly include uses reasonably relating to submission of information required by laws outside India.

22. Section 107A(a) of the Act was subsequently amended in 2005 to also include import of a patented invention. Further, the scope of clause (b) of Section 107A was also widened. In the pre-amended provision, the exemption was available only to imports made from a person authorised by a patentee. This was expanded to also include imports from a person who was duly authorised under the law to produce, sale or distribute the products. Section 107A of the Act as it stands now on the statute book reads as under:-

“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 relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;

- (b) importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product,

shall not be considered as an infringement of patent rights.”

23. Bayer’s contention that the exception under section 107A is available only in respect of certain activities to a person, who is required to submit information under any regulatory law and not to any other person, has to be evaluated in the backdrop of the aforesaid legislative history and the express language of section 107A of the Act.

24. As is seen from a plain language that the exclusion to a patentee’s right as provided under Section 107A of the Act is wider than the exceptions provided by law in United States.

25. Mr Sudhir Chandra, the learned senior counsel for Bayer, relied heavily on the decision of the Supreme Court of Poland in **Polpharma** (*supra*) to contend that the applicability of Section 107A of the Act must be restricted to only self use. In **Polpharma** (*supra*), Astellas Pharma Inc. held the patent on API Solifenacin Succinate and Pharmaceutical works Polpharma S.A. (Polpharma) advertised sale of Solifenacin Succinate in different professional journals (SCRIPS) as well as on its website. The advertisement published in SCRIPS reads as “*We offer: a broad range of commercially available pharmaceutical active substances: (Solifenacin Succinate).....*”. In addition to supplying Solifenacin Succinate to two

other overseas companies, Polpharma also supplied 30.5 kg of Solifenacin Succinate to a German company engaged in manufacture of generic versions. Astella successfully sued Polpharma for infringement of its patent before the District Court at Gdansk. The Court of Appeal also rejected Polpharma's appeal against the decision of the District Court and, thereafter, Polpharma appealed to the Supreme Court of Republic of Poland. One of the defence raised by Polpharma was that it's alleged infringing activities were covered under the exception as available under Article 69(1)(iv) of the Act of 30 June, 2000 on Industrial property law. The Polish Supreme Court also held that the privilege granted (the so called Bolar exception) did not cover the use of the patented invention by an entity that did not plan to submit application for registration of generic versions. The Court held that the sole purpose for manufacture of the active substance was its sale to a third party and such action was not covered by the exception provided.

26. Before considering the persuasive value of the said decision, it would be necessary to refer to the relevant provision of the polish law. Article 69(1)(iv) of the Act of June 30, 2000 – on Industrial Property Law embodies the Bolar exemption and reads as under:-

“a patent is not infringed by exploiting an invention to the extent necessary with a view to perform actions which are legally required to obtain an entry into a register or licence, being a precondition for admitting certain products into trade given their purpose, in particular medicinal products.”

27. It is, at once, apparent that the Bolar exemption as embodied in Polish Law is restrictive in comparison with the exemption offered by

Section 107A of the Act. The language of Article 69(1)(iv) of Act of June 2000, is completely different from the language of section 107A of the Act. Thus, in my view, the reliance placed by the learned counsel for Bayer on *Polpharma* (supra) is misplaced. The safe harbour under the Polish law is limited to exploitation of an invention to the extent necessary with a view to perform actions which are legally required for obtaining a licence. Section 107A(a) of the Act permits actions including “*selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any laws*”. Thus, a sale which is related to submission of information as required by any law in India or outside India would be permissible. In contradistinction, the relevant statutory text of the Polish law permits actions that are *legally required* to obtain entry in a register or a licence. This, naturally, would exclude sale of patented products as the same is not a legal requirement for the regulatory approval. It could also mean - as held by the Polish Supreme Court - that the exemption is available only to the person actually involved in the permitted use of the patent. In this view, the Polish Supreme Court’s decision in *Polpharma* (supra) would be wholly inapplicable to the law in India.

28. As noted before, the provision of Section 107A as proposed by the 1999 Bill did not include the word ‘selling’ in Section 107A(a) of the Act but the Parliament included the act of selling within the exception provided by the said provision. Such inclusion of the act of ‘selling’ would have little meaning if Bayer’s contention that the exception is only available for the

self use, is accepted. In my view, the plain language of Section 107A does not permit this interpretation.

29. Under Article 30 of the TRIPS Agreement, each subscribing nation could introduce an exception to the exclusive rights conferred by a patent, taking into account the legitimate interest of the patent owners and of the third parties. Different nations have worded this exception in different language. India is one of the largest producers of generic versions of drugs around the world. Given the economic realities of our country, providing cheaper medicines is a necessity. The parliament in its wisdom has, thus, couched the exclusion to a patent, as provided under Section 107A, in wide terms. The sweep of the plain language of Section 107A, thus, cannot be restricted in the manner as canvassed on behalf of Bayer.

30. The contention that the provisions of section 107A of the Act must be read restrictively; in the context of the historical origin of the safe harbour provisions in ***Roche v. Bolar*** (supra) and with the perspective that the Polish Supreme Court came to bear in ***Polpharma***, is difficult to accept. Applying the opinion of the Polish courts with regard to the polish statute, to the Act as enacted by the Parliament – given the express language of section 107A of the Act - would be erroneous. And, in so far as the historical origins of the Bolar Exemption is concerned, much water has flown under the bridge since ***Roche v Bolar*** (supra).

31. It is settled law that the intent of a legislature must be understood from the language of the legislative enactment. This rule was reiterated by the Supreme Court in ***Mahadeolal Kanodia v. Administrator General of***

West Bengal: AIR 1960 SC 936 in the following words: “ *The intention of the Legislature has always to be gathered by words used by it, giving to the words their plain, normal, grammatical meaning*”. Further aids to interpretation of a statutory provision are required only when its plain language leads to an absurdity or some inconsistency or repugnance within the statute. In the present case, no such need for other aids to interpretation arises as the text of section 107A neither leads to an absurdity nor to any inconsistency or repugnance within the Act. The language of section 107A of the Act is unambiguous; it must, therefore, mean as it reads.

32. Plainly, Section 107A of the Act takes within its fold any sale of a patented invention which is required for development and submission of information under any law in a country other than India that regulates the manufacture or sale of any product. Indisputably, under the Chinese Law, submission of studies and data related to bio-equivalence and bio-availability of API in a generic version, is required as discussed earlier and the sale of 1 kg. of Sorafenat to HPCL can be reasonably stated to be related to the studies that are required to be conducted by HPCL for obtaining the regulatory approvals.

33. In **Intermedics, Inc. v. Ventritex Co.**: 1993 U.S. App. LEXIS 3620, the U.S. Courts of Appeals for Federal Circuit rejected an appeal filed by a patent holder against a summary judgment of a U.S. District Court for the Northern District of California. In that case, Intermedics, Inc. had filed a suit against Ventritex Co. for infringement of its patent. Intermedics, *inter alia*, contended that Ventritex intended to commercialise the patented invention before expiry of Intermedics patent. Ventritex, on the other hand,

asserted that its sale of the patent invention to researchers in Germany was solely and reasonably related to generating data for FDA approval. The Federal Court did not find sale of the patented invention by Ventritex to be an infringement of the patent and held that the language of the exception was clear and could not be limited. The relevant extract of the said judgment is as under:-

“If the statutory language is clear, the plain meaning of the statute controls. *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1579, 16 USPQ2d 1614, 1618 (Fed. Cir. 1990), *cert. denied*, 111 S. Ct. 1315 (1991). The plain language of section 271(e)(1) does not contain the limitation Intermedics desires to find therein. Section 271(e)(1) only states that all making, using or selling of a patented invention be solely for uses reasonably related to developing and submitting information to the FDA. There is no suggestion that a producer may only rely on the exemption if it does not intend to commercialize the product before expiration of the patents.”

34. In the present case too, the language of Section 107A of the Act is determinative of the question whether export as sought for by NPL is permissible within the exemption of Section 107A of the Act. The use of the expression “*reasonably relating to*” as used in Section 107A of the Act would plainly mean a reasonable nexus. Thus, the only question that needs to be answered is whether there is any reasonable nexus between the sale of Sorafenat by NPL to HPCL and submission of information under the law in force in China. In my view, the answer to this question is clearly in the affirmative.

35. It is also important to note that the language of Section 107A of the Act is materially different from the law as applicable in U.S. Whilst, the US

Law restricts the safe harbour to a sale within United States and solely for purposes related to information under a Federal Law, Section 107A of the Act is circumscribed by no such conditions. Thus, a sale even outside India would fall within the sweep of Section 107A, provided it is reasonably related to development and submission of information as required under a law in force in India or outside India.

36. As pointed out by the learned counsel appearing for NPL, Section 107A of the Act is similar to Section 55.2 of the Patent Act as applicable in Canada which reads as under:-

“55.2 (1) 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.”

37. The above provision for safe harbour as applicable in Canada was subject matter of disputes raised by European Communities and its member states with respect to its compliance with TRIPS Agreement (in WT/DS114/R dated 17.03.2000). The European communities and their member states argued that Section 55.2 of the Canadian Patent Act allowed all activities related to development and submission of information required to obtain marketing approval for pharmaceutical products without the consent of the patent holder. It was contended that the activities permitted under Section 55.2(1) of the Canadian Patent Act were completely unlimited in quantity and extent and the only limitation set out was in the objective of the activities, that is, the activities must be “....*reasonably related to the development and submission of information*” required for

obtaining marketing approval anywhere in the world. It was submitted that provisions were incompatible with Article 28.1(a) and (b) of TRIPS Agreement. In defence, Canada contended that the provisions of Section 55.2 were limited exceptions to the exclusive rights conferred by a patent within the meaning of Article 30 of the TRIPS Agreement. It is relevant to note that India supported the stand of Canada and contended that exceptions in the Canadian Patent Act were legitimate exceptions within the meaning of Article 30 of the TRIPS Agreement. Insofar as the exceptions offered by Section 55.2(1) of the Canadian Patent Act are concerned, the same was upheld by the Disputes Settlement Body (hereafter 'DSB'). The DSB noted that the pharmaceutical industry often involved generic producer procuring the API from a specialized manufacturer. The relevant extract of the findings is quoted below:-

“7.4 The structure of the generic pharmaceutical industry illustrates the actual operation of the regulatory review exception. Production of generic pharmaceuticals often involves a two-tier production arrangement. The firm that assembles and markets the final generic product often does not have the technological capacity/expertise or the commercial motivation to produce the so-called “active ingredient” – the chemical product that generates the desired medicinal effect. The active ingredient is thus often manufactured by a specialized producer of fine chemicals, and then sold to the generic producer which assembles the active ingredient with other agents to create the final product in a form that can be used by the ultimate consumer. In such cases, both producers must engage in conduct that, in the absence of a regulatory review exception, would be potentially infringing, if they are to satisfy the requirements of the regulatory review process – the fine chemical producer in developing, making and selling the necessary amounts of the active ingredient to the generic

producer, and the generic producer in combining the various elements to make the final product and then demonstrating its safety, stability and effectiveness by appropriate tests. The regulatory review exception applies to these activities of both producers.”

38. The DSB further found that Canada’s Regulatory Review Exceptions was “*a limited exception within the meaning of Article 30 of the TRIPS Agreement*”. The DSB further noted that even though regulatory approval processes would require substantial amount of test production to demonstrate reliable manufacturing and the patent owners rights were not impaired so long as production runs were solely for regulatory purposes and no commercial use was made of the final products. The relevant extract of the said conclusion is quoted below:-

“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 unauthorized 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.”

39. The practice of a Fine chemical manufacturer selling API to a manufacturer of generic formulations was examined and it was found that the same was permissible within the framework of the Canadian patent law, which is similarly worded as Section 107A of the Act. Notably, it was

common ground that the Canadian statute permitted this; Canada did not dispute that its statute was wide enough to permit manufacture and sale of patented products to a generic formulator for the generic formulator to apply for regulatory approvals. But, argued that its statute did not offend Article 30 of the TRIPS Agreement. In my view also, the contention that the affirmative defense of section 107A of the Act is available only to the manufacturer who uses the patented products for obtaining regulatory approvals for itself, is neither supported by the plain language of section 107A of the Act nor is such interpretation warranted, given the general practice amongst drug manufactures.

40. There is yet another aspect that requires consideration; whether export of patented API for the use by the importer for obtaining regulatory approvals, is covered within the exception of Section 107A of the Act. The learned senior counsel for Bayer contended that the language of Section 107A of the Act excludes exports because although import has been specifically mentioned, the expression 'export' does not find mention in the said Section. I am not inclined to accept this contention for the reason that the expression 'selling' is wide enough to even include cross border sales (i.e. exports). If the Parliament intended to restrict the exception to only sales within India, the same would have been expressly stated as was done by the US Congress under 35 US Code 271(e)(1).

41. A substantial aspect of the controversy is that export of a patented product would remove the product from the influence of the statutory regime of this country and consequently further exploitation of the product would not be subject to the protection afforded by the Act. And in the

circumstances, the question that needs to be considered is whether should the provision of section 107A of the Act be read to only include sales made within India? In my view, this question must be answered in the negative for the following reasons:

41.1 First and foremost, for reason that the plain language of the text does not support such interpretation. There are no words or expressions to read in such restriction; on the contrary, section 107A of the Act expressly permits use for submission as may be required by laws in force outside India.

41.2 Secondly, even if a purposive interpretation of Section 107A of the Act is attempted, it would have to be in favour of permitting export. The purpose for excluding development activities and uses for regulatory approvals is to ensure that exploitation of patented invention is not restricted beyond the period or sphere of exclusivity granted to the patentee. Thus, although initiative and effort of an inventor must be rewarded, the protection is limited and should not stifle further development and restrict participation beyond the period of exclusivity. There is a strong case for enhancing availability of essential drugs at affordable prices and the safe harbor exception must extend to permit developing overseas sources also.

41.3 Thirdly, in the world as is now shaping up, national borders offer only limited barriers to trade. As such, confining the exclusion of section 107A to sales within India would not aid the object of the said exclusion. It is relevant to note that China is also a signatory to TRIPS agreement and as such bound to recognize and protect Intellectual Property Rights.

42. In my view, export of Sorafenat for carrying on activities for obtaining regulatory approvals, would fall within the exception under Section 107A of the Act. Accordingly, the present application is allowed.

43. List the writ petition (W.P.(C) No.1971/2014) on 17.12.2014.

VIBHU BAKHRU, J

NOVEMBER 05, 2014
RK

