HIGH COURT OF DELHI AT NEW DELHI

Judgment reserved on: 1st December, 2009
Judgment pronounced on: February 9, 2010

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LPA 443/2009

BAYER CORPORATION & ANR ..... Appellants
Through Mr. Shanti Bhushan, Senior Advocate
with Mr. Sanjay Kumar, Ms. Arpita Sawhney,
Mr. Vineet Rohilla, Mr. Peeyoosh Kalra,
Mr. Puneet Kalra, Advocates.

versus

UNION OF INDIA & ORS ..... Respondents
Through Mr. A.S. Chandhiok, ASG with Mr.
Neeraj Chaudhari, Mr. Khalid Arshad, Mr. Ritesh
Kumar, Mr. Sandeep Bajaj, Advs. for UOI.
Mr. A.M. Singhvi, Sr. Adv. with Ms. Prathiba M.
Singh, Ms. Saya Choudhary, Mr. Kapil Wadhwa,
Advs. for R-3/ Cipla.
Mr. Anand Grover, Ms. Nandita Rao, Ms Julie
George, Ms. Prathibha Siva Subramaniam, Mr.
Arvind, Advs. for R-4.Mr. Jayant K. Mehta with
Mr. Sandeep Phogat Advs. for applicant / Indian
Pharmaceuticals.

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE DR.JUSTICE S. MURALIDHAR

1. Whether the reporters of local papers may be allowed to see the judgment? Yes
2. To be referred to reporter or not? Yes
3. Whether the judgment should be reported in the Digest? Yes

S. MURALIDHAR, J.

1. This appeal is directed against the judgment dated 18 th August, 2009 passed by a learned Single Judge of this court dismissing the appellants‟ LPA 443/2009 page 1 of 27 Writ Petition (C) No. 7833 of 2008. In the writ petition the appellants Bayer Corporation and Bayer Polychem (India) Ltd. (hereafter collectively referred to as „Bayer‟) sought directions inter alia to restrain the Drug Controller General of India (DCGI), respondent No. 2 herein, from granting a drug licence to Cipla Ltd. (hereafter „Cipla‟), respondent No. 3 herein (a generic drug manufacturer), to manufacture, sell and distribute its drug "sorafenib tosylate", prescribed for the treatment of advanced renal cell carcinoma. Facts in brief

2. On 5th July, 2001 Bayer Corporation, Appellant No.1, filed a patent application in India in respect of an invention entitled "Carboxyaryl Substituted Diphenyl Ureas". On 1st January 2003 Bayer Corporation transferred its rights to Bayer Pharamceuticals Corporation (BPC) and on 1 st August 2007 BPC in turn transferred its rights, including the Intellectual Property rights in the drug "sorafenib tosylate" portfolio in India to Bayer HealthCare LLC, a wholly owned subsidiary of Bayer Corporation. On 1st August, 2007 the DCGI granted permission to Bayer Polychem (India) Ltd. Appellant No. 2, in terms of Rule 122 A of the Drugs and Cosmetics Rules 1945 („DCR‟) [relatable to Section 12 (2) of the Drugs and Cosmetics Act 1940 („DCA‟)] to import "sorafenib tosylate" 200 mg. Separately, on 18th January 2008 the DCGI granted a licence (in Form 10 under Rules 23 and 27 DCR) to Appellant No.2 to import "sorafenib tosylate" 200 mg (nexavar tablet). This was to be in force from 8th January 2008 to 31st December 2010. The Patent Office granted the subject patent to Bayer Corporation Appellant LPA 443/2009 page 2 of 27 No.1 on 3rd March, 2008 for a period of twenty years from 12th January 2000 in accordance with Section 53 of the Patents Act 1970 („Patents Act‟). Effective 16th October 2008, Bayer HealthCare LLC assigned its titles to the patented drug "sorafenib tosylate" portfolio in India to Appellant No. 1 which became the patentee of the drug "sarafenib tosylate" in India.

3. According to Bayer, it learned in July 2008 that Cipla had announced the introduction inter alia of a drug "Soranib" which was a substitute for Bayers‟ drug "sorafenib tosylate". On 31st July 2008 Bayer wrote to the DCGI inter alia requesting that marketing approval be not granted to Cipla for its drug "Soranib". It was pointed out that the proprietary rights to the molecule "sorafenib tosylate" vested in Bayer HealthCare LLC, a wholly- owned subsidiary of Appellant No. 1. It alone had the marketing rights to sell the drug in India. Bayer Corporation along with Bayer HealthCare LLC asked the DCGI to acknowledge their patent rights and not grant marketing approval to Cipla for launching the generic version of "sorafenib tosylate". Bayer and Bayer HealthCare LLC wrote another letter dated 2nd September, 2008 to the DCGI with complete specifications along with claims in respect of "sorafenib" and "sorafenib tosylate" granted in favour of Bayer Corporation by the Patent Office. It was submitted that the DCGI ought "to reject the representation of Cipla for grant of marketing approval for spurious adaptation of its patented drug sorafenib tosylate, as the same LPA 443/2009 page 3 of 27 would be in contravention of the DCA. Bayer requested for an opportunity of being heard by the DCGI.

4. On 25th September, 2008 Bayer wrote to Cipla asking it to confirm whether it had filed an application before DCGI for grant of marketing approval for a drug covering "sorafenib tosylate". No reply was received from Cipla. In the circumstances, on 31st October 2008

Bayer filed the above mentioned writ petition praying inter alia for a writ restraining the DCGI from granting licence to Cipla "to manufacture and market, to imitate/ substitute sorafenib tosylate protected under subject patent number 215758". A further prayer was for a direction to Cipla to furnish an undertaking that the drug for which it has made an application before Respondent No. 2 was not an imitation of or a substitute for Bayer‟s patented drug "sorafenib tosylate" and consequently would not result in an infringement of the subject patent. Bayer claimed that Soranib was an imitation of, or a substitute for its patented drug and that by granting such licence, the DCGI would have permitted the marketing of a „spurious drug‟ as defined under Section 17 B DCA. It was contended that since it was known at the time of Cipla‟s application for marketing approval that Bayer held the patent for sorafenib tosylate, the DCGI was under an obligation, flowing from a collective reading of Section 2 DCA and Sections 48 and 156 of the Patents Act, to decline Cipla‟s application for marketing approval for Soranib.

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5. Initially an interim ex-parte order was passed by learned Single Judge on 7th November 2008 restraining the DCGI from passing a final order on the application made by Cipla for grant of marketing approval for Soranib. Cipla then applied for vacation of the order. Cipla characterised Bayer‟s contention that an application for grant of marketing approval under DCA was "circumscribed by and controlled by a registered Patent" as "completely untenable" inasmuch the Patents Act and the DCA "operate in completely different fields and there is no overlap".

6. The DCGI in its counter affidavit submitted that the writ petition was "entirely misconceived". It was not within the scope of DCA to not grant the said licence on the alleged ground of violation of the provisions of the Patents Act. The DCGI contended that the scheme of the Patents Act and the DCA were completely different and that "these legislations operate in separate areas and do not overlap with each other." It was stated by the DCGI that it had asked Cipla to furnish comments on the objections raised by Bayer and that it was yet to receive reply from Cipla. The judgment of the Single Judge

7. The learned Single Judge negatived the above contentions of Bayer and concluded that:

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(i) Given the disparate objectives of the DCA and the Patents Act, and both being separate codes enacted for different purposes, there was no merit in the contention that there was a „patent linkage‟. To accept Bayer‟s contention that the DCGI is by virtue of Section 156 of the Patents Act read with Section 2 of DCA bound by the patent granted to Bayer "would be to extend the boundaries of the Patents Act and broaden the reach of drug agencies, who cannot apply patent standards, in their legitimate scrutiny." It was observed that "an overbroad or liberal interpretation of Section 156 can also mean that wherever patents are granted, all other regulatory agencies are bound, and cannot even apply their standards, to judge the safety, prescribed criteria for public use etc." Bayers‟ argument that patent linkage was evident from reading Rule 122 B (1) (b) DCR, with Form 44 thereof and the data required (Appendix I to Schedule Y) was negatived.

(ii)The linear argument that once a patent is granted for a drug under the Patents Act, then in terms of Section 2 DCA no application by a non- patenetee for marketing approval of such

drug can even be entertained, could not be accepted since that was not the intention of the Parliament. It was pointed out that although important amendments were made to the Patents Act in 2005, "Parliament never expressed any intention, significantly, to place patent superintendence, or policing powers, with drug agencies." Courts were not expected to fill the gaps in public policy spaces. Further when there was an overlap between the provisions in two enactments, "the court should not do violence to one, and undermine its purpose."

(iii)There was a growing opinion, in developed countries, including those of the European Union cautioning against patent linkage. It was believed that the entry of generic drugs resulted in saving of expenditure and health costs. It was pointed out that patent linkage "transforms patents rights which are private property rights that depend on the owner‟s promptitude and desire to enforce them, into LPA 443/2009 page 6 of 27 public rights, whose enforcement is dependent on statutory authorities, who are publicly funded." Such linkage would undermine the "Bolar/Early Working" of the patent and deny space for generic medicines.

Submissions of Counsel

8. Mr. Shanti Bhushan learned Senior Counsel appearing for the appellant first contended that under Section 48 of the Patents Act a patent holder has an absolute right to restrain anyone from "making, using, offering for sale, selling or importing" the drug covered by subject patent in India, which in this case was "sorafenib tosylate". Further Section 2 DCA stated that the provisions of DCA "shall be in addition to a law, and not in derogation of any other law" which would include the Patents Act. Consequently, Section 2 DCA read with Section 48 of Patents Act provided the concept of patent linkage. It is then contended that the interpretation given by the Supreme Court in Cadila Healthcare Ltd. v. Cadila Pharmaceutical Ltd. (2001) 5 SCC 73 relating to manufacture of a medicine under the trade mark registered in the name of another party would equally apply to a situation where marketing approval is sought for a product which is already patented in favour of another entity. Reliance is placed on the decision of Allahabad High Court in Cattle Remedies V. Licensing Authority (2007) 2 AWC 1093.

9. Mr.Bhushan traced the history of patent legislation in this country to urge that the concept of a patent linkage did exist in some form even earlier.

LPA 443/2009 page 7 of 27 According to him Form 44 (relateable to Rule 122 B DCR) was recast after 1995, when India became a signatory to TRIPS. The inclusion of the column in the form requiring the applicant to indicate the „patent status‟ of the drug was done consciously and only with a view to bringing about patent linkage. An applicant was required to mention the patent status of the drug and that this indicated that Parliament intended patent linkage. An applicant seeking marketing approval for a new drug was required to furnish data of clinical trials of the drug in question including its name, composition of the formulation, active and inactive ingredients, pharmacological classification etc. Since the applicant would have to rely on the data generated by the patent holder, by granting marketing approval to Cipla, the DCGI would, in fact, be not only acting in contrary to Section 2 DCA but would be „abetting‟ the tort of infringement of a patent. According to Mr.Bhushan, Section 156 of the Patents Act read with Section 48 thereof obliges the DCGI, whose office is part of the central government, to ensure that the patent granted in favour of Bayer is not infringed and by

granting marketing approval to Cipla in respect of an imitation of Bayer‟s patented drug, the DCGI would be party to the infringement by Cipla of Bayer‟s patent.

10. Reliance is placed on the judgment of this Court in Hoechst Pharmaceuticals v. CVS Mani ILR1983 Delhi 548 where Section 2 DCA and the DCR were interpreted as requiring the DCGI to adhere to the requirements of the Trade and Merchandise Marks Act 1958. Reliance has LPA 443/2009 page 8 of 27 also been placed on the decision of Supreme Court in Arvind Mills v. Associated Roadways (2004) 11 SCC 545 in which the Supreme Court was interpreting Section 3 of the Consumer Protection Act 1986 (CPA) vis-à-vis the Section 10 of the Carriers Act 1865. It was explained by the Supreme Court that remedies under the CPA being in addition to any other law did not mean that the rights under the Carriers Act could be exercised in the manner in consistent with the requirement of the Act. Merely because the procedure under the CPA were summary in nature did not warrant the abrogation of the requirement to serve a notice under Section 10 of the Carriers Act before fastening any liability on the carriers.

11. Although it was argued at length before the learned Single Judge, and also urged in the grounds of appeal, that Cipla‟s generic version of Bayer‟s patented drug would in fact be a „spurious drug‟ as defined under Section 17 B DCA, before this court Mr.Bhushan did not stress on this point. Nevertheless it has been urged in the written submissions and will be dealt with later in this judgment.

12. Appearing for Cipla, Dr. A.M. Singhvi, learned Senior Counsel submits that there is no concept of patent linkage in India at all. The Parliament has consciously avoided it despite being aware of the existence of patent linkage in other countries including the United States of America (U.S.A). The LPA 443/2009 page 9 of 27 DCA itself has been amended several times since its initial enactment in 1940 and there has never been an attempt to being about any linkage between the DCA and the Patents Act. He reiterates the submission made before the single Judge that the scheme and purpose of the two enactments are entirely different. While DCA is concerned with the standards to be followed in the manufacturing, sell, importation and distribution of drugs and chemicals in the country to minimize the risk and promote safety among drug users, the Patents Act is concerned with the grant of patents for inventions.

13. It is submitted by Dr.Singhvi that merely because the Form 44 requires the applicant to indicate the patent status does not mean that the DCGI is bound to ensure that no patented drug is granted marketing approval. He points out that this is not the concern of the DCGI. If the drug for which marketing approval is sought is covered by a patent, and the patent holder (like in this case Bayer) has already been granted approval to import or to market the drug in India as a "new drug" (as defined under Rule 122 E DCR), then the subsequent applicant for marketing approval (in this case Cipla) has in Column 2 B of Form 44 only to indicate the bio availability/ bio-equivalence protocol. This requirement is also only for a period of four years, since the said drug would cease to be a new drug thereafter. In that event approval for marketing would have to be sought only from the local state Food and Drugs Department and not the DCGI. It is submitted that if LPA 443/2009 page 10 of 27 Bayer‟s argument of patent linkage were to be accepted then the DCGI will have to presume that the patent granted is valid, and has to outright reject every application made by a generic manufacturer till such

time the said patent is not challenged before the IPAB or the court and revoked. This only would make the entire process uncertain. If the court grants a stay of the patent then during that period the DCGI would be able to grant approvals. When the stay is vacated, the generic drug would become a „spurious drug" inviting punishment for the offence under the DCA. It is submitted that Bayer"s submission is both impractical and unintended on a collective reading of the DCA and the Patents Act.

14. The Cancer Patient Aid Association impleaded itself in the writ petition and is Respondent No. 4 here. On their behalf it is submitted by Mr.Anand Grover, learned Senior Counsel that if the appellant"s attempts to introduce a patent linkage system in India were to succeed it will inevitably have an adverse impact on access of a large number of cancer patients to safe, effective and affordable medicines. By and large supporting the stand of Cipla, Mr.Grover urges that patent rights are private rights and cannot possibly be enforced by the State. The DCGI is not the appropriate body to enforce a patent. It is submitted that under the DCA read with the DCR, the main function of the DCGI is to ensure safety, quality and efficacy of the drugs available to the public in India. The DCA specifically sets out the procedures and criminal sanctions relating to spurious drugs. Section 27 LPA 443/2009 page 11 of 27 DCA states that if the drugs are below the standard quality the manufacturer of such drug is liable for penal sanctions. It is submitted that the generic drugs cannot be held to be spurious drugs inviting such criminal sanction merely because they infringe a patent. The patent holder has adequate remedies under the Patens Act to enforce and protect its patent. It is urged that the adverse effect of patent linkage on access to affordable medicines has been documented extensively. Reference in this regard is made to the briefing note of the World Health Organization (WHO). It is submitted that the issue of patent linkage is a TRIPS plus concept and a policy issue and the court cannot possibly compel the Government to take a policy decision. More importantly it is urged that patent linkage would delay the entry of generic medicines and thereby adversely affect the numerous cancer patients whose survival depends on the availability of such medicines. He points out that TRIPS itself has in-built flexibilities. He points out that „Bolar" clauses (like Section 107 A of the Patents Act, introduced in 2002) are a TRIPS innovation that is meant to encourage competition. The greater the competition the better it is for the protection of public health.

15. On behalf of the DCGI, it is submitted by Mr. A.S. Chandhiok, learned ASG that the nodal ministry for the administration of the DCA and the DCR is the Ministry of Health and Family Welfare whereas for the Patents Act it is the Department of Industry Promotion, under the Ministry of Industry and Commerce. A reference is made to Section 68A DCA which deals with the grant or renewal of licence by the Central Licence Approving Authority, LPA 443/2009 page 12 of 27 which is the DCGI. In terms of the said provision, an application for grant of permission to import or manufacture a new drug or to undertake a clinical trial has to be submitted in Form 44. It is confirmed by the DCGI that it had granted Appellant No.2 permission to import „Sorafenib Tablet" by a permission dated 1st August 2007. Cipla had also applied to it for permission to manufacture and market „Sorafenib Tosylate" 200 mg tablets. It is acknowledged that the petitioner had written to the DCGI asking it not to grant market permission to Cipla and its representations were sent to Cipla for its comments. It is submitted that the DCA primarily deals with the issue of safety, efficacy

and quality of a drug. It is submitted that the scheme, aims and objects of the two legislations viz., the Patents Act, 1970 and the DCA are completely different.

16. Mr. Jayant Mehta, learned counsel appearing on behalf of the intervener, the Indian Pharmaceutical Alliance, supported the stand of Cipla. It is pointed out that an administrative body like the DCGI is not competent to adjudicate upon rights flowing from a patent. If Bayer‟s arguments were to be accepted then the court would be allowing for penal consequences for the infringement of a patent, whereas the Patents Act itself does not contain any such provision. He points out that Patents Act is traceable to Entry 49 of List 1 (Union List) of Schedule 7 to the Constitution whereas the DCA is traceable to Entry 19 of List 3 (concurrent list) which relates to drugs and poisons. While a person covered by the DCA cannot avoid the obligations under the Patents Act, in terms of Section 2 DCA, the DCA itself is not LPA 443/2009 page 13 of 27 meant to be exhaustive to cover all aspects of the drug which is sought to be marketed including the enforceability of its patent. The issues

17. The issues that arise for consideration are: (a) whether the DCGI can grant marketing approvals under the DCA to generic versions of patented drugs, (b) whether the grant of such marketing approvals to generic versions of a patented drug is in derogation of the Patents Act and (c) whether generic drugs are spurious drugs in terms of the DCA?

Is there a patent linkage in terms of the Patents Act and the DCA?

18. In the first place, an analysis is required to be undertaken of the provisions of the Patents Act, the DCA and the DCR. Under Section 13(4) of the Patents Act the grant of a patent shall not deemed in any way to warrant its validity and no liability shall be incurred by the Central Government in connection with any examination or investigation or any report or proceedings consequent thereon. In another words, a patent has been granted to an applicant can be challenged on various grounds in accordance with the Patents Act. When a suit for infringement is filed by the patent holder, the defendant can always raise, as part of its defence, a challenge to the validity of the patent. The decision of the Supreme Court in M/s. Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979) 2 SCC 511 reiterates the settled law that "the grant of the patent does not guarantee its validity."

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19. Section 48 of the Patents Act, which has been expressly made subject to the other provisions of the Patents Act, confers on the patentee, both where the subject matter of the patent is a product or a process, the exclusive right to prevent third parties, without prior permission of the patent holder, from "making, using, offering for sale, selling or importing for those purposes" in India the patented product or a product obtained by the patented process. This is a negative right which is enforceable at the instance of the patent holder and only subject to other provisions which permit challenge to the validity of the patent to be raised as a defence in a suit for infringement of the patent. This is evident from Sections 64 and 107 of the Patents Act. Therefore, it appears that in relation to any steps that a patent holder might wish to take protect the patent from being infringed, resort should be had only to the provisions of the Patents Act.

20. The contention that the DCGI is bound by the injunction in Section 48 prohibits any third party from even "offering for sale" the patented product without the consent of the patent holder, is based on a misreading of Section 156 of the Patents Act which states that the

central government is also bound by such patent. In the considered view of this court, the purport of Section 156 is not that the DCGI, who is no doubt an officer of the central government, is prevented from granting marketing approval to a non- patentee in respect of a patented drug. No such obligation flows from Section 156 Patents Act as such. This submission also misses the point that LPA 443/2009 page 15 of 27 the right conferred under Section 48 is essentially a private right and negative right as is and does not confer a right to market the product even on the patent holder. In fact a patent holder has also to apply to the DCGI, in terms of the DCA, for permission to import and/or to market the patented product.

21. Much emphasis was laid on Section 2 DCA to suggest that this provision requires the DCGI to account for the Patents Act since the provisions of the DCA are expressly stated to be "in addition to, and not in derogation of, any other law for the time being in force". This submission proceeds on a misconception that the DCGI is required to account for the provisions of the Patents Act. The reference to Section 156 of the Patents Act which states that "a patent shall have to all intents the like effect as against Government as it has against any person", does not mean that the DGCI has to enforce and protect the patent for the product, in respect of which marketing approval is sought, from being infringed. Section 156 only states that the government cannot also infringe a patent. It is a negative obligation on the government not to infringe. It creates no duty or positive obligation on the central government, or any department thereof, to protect a patent from infringement. The context in which the decisions in Hoechst Pharmaceuticals v. CVS Mani by this Court and in Arvind Mills v. Associated Roadways by the Supreme Court were rendered was very different. For instance, Section 20 (2) of the Companies Act expressly states that the central government can determine that it would be undesirable to LPA 443/2009 page 16 of 27 register a company the name of which resembles a registered trade mark under the Trade Marks Act. Such a protection for the trade/brand name of a drug is also found in Section 17 B (a) DCA. However, there is no corresponding provision in the DCA that requires marketing approval to be refused when it is sought for a patented drug by a non-patentee.

22. In granting marketing approval to a patented drug, the DCGI is by no means itself infringing any patent or abetting the infringement of any patent by the applicant in whose favour the marking approval is being granted. Such an argument proceeds on a misconstruction of the scheme of the DCA. The object of the DCA is to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The numerous amendments made to the DCA including the ones made in 1982 which widened the definition of „drugs‟, or „patent or proprietary medicine‟, and introduced the concept of „spurious‟ drugs did not require the DCGI to itself enforce a patent granted under the Patents Act and deny marketing approval to a generic version of a patented drug manufactured by a non-patentee.

23. Form 44 is part of the DCR and was introduced in December 2001. It requires the requisite information to be provided as indicated in Appendix-I to Schedule Y DCR. Where the application is made in respect of a "new drug" as defined in Rule 122 E DCR, the applicant has to furnish: (i) Animal pharmacology studies (Appendix-IV), (ii) Animal toxicology studies (Appendix-III), (iii) Human clinical pharmacology Phase-I, II and III and LPA 443/2009 page 17 of 27

(iv) Special studies including bio-availability or bio-equivalence, (v) Regulatory status in other countries, (vi) Prescribing information including draft labels and cartons and (vii) Sample of the product. In the event that the drug in question has already been approved by the competent authority of a foreign jurisdiction, the published toxicity report and clinical trial data (Phase I and Phase II) as submitted in the said foreign country can be annexed with the application and a waiver can be sought by the applicant from actually conducting the same Phase I and Phase II trials/studies in the country. However, except when it comes to drugs for life threatening diseases like cancer/HIV, Phase III clinical trials are required to be conducted in India. When the drug for which approval is being sought is not approved in any other foreign country then the applicant has to necessarily perform and provide toxicity data and Phase I, Phase II, Phase II clinical trial data to the DCGI.

24. Rule 122 E DCR defines a „new drug". It is a drug "which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under Rule 21 for the proposed claim". It also includes a drug already approved by the licensing authority which is proposed to be marketed with modified or new claims in the matter of indications, dosage form and route of administration. It also includes a fixed-dose combination of two or more drugs. Explanation (ii) states that for the purposes of Rule 122E "a new drug LPA 443/2009 page 18 of 27 shall continue to be considered as new drug for a period of four years from the date of its first approval or inclusion in the Indian Pharmacopoeia, whichever is earlier". Therefore, when the drug for which approval is being sought is a new drug, the details that are required to be given by the applicant include: (i) marketing information including proposed package insert/promotional literature and draft specimen of labels/cartons (ii) special studies including information in respect of bio-availability and bio- equivalence and comparative dissolution studies for oral dosage.

25. The scheme of the DCA and the DCR envisages that when an application is made for grant of marketing approval for generic version of a patented drug, in respect of which marketing approval has already been granted to the patent holder, the applicant has only to satisfy the DCGI that its drug is bio-available and bio-equivalent to the patented drug. For instance, in the present case once marketing approval for its patented drug is granted to Bayer and thereafter Cipla seeks permission to market the generic version of the same drug, it need not undertake the Phase-III clinical trials. (See Appendix IA to the DCR) However, post marketing trials, known as Phase-IV trials, have to be performed by all companies to whom the marketing approval is granted. Therefore, the DCA read with the DCR clearly envisage a situation where marketing approval may be sought by a manufacturer of the generic version of a patented drug. The role of the DCGI is clearly cut out under the DCA and the DCR. Therefore, there is no scope for the DCGI to travel beyond the DCA and the DCR and ensure protection LPA 443/2009 page 19 of 27 of a patent by refusing marketing approval to a generic manufacturer only because the drug in question is patented. Given the above scheme, to suggest that patent linkage is established only because one column of Form 44 asks the applicant to indicate the patent status of the drug, is to misconstrue the provisions as they stand. A form in an appendix to a statutory rule (in this case the DCR) cannot be understood contrary to the scheme of the statute. Patent linkage that is not evident from the reading of the

Patents Act and the DCA cannot by a judicial interpretative exercise, howsoever creative, be discerned from one column in Form 44 appended to the DCR.

26. There is merit in the contention that if it was the intention of the Parliament to link the entry of information in respect of patent status with the grant of marketing/manufacturing approval, then the definition of „new drug" under Rule 122 E DCR ought to have been amended. A patent is valid for 20 years and if such linkage is recognized, then every time a marketing approval is sought by a generic manufacturer of a patented drug, the DCGI will have to perforce reject such application as long as 20 years have not elapsed from the date of grant of the patent. This is contrary to the provisions of the DCA as well as the provisions of the Patents Act. This court cannot possibly read into the statute a provision that plainly does not exist. (See e.g., Unique Butyle Tube Inds P Ltd. v. U.P. Financial Corprn (200)3 2 SCC 455 at 462 and Dadi Jagannadham v. Jammulu Ramulu (2001) 7 SCC 71 at 78) LPA 443/2009 page 20 of 27

27. Although arguments were advanced on what would be the position once the drug ceases to be a new drug i.e after four years from the date of its approval, this Court finds that issue to be academic as far as the present case is concerned and therefore does not consider it necessary to decide such issue.

28. This Court concurs with the learned Single Judge that the scheme of both the Patents Act and the DCA are distinct and separate and that the attempt by the appellant Bayer to establish a linkage cannot be countenanced. If Bayer"s argument were to be accepted, it would mean that instead of the validity of the patent being tested, if at all, either in revocation proceedings or by way of a counter-claim in infringement proceedings instituted by the patent holder, the DCGI will begin with the presumption that the patent granted in respect of the drug for which marketing approval is sought has been validly granted. He will then either outright refuse the marketing approval sought for a patented drug by the applicant (a generic manufacturer) or, as was suggested by Mr.Shanti Bhushan, put the application „on hold" till the applicant gets the question of the validity of the patent settled in proceedings that the applicant will have to institute before the Intellectual Property Appellate Board (IPAB). This argument is premised on a procedure that is not at all envisaged under the DCA and clearly is beyond the scope of the powers of the DCGI. As has been stressed by the DCGI, that office is plainly not equipped to deal with issues concerning the validity of a patent. That is a complex process as is evident LPA 443/2009 page 21 of 27 from the provisions of the Patents Act. What Bayer wants the DCGI to do is to enforce its rights as a patent holder in terms of Section 48 of the Patents Act. That is plainly not the function of the DCGI. His powers and jurisdiction are circumscribed by the DCA and not the Patents Act. It is entirely up to the patent holder to seek whatever remedies are available to it to enforce and protect its patent from infringement. This is in the private law domain. The DCA has nothing to do with it. There is merit in the contention that when a private right is conferred by a statute, the remedy for an infringement of that right has to be in terms of that statute and no other. (See U.P.State Bridge Corprn Ltd. v. U.P.Rajya Setu Nigam S. Karamchari Sangh (2004) 4 SCC 268 at 275-276)

29. There are other problems in accepting the submission of Bayer. If the patent holder in respect of a life saving drug decides only to seek marketing approval and not manufacturing approval, it would mean that it will be importing into the country that drug which will

consequently be priced very high. Accepting on the other hand, Bayer‟s contention would mean that the patent holder would be able to block off all generic manufacturers who might have been able to make the drug available in the market at affordable prices, subject of course to their being able to successfully resist injunctions in infringement suits instituted by the patent holder. If the patent holder does not apply for even a marketing approval, then the drug will be virtually unavailable in India till such time the patent holder decides it should be available. Although the Patents Act recognises the monopoly of the patent LPA 443/2009 page 22 of 27 holder for a period of three years, after which the compulsory licensing route opens up, the question of preventing the DCGI to grant marketing approval for the generic version of the drug during that period is not envisaged by the provisions of the DCA as they presently stand. The expectation is that the patent holder will institute appropriate proceedings during the „monopoly‟ period to safeguard its rights in terms of Section 48 of the Patents Act. It does not require the DCGI‟s help in this.

30. Whether patent linkage should be introduced is an issue that requires a policy decision to be taken by the government. It is not for the court to determine if the government should bring in a system of patent linkage. There is considerable literature on the topic with many a developing country resisting it in the interests of public health care that is both affordable and accessible. The court cannot and ought not to dictate that policy shift. (see M.P. Oil Extraction v. State of M.P. (1997) 7 SCC 592 at 610-11)

31. The complexity of the factors and the issues that might possibly weigh with the government in taking a call on such a policy matter is best brought out in the following observations of a legal scholar:

"Patents remain by far the most controversial of the IP rights harmonized under TRIPS. Not only do patents confer significantly stronger rights of exclusivity than other IP regimes, the subject matter of patents-technology-most directly impinges on economic prosperity. In the case of pharmaceuticals, access to patented technology can literally become an issue of life or death. Indeed, LPA 443/2009 page 23 of 27 the recent showdown in the World Trade Organization (WTO) over compulsory licensing of AIDS medication served as a wake-up call for many who had previously dismissed patents as a technical domain of interest only to specialists. Patent protection suddenly became the ugly face of globalization, seemingly a hazard to public health and travesty of social justice.

Discontent over TRIPS' patent provisions goes well beyond pharmaceuticals. Patent systems are, by nature, the most administratively demanding form of IP protection, requiring extensive record-keeping and sophisticated technical analysis. Yet, given that the top ten industrialized countries account for 94% of patents granted worldwide, the benefits of patent protection are heavily skewed. Even TRIPS' defenders concede that its patent mandate represents an onerous and costly obligation whose immediate benefits will redound primarily to rich multinational companies.

Furthermore, because technology is a cumulative enterprise, TRIPS opponents worry that enforcing patent monopolies will deny developing countries access to vital technology, relegating them to a future of economic dependency." [Sean A. Pager, "Patents on a Shoestring: Making Patent Protection Work for Developing Countries", 23 Ga. St. U.L. Rev. 755at 756-57] (emphasis supplied, footnotes omitted)

32. There is also merit in the contention that patent linkage is a TRIPS Plus concept and India has only signed on to TRIPS. Worldwide there is a raging debate on whether patent linkage should be permitted. There is no uniformity in the policy of different countries. In the U.S.A for a short period of 30 months, during which the onus is on the patentee to seek an LPA 443/2009 page 24 of 27 injunction against the alleged infringer, patent linkage is recognised. If within that period no injunction is granted by the court of law, then the marketing/manufacturing approval is granted to the generic manufacturer. Unless, there are express provisions in the DCA requiring the DCGI not to grant marketing approval to a generic manufacturer in respect of a patented drug, it is not possible for this court to read such a requirement into the law. Are Generic drugs 'spurious'?

33. That brings us to the last issue, whether generic drugs are „spurious‟ drugs within the meaning of the DCA? Section 17B DCA states that a drug shall be deemed to be spurious "if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug". It is difficult to appreciate how the elements of Section 17B DCA stand attracted when a generic manufacturer merely applies for marketing approval in respect of a patented drug. The contravention of the DCA as a result of the drug being a „spurious‟ drug cannot possibly occur even before such drug is manufactured or marketed. At the stage of application for permission to manufacture or market, all that the DCGI can ensure, consistent with Section 17 B (a) DCA, is that the proposed brand name of the drug is not similar to the brand name of any other drug. To that limited extent, Section 17 B (a) is a provision that LPA 443/2009 page 25 of 27 requires to be factored in by the DCGI at the time of grant of marketing approval.

34. The decision of the Division Bench of the Allahabad High Court in Cattle Remedies v. Licensing Authority, on which considerable reliance was placed by Mr.Shanti Bhushan, was in the context of a brand name of a patented drug for which an obligation on the DCGI lay in terms of Section 17 B (a) DCA to ensure that the drug proposed to be marketed does not have a brand name similar to that of an already approved drug. It was in that context that the Allhabad High Court relied on the observations of the Supreme Court in Cadila Healthcare Ltd. v. Cadila Pharmaceutical Ltd.

35. The situation here is different. Cipla rightly states that it will use its own brand name and label and therefore there is no question of manufacturing a drug under a name which belongs to another drug. Further, the terms „imitation‟ and „substitute‟ occurring in Section 17 B (b) DCA should be read in conjunction with the other words "in a manner likely to deceive". This envisages a situation where a generic manufacturer is passing off its drug as that of the patent holder by way of deception. Cipla states that it is not trying to pass off its drug as that of the appellant. It would be stretching the language of Section 17B (b) DCA to an impermissible limit to hold that all generic versions of patented drugs, for which marketing approval is sought from the DCGI in terms of the DCA, should be considered to be „spurious‟ drugs.

36. There is another aspect of the matter that requires to be adverted to. The manufacture or marketing of spurious drugs under the DCA attracts penal consequences whereas the Patents Act itself does not envisage penal consequences in the event of an infringement of a patent. Therefore, by accepting Bayer‟s contention that every generic drug would be a spurious drug, this court would be subjecting manufacturers of generic versions of patented drugs to prosecution under the DCA although the Patents Act does not provide for such a consequence. This is yet another reason why the attempt at bringing in patent linkage on the basis of the existing provisions of the Patents Act and the DCA cannot be countenanced.

37. For the aforementioned reasons this court does not find any ground having been made out to reverse the well reasoned judgment of learned single Judge in which we fully concur. The appeal is accordingly dismissed.

Sd/-

S. MURALIDHAR, J.

Sd/-

CHIEF JUSTICE

February 09, 2010