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

Date of Reserve : 25.02.2009
Pronounced on : 18.08.2009

\+ WP(C) No.7833/2008

BAYER CORPORATION & ORS. ..... Petitioners

Through: Mr. Shanti Bhushan, Sr. Advocate with Mr. Sanjay Kumar, Ms.Arpita and Mr. Vineet Rohilla, Mr. Peeyoosh Kalra, Advocates.

versus

UOI & ORS. .....Respondents

Through: Mr. Arun Jaitley, Sr. Advocate with Ms.Pratibha M. Singh, Mr. Saya Chaudhary & Mr. Kapil Wadhwa, advocates for Resp. No.3.
Mr. Anand Grover with Ms. Nandita Rao and Ms. Pratibha M. Singh, advocate
Mr. Gaurav Duggal, Advocate for UOI.
Mr. Sandeep Sethi, Sr. advocate with Mr. R.Singh, Mr. J.Mehta and Mr. Kaushik Poddar, Advocates

CORAM:
HON'BLE MR. JUSTICE S. RAVINDRA BHAT

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.RAVINDRA BHAT, J.

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1. The writ petitioner, a pharmaceutical company manufacturing various kinds of drugs, (hereafter "Bayer") seeks directions to, *inter alia,* restrain grant of drug license in regard to an application by the third Respondent for the license to manufacture, sell and distribute its drug "Soranib". Bayer claims that the said drug is an imitation of, or substitute for its (the first petitioner's) patented drug. It is submitted that the said drug "Soranib", being a "spurious drug"

as defined in Section 17B of the Drugs and Cosmetics Act, (hereafter called "the Drugs Act") and the second respondent Drugs Controller (hereafter "the Controller" and "DGCI") would be exceeding his jurisdiction, and deciding in contravention of Chapter IV of the Drugs Act, if the application for marketing license is processed.

2. Bayer is a corporation organized and incorporated under the laws of Indiana, USA; the second petitioner is its Indian subsidiary. It is owner of Indian Patent number 215758 (hereinafter referred to as "the subject patent") which was granted by the Patent Office on March, 3, 2008. Therefore, by virtue of section 48 of the Act, Bayer has exclusive right to prevent third parties who do not have its consent from the acts of making, using, offering for sale, selling or importing the patented product in India. Bayer relies on Sections 43, 48 and 53 of the Patents Act, 1970 to say that the said provisions clarify that upon grant of a patent, a patentee secures, for a term of twenty years from the date of filing of the application, the exclusive right to prevent third parties who do not have its consent from making, using, offering for sale, selling or importing patented product in India.

3. Bayer submits that in the present case the application of the third Respondent ("Cipla") is for the license to manufacture, sell and distribute its drug "Soranib" which is an imitation of and/or substitute for the patented drug under its (Bayer's) patent. It is alleged that this drug "Soranib" therefore, being "spurious drug" as defined in Section 17B of the Drugs Act, the second Respondent would not only be exceeding his jurisdiction but also give a decision which would be *ultra vires* Chapter IV of the Drugs Act.

4. Bayer contends that the term "spurious drug" as defined in the Drugs Act has to be understood in light of the fact that after January 1, 2005, full-fledged product patent regime has come in place, in India. Therefore, the term "spurious drug" as defined by Section 17B of the Drugs Act has to be read not only to accommodate the relevant provisions of the Patents Act but also to accomplish the goal that was contemplated to the achieved by Indian legislation while ushering in a full-fledged product patent regime. Reliance is also placed on Section 2 of the Drugs Act, which is as follows:

> *"Application of other laws not barred : The provisions of this Act shall be in addition to and not in derogation of, the Dangerous Drugs Act, 1930 (2 of 1930), and any other law for the time being in force."*
>
> *(emphasis supplied)*

Section 2, it is contended, manifests legislative intention to read the provisions of the Drugs Act, in addition, and not in derogation with any law for the time being in force. Section 48 of the Patents Act is one such "law for the time being in force", in the present case, that has to be read in, and not excluded, by the second respondent.

5. Bayer also submits that the absence of an overriding provision in the Drugs Act, reinforces the intention of the legislature that its provisions (of the Drugs Act) are to be read in addition, and not in derogation with any law for the time being in force. Therefore, according to it, the conclusion is irresistible that the relevant provisions of the Drugs Act have to be read in conformity with the relevant provisions of the Patents Act (Section 48 of the patents Act in the present case). Therefore, in the event Respondent no.2 grants marketing approval to Cipla on the application made by the latter for a product covered by Bayer's patent for "Sorafenib tosylate", Section 48 of the Patents Act will be derogated from which in turn, under Section 2 of the Drugs Act, is impermissible. Bayer contends that Section 2 of the Drugs Act read with Section 48 of the Patents Act, provides the concept of "Patents Linkage". With the power to grant marketing approval which vests with the Drug Controller. By virtue of Section 2 of the Drugs Act, the Drug Controller needs to ensure that his decision on the grant of marketing approval should not derogate from any other law for the time being in force. It is contended that in other words, the scheme of the Drugs Act mandates the Drug Controller should ensure that while granting marketing approval, he does not violate any other law for the time being in force. Here, in the present case, when all facts are before him, Respondent No.2 has no reason to grant marketing approval to CIPLA, especially when it will be contrary to section 2 of the Drugs Act (as it will be in derogation of Section 48 of the patents Act), which he is duty bound to follow. Bayer concedes that the second Respondent can grant marketing approval to Cipla once the patent protecting the product expires, or it (Cipla) obtains a licence from the patentee.

6. Bayer relies, besides Section 2 and 17-B of the Drugs Act, upon Section 18 of the same enactment, as well as Form 44 along-with data, under Appendix 1 to Schedule Y of the Rules, which, it says, must have been filed by CIPLA before the second Respondent, apart from other information; they require mention of the patent status of the drug. It is submitted that this is acknowledged by Respondent Nos. 1 & 2 in their counter affidavit; the composition of the formulation of the drug for which an application is made and also requires submission of date as per Schedule Y. It is submitted that while making an application before the Drug Controller, CIPLA ought to have mentioned the subject Patent of Bayer. Therefore, by a mere reading of Form 44, and also by virtue of publication of grant of the subject patent, it would be well within the knowledge of the Drug Controller that the subject patent exists in relation to the product for which CIPLA has applied for; consequently, if the marketing approval is granted, it will contravene the provisions of Section 17B of the Drugs Act, as well as the provisions of Section 48 of the Patent Act.

7. It is submitted that when a pharmaceutical company first markets a drug, it is usually under a patent that allows only the pharmaceutical company that developed the drug to sell it. Generic drugs can only be legally produced for drugs which are free of patent protection. The expiration or invalidation of the patent removes the monopoly of the patent holder on drug sales or licensing patent lifetime differs from country to country, and typically there is no way to renew a patent after it expires or to revive it after it is invalidated. A new version of the drug with significant changes to the compound could be patented, but this requires new clinical trials. This allows the company to recoup the cost of developing that particular drug. After the patent on a drug expires, any pharmaceutical company can manufacture and sell that drug for a fraction of the original cost of testing and developing that particular drug; in essence, says Bayer, this is a “generic” product. Therefore, a product for which CIPLA has applied for the grant of marketing approval is not generic drug but “spurious drug” as defined under Section 17B of the Drugs Act for which marketing approval cannot be granted as per Section 18 of the Drugs Act. In view of the aforesaid submissions, it is submitted that “generic drug” and “spurious drug” are two different concepts and cannot be interpreted in the manner sought to

be canvassed by CIPLA, in its opposition to the present proceeding. Bayer's product is protected by a patent; it is not "generic"; CIPLA's products are "spurious".

8. Mr. Shanti Bhushan, Bayer's Senior counsel, besides reiterating the combined effect of Section 2, 17-B and 18 of the Drugs Act read with provisions of the schedule (which oblige an applicant to disclose particulars relating to patent in respect of the drug for which marketing license is sought) also submitted that this court should interpret Section 2 purposively to further legislative intent, rather than otherwise. He contended that with amendments to the Patents Act in 2005, pursuant to India's commitment to be part of the WTO *regime,* the court had to recognize the need for patent linkage with the drug licensing mechanism. He contended that a patent is granted after elaborate examination, scrutiny and inspection of the product and process, for ensuring its efficacy, novelty, existence of inventive step and industrial application. It can even be challenged by persons aggrieved, after its grant. If, after a patentee, rewarded for his toil – in the form of protection against infringement – were to be informed that someone, not holding a patent, would be reaping the fruits of his efforts and investment, such a result would be destructive of the objectives underlying the Patents Act. A patentee has, the untrammeled right to exclude anyone else from manufacturing, selling, importing or marketing that product, by virtue of Section 48:

> *"**Section 48 Right patentees-** Subject to the other provisions contended 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)……"*

9. Bayer's senior counsel relied upon Rule 122-B(1) (b) of the Drugs and Cosmetics Rules, 1954 (hereinafter referred to as "the Drugs Rules" which reads as follows:

> *"An application for grant of approval to manufacture the new drug and its formulations shall be made in form 44 to the Licensing Authority as defined in clause 9(b) of rule 21 and shall be accompanied by a fee of fifty thousand rupees."*

It is contended therefore, that logically, Form 44 along-with data (Appendix 1 to Schedule Y) must have been filed by CIPLA; it requires disclosure of patent status of the drug, a fact conceded by Respondent Nos. 1 & 2 in their counter affidavit; composition of the drug formulation, for which an application is made and also requires submission of data, under Schedule Y. All these facts would be within the knowledge of the Drug Controller that subject patent exists in relation to CIPLA's product, for which it has applied and consequently, if marketing approval is granted it will contravene the provisions of Section 17B of the Drugs Act, as well as the provisions of Section 48 of the Patent Act. It is argued that applications for permission to market a new drug, contained in Appendix 1 to Schedule Y, under the heading "chemical and pharmaceutical information" require many details, some of which are chemical name of the drug, non proprietary or generic name of drug, structure of the drug and its composition particularly, the composition of the active and inactive ingredients. The data disclosure of CIPLA in its application, and the information in the subject patent specification would disclose that the drug "Soranib" for which it (CIPLA) has applied for grant of marketing approval is the same as the drug for which subject patent has been granted by the Patent Office to Bayer. These facts, it is urged, conclusively establish that grant of approval would plainly contravene the petitioners' patent, and therefore, rights under Section 48, Patents Act.

10. It is argued that CIPLA does not deny having applied for marketing approval for the patented drug "Sorafenib tosylate" before Respondent No.2. Bayer urges that this emerges from CIPLA's counter affidavit. In light of this above admission, it is no more a case of Bayer's mere apprehension of the subject patent being infringed, if the marketing approval is granted (to CIPLA) for the drug in question, as it is an admitted fact that CIPLA has applied for grant of marketing approval for a product which is covered by the subject patent. It is further submitted that the present writ petition is to prevent and pre-empt CIPLA from introducing their drug in the market by seeking a declaration that if it (CIPLA) introduces the product in question in the market, it would constitute infringement of the petitioners' subject patent. It is submitted that such a declaration would put CIPLA, on notice and prevent it from introducing the infringing product in question in the market, thereby preventing future litigation.

11. It is further argued, by placing reliance on two judgments, that the expression *"in addition to, and not in derogation of"* in Section 2 should be construed as obliging the officials under the Drugs Act to defer to rights, particularly intellectual property rights recognized under other Indian laws, and conferred after satisfaction of rigorous standards. Bayer points out that unlike the device of a *non-obstante* clause, which manifests legislative intention to subordinate one legislation, or provision, to another, a non-derogation clause compels the authority administering the particular statute to respect obligations arising, and rights conferred by, or under other laws. Reliance is placed on the judgments reported as *Cattle Remedies and Anr. Vs. Licensing Authority/ Director of Ayurvedic and Unani Services* (2007 (2) AWC 1093, where, interpreting Section 2, the Allahabad High Court held that:

> *"52. Our conclusions are as follows :*
>
> *(a) The licence to manufacture drugs that fall under the category of patents and proprietary medicines' cannot be granted:*
>
> *(i) If these drugs are patents of any one else;*
>
> *4.1. Spurious drugs are defined under Section 17 B and Section 33EEA of the Drugs Act. Though, these sections, do not use the word trademarks but they say that spurious drugs is the one that resembles another drug in a manner likely to deceive. We have already held that the disputed drugs manufactured by the parties are different (see discussion under sub-heading "drugs of the parties – Different' of the 3rd point). In case same names are given then there is likelihood of the persons being deceived. And a medicine that is patented under the patents Act cannot be manufactured by any one else except under a licence. In our opinion the licensing authority while granting licence to manufacture 'patent or proprietary medicine' under the Drugs Act should not grant licence in the trade name/ mark of any other party. At the time of grant of licence, the licensing authority should consider the following two points:*
>
> *(i) Whether the name is trade mark of any one else or not, and*
>
> *(ii) Whether the medicines are patented under the Patent Act or not.*
>
> *It is for this reason that the Supreme Court made the following observations in Cadila Health Care Ltd., Vs. Cadila Pharmaceuticals ltd.,*

It is but proper that before granting permission to manufacture drug under brand name the authority under that act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade office pertaining to the trade mark in question which will enable the drug authority to arrive at a correct conclusion."

Bayer next relies on the decision in *Hoechst Pharmaceuticals Vs. C.V.S. Mani,* (ILR 1983 Delhi 548) where this Court, dealing with the scope of Section 2 of the Drugs Act, in the context of amendment to the rules, by which those selling drugs were prohibited from using trade or proprietary marks, observed that:

"The effect of the amendment, inter alia, is that drugs specified in the said notification in Schedule 'W' thereto containing a single active ingredient is required to be labelled only with the proper name of the drug and not with any trade name. The impugned notification further amends the rules to the effect that preparations containing any new drug with a single active ingredient and approved under Rules 30A, 69B and 75B were to be marketed under the generic name only. It is the petitioners' contention that though representations were made by the petitioners and others, no opportunity of being heard was granted to them by the Central Government. The impugned notification is challenged and in particular amendment to Rule 96 is challenged, inter alia, on the following grounds:—

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(2) That though misbranding would include branding in such a manner which is contrary to the rules, giving of trade name or brand name on the label or packing of a drug cannot fall within the scope of the rule making power. In, other words, by purported exercise of the power conferred by Section 33(1) in framing rules the Central Government cannot impinge upon the law relating to trade mark and prevent the use of trade names or brand names.

(3) That prohibition to use trade names or brand names amounts to interference in the proprietary or property rights of the petitioners who are registered users or/and proprietors of trade marks. Thus, the impugned amendments amount to infringing property rights of the petitioners.

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(22) From the above two observations of Supreme Court it becomes obvious as to what is the real object of the Act and what is the legislative scheme and policy of this

enactment. Indeed, the Act, as Section 2 lays down, is in addition to and not in derogation of any other law and the real purpose of the enactment is to ensure quality and standards of drugs manufactured, imported, distributed and sold in the country. If that be correct, as indeed it must beheld to be, we have to read Section 12 and Section 33 giving the rule making power in the above context and of the provisions of Chapter Iii and Chapter Iv of the Act We have also to see that no rule is made under the Act which is vocative of any other law or impinges upon any other right recognized or conferred by any other law. If a rule impinges upon any other law or any other right, it must be held to be outside the rule making power of the Central Government Section 2 on the one hand and Sections 12 and 13 of the Act on the other have all to be read together, being part of the same enactment and part of the same legislative scheme.

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(27) The impugned rules must also be held to transgress the scope of the power conferred by relevant clauses of Rules 12 and 33, read with Section 2 of the Act. In terms Section 2 lays down that the provisions of the Act shall being addition to and not in derogation of the Dangerous Drugs Act and any other law for the time being in force. The Trade marks Act is a valid law in force. We have earlier noticed the relevant provisions of the Trade Marks Act. Prohibiting the use of trade names under the garb of the power conferred by Section 12 and 33 brings the impugned portion of Rule 96 in conflict with the provisions of the Trade Marks Act. The petitioners, who are proprietors or users of the trade marks, have a right to sue their trademarks under the provisions of the Trade marks Act. Denying them this use not only puts their property rights into jeopardy but is in clear derogation of the rights guaranteed by the provisions of the Trade marks Act, therefore, any rule which is framed which would be in "derogation of another valid law cannot be countenanced in view of the provisions of Section 2 of the Act. The Rules have to be complementary to the provisions of the Act and the provisions of other valid laws. Rules cannot be in conflict with the provisions of the Act or the provisions of other valid laws."

12. Bayer emphasizes that the object of Section 2 is further reinforced by Section 156 of the Patents Act, enjoining the Government, and declaring that for all intents and purposes, a patent granted under the Act has the same effect on the Government, as on others. It is therefore, contended that the Court should be mindful of this provision, and hold that the authorities under the Drugs Act, being functionaries of the Central Government, are equally bound by, and obliged to, respect the patent granted to Bayer. It also submits that the Patent Act expressly

stipulates, by Sections 84 and 92-A, situations where the Central Government can issue compulsory licenses; the latter provision is specific as regards pharmaceutical patents. Such being the reality, the Central Government should not defeat patent owners' rights by granting permission to manufacture, or market drugs or formulations for which applicants do not have any such rights.

13. The next submission is that the concept of "Patent Linkage" is statutorily provided in the US under the legislation known as the Hatch- Waxman Act (1984), amending the Federal Food, Drug and Cosmetic Act. The Food and Drug Administration (FDA) maintains a listing of pharmaceutical products and their uses currently under patent, known as the Orange Book. The FDA may not authorize the marketing approval for a generic copy of a pharmaceutical product that is protected by a patent listed in the Orange Book. Bayer states that similar patent linkage provisions exist in other countries. It is submitted that the two statutes in question read together- i.e Section 2 of the Drugs Act read with section 48 of the Patents Act- have an inbuilt provision of "patent Linkage". The power to grant marketing approval vests with the Drug Controller. However, by virtue of Section 2 of the Drugs Act, the Drug Controller needs to ensure that his decision on the grant of marketing approval should not derogate from any other law for the time being in force (Section 48 of the patents Act in the present case).

14. It is submitted that Cipla's reliance on Section 107-A (a) of the Patents Act, 1970 is misplaced; and that such provision that despite subsisting patent rights, any act of making, constructing, using, selling or importing a patented invention for usage reasonably related to the development and submission of information required under any law shall not be considered an act of an infringement. It argued that the Indian Draft Manual on patent practice and procedure, also interprets the said section in the following terms :

> *"20.3 Bolar-Like Provision And parallel Import Provision*
>
> *Some countries allow manufacture of generic drugs to use the patented inventions for development and submission of information required under law – for example – from public health authorities – without the patent owners permission and before the patent protection expires. The generic producers can then market their version as soon as the patent expires.*

This provision is called Bolar-Like provision or regulatory exception. Indian Patent Act provides such a provision under S. 107 A(a)"

In view of the above the legislative intention is clear that the submission of information required under the law is to enable generic producers to market their version as soon as the patent expires or it is revoked, as the case may be, but not to market their version when the patent is in force.

Cipla's submissions

15. Cipla contests this proceeding, arguing that Bayer's claim for patent linkage, based on an interpretation of Section 2 of the Drugs Act is misleading, because
i) The grant of drug regulatory approval by the DCGI cannot, by itself amount to a patent infringement
ii) The existence of patent infringement cannot be assumed merely because the patentee states so, but has to be clearly established before a court of law in accordance with the infringement provisions mentioned under the Patents Act, 1970. Such an assessment is beyond the statutory powers of the DCGI, which is institutionally incapable of dealing with complex issues of patent scope, validity and infringement.

16. Cipla says that Section 48 of the Patents Act, spells out the various exclusive rights of a patentee and includes the acts of "making, using, offering for sale, selling or importing" the patented product or process as the case may be. It is submitted that grant of a drug regulatory approval by the DCGI to Cipla on the basis that its drug is safe and effective does not amount to an act of "making, using, offering for sale, selling or importing" the petitioners' patented product. Cipla states that Section 107A of the Patents Act, clearly exempts from patent infringement any of acts of making, using or even selling a patented invention, in so far as such acts are necessary to obtain information for the filing of a drug regulatory application before the DCGI. It is highly illogical to argue that when all acts leading upto the stage of drug approval are exempt from patent infringement, the very act of approval itself amounts to an infringement.

17. It is argued that Section 107A (a) of the Patents Act, commonly referred to as the

"Bolar" provision permits any drug manufacturer to experiment with any patented drug with a view to generating data that could then be submitted to a drug control authority. The aim of this section is to ensure that generic drugs are introduced into the market as soon as the patent expires or is invalidated, so that consumers may benefit from this early entry of affordably priced drugs. Cipla's senior counsel, Shri Arun Jaitley submits that If Bayer's argument were accepted, it would hit at the very essence of the Bolar provision that is aimed at speeding up generic entry into the market and the availability of low cost drugs to the consumer. Cipla argues that Bayer's submissions are premised on the notion that the patent is a valid one and that it is infringed. Cipla states about its intention to challenge the validity of the Bayer's patent. More importantly, neither is the DCGI authorized by the DCA to make such an assessment nor does it possess the institutional competence to make such an determination. From section 104, it is only a court of law that can make such an assessment in an infringement suit filed under the Patents Act.

18. Cipla states that Section 19 of the Patents Act provides limited powers to the Controller in the context of a new patent application that potentially infringes an existing patent. It is contended that in such cases, the Controller may at best only direct that a reference to the earlier patent (that has been potentially infringed) be inserted in the new applicant's complete specification, so that it serves as "notice" to the public. It does not authorize the controller to deny the grant of the patent itself to the applicant. Cipla urges that absent a specific statutory provision authorizing it to do so, an institutionally incompetent authority such as the DCGI cannot assess the possibility of patent infringement and deny drug regulatory approval on such ground.

19. Cipla next submits that the petitioners have misinterpreted the term "spurious drug" defined under section 17B of the Drugs Act. It points out that under the provision a 'Spurious drug' is

(a) if it is manufactured under a name which belongs to another drug or

(b) if it is an limitation 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 back of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist ; or

(d) if it has been substituted wholly or in part by another drug or substance or

(e) it is purports to be the product of a manufacturer of whom it is truly not a product.

20. Cipla, thus states that the terms "limitation" and "substitute" in Section 17B (b) cannot be read in isolation to the remainder of the sub-clause. The words "substitute for" are to be read along with "another drug in a manner likely to deceive". The text of the said sub clause reveals that the same covers a situation where an individual is passing off his drug as that of another by way of using deceptive marks get-up or packaging. By no stretch of imagination can this include patents. Hence the interpretation of the petitioners that the said sub-clause covers Cipla's drug Soranib is incorrect and is liable to be rejected in as much as the respondent no.3 is not trying to pass off its drug as that of the petitioners or of any other drug manufacturer.

21. It is submitted that there is no patent linkage *regime,* in the country, and what Bayer wants this court to do is to legislate it through interpretation, which is impermissible. Counsel contends that the TRIPs provisions, to which the country is a party leaves it to municipal legislation to establish patent linkage of the kind sought. All that is mandated in the TRIPS is that a "Bolar" provision, should be introduced, to encourage research and development, which has actually been done. The question of patent linkage is in reality a TRIPS plus policy, which is unsupported by Indian legislative policy. In these circumstances, the court should desist from making policy choices which are to be made by the executive and then made into law. It is argued that that the patent linkage concept is controversial in nature, since regulatory

authorities granting manufacturing licenses lack the resources and the man power to check the patent status of each product. Moreover, they may not have the expertise to assess whether the patent is valid and whether the same is being infringed. As a result, it is likely that they will enforce all patents including the invalid ones thereby creating additional and unnecessary hurdles for generic competition to the derogation of the public welfare and interest. It is further stated that various nations who have introduced the said concept of patent linkage are facing many problems in respect of working of the same despite the fact that steps were taken to establish sufficient safeguards in place.

22. It is urged that the Patents Act is a complete code which provides for protection of rights of both the patentee and third parties (including the general public). As a result, in respect of a valid patent, the patentee is free to file a suit for infringement and seek necessary relief towards protection of his rights as provided under sections 48 and 108 of the Act. On the other hand it is also open to a third party to challenge a invalid patent at various stages such as :

(a) pre-grant opposition (section 25 (1)]

(b) Post – grant opposition [section 25 (2)

(c) revocation of patent before the intellectual property Appellate Board (Section 64)

(d) revocation through a counter claim in a suit for infringement (Section 64 read with section 107)

It is argued that to read the provisions of the Drugs Act as having been enacted for protection of individuals rights as a patentee is wrong and erroneous. Further, the same would be contrary to the scheme of the patents act as well as the Drugs Act.

23. It is submitted that patents stand on a different footing when compared to other intellectual property rights inasmuch as violations of trademarks and copyrights have consequences which result in imprisonment, fine etc and are regarded as offences under the

respective enactments. However, under the Patents Act, except for a violation which falls in Chapter 20, infringement of a patent is not considered a criminal offence. On the other hand, under the Drugs Act, violation of any of its provisions constitutes a criminal offence. If patent linkage is directed, an act of infringement which is not an offence would indirectly be alleged to be an offence.

24. It submitted that the Patents Act also specifically provides that a counter claim for revocation of a patent, is in the exclusive jurisdiction of the High Courts irrespective of whether the High Court has original jurisdiction or not. In fact the Act vests the High Courts with powers to frame special rules in this regard (Sec. 158),. These clearly establish the seriousness with which the legislature views issues concerning infringement and revocation of patents. If the petitioners' contentions were to be accepted, the powers of High courts would be vested with the Drug Controller who will examine the merits of a patent while granting a drug approval, a situation unsupported by, and beyond contemplation of the legislature. The jurisdiction of the High Courts to hear infringement actions and simultaneously decide upon counter claims for revocation being exclusive in nature, cannot be indirectly shifted to the office of Drug Controller General of India, who neither has the expertise nor the competence to deal with patent related issues, just as the patent office does not possess the expertise or competence to grant a drug marketing approval in respect of a pharmaceutical preparation. The two statute's authorities therefore operate in completely different fields.

25. It is argued that the Drugs Act does not contain a provision which obliges the DCGI, in the course of performance of his statutory duties under the drugs act to deny a manufacturing license to an applicant if the same is patented. The criteria which the Drug Controller General of India (DCGI) is required to look into before granting a manufacturing approval for a drug is whether the said it is safe and efficacious in nature for usage in the country along with ensuring that the applicant has proper manufacturing units and necessary infrastructural facilities. Thus, the petitioners cannot under the auspices of the Act, enforce their patent rights in relation to a drug. On the country, if an applicant fulfils all the essential requisites as per the Drugs Act, the DCGI is under a statutory duty to grant the manufacturing approval marketing license.

26. Cipla argues that the present writ petition is an attempt to block marketing of generic drugs, by seeking to re-define "counterfeit" drugs, which was severely opposed by developing countries including Brazil and India. It is also urged that the concept of patent linkage is being used to enforce invalid patents and to prevent generic manufacturers from entering the market. By using such model, an additional level of protection for the purpose of extending the terms of the monopoly granted to a drug patent. It is submitted that such result should not be encouraged in the larger public interest.

27. The DGCI also argues that Patents Act is a self-contained code of all issues respecting to patents, their grants and enforcement, setting out the limited rights of the patentee, viz to prevent others from the act of making, using, offering for sale, selling or importing the patented product. The Patent Controller, the Intellectual Property Appellate Board (IPAB) and the courts- before which infringement suits are filed -are the only bodies competent to determine issues relating to patents. It argued that the scheme of the Patents Act discloses that grant of a patent is never conclusive and the Act has provides that different mechanisms for opposing grant of a patent at various stages. Section 47 allows the Government to import a patented medicine or drug for its own use or for distribution in certain dispensaries, hospitals and medical institutions. It argued that the established position of law is that patents confer negative rights on patentees to exclude others from doing certain specific acts. Reliance is placed on Section 107A of the Patents Act to say that certain acts required for the purposes of obtaining regulatory information are not to be considered as infringement. Similarly, DGCI urges that Section 107 of the Patents Act sets out the defences available in suits for infringement. It states that in a suit for infringement, every ground of revocation enumerated under section 64 shall be available as a defence. In relevant cases, the conditions under which a patent is granted are also available as a defence. The Patents Act actually contemplates that a person can take the risk of facing an infringement proceeding and seek revocation in its counterclaim. This remedy to challenge a patent by way of counterclaim cannot be closed off, by injuncting or preventing a party other than the patentee from selling a patented product, before the other party has actually infringed the patent.

28. The DGCI contends that patent rights are private rights and refers to Section 48 of the Patents Act, as well as Section 104, which sets out the jurisdiction of courts in respect of infringement suits. Therefore, the State – the DCGI in this instance – cannot enforce the private rights of a patentee. The DCGI is not the appropriate forum to enforce a patent, which is a private right. It is urged that the Drugs Act too is a self contained code with respect to matters pertaining to import, manufacture, sale and distribution of drugs and cosmetics. Chapter IV of the DCA sets out the provisions relating to standards of quality of drugs and cosmetics that are manufactured, sold and distributed in India and also defines "misbranded drugs" [Section 17], "adulterated drugs" [Section 17A] and 'spurious drugs' [Section 17B]. It prohibits their manufacture and sale [Section 18] and further penalizes such prohibited acts [Section 27]. The further contention is that the objects and reasons of the Drugs and Cosmetics (Amendment) Act, 1982, clarify that the definition of "spurious drugs' was mainly introduced because of the problems of adulteration of drugs and production of spurious and sub-standard as posing a serious threat to the health of the community.

29. The manufacturer, according to the DGCI, has to apply under Form 44 to obtain marketing approval [Rule 122B (1) (b)]. Marketing approval for a drug already approved drug can be obtained by submitting data as required under Appendix IA of Schedule Y. [third proviso to Rule 122B (1) (b)]. Further data demonstrating the safety and efficacy of the drug for which marketing approval is being sought [Form 44] has to be furnished. Item 2B Form 44 details conditions for subsequent approval also prescribes that the bio-availability/ bioequivalence protocol is a requisite for marketing approval [Item 2B (a)]. The marketing approval is then granted by the Licensing Authority if the bioequivalence protocol is satisfactory. Every manufacturer applying for approval for manufacture for sale also has to submit the information detailed under item 1 of Form 44 which includes patent status of the drug. However, this is mere information status and is not supported by any provision in the DCA and DCR. The DCGI does not have the legislative mandate as there is no provision which permits the DCGI to refuse marketing approval based on the patent status of a drug. It is therefore urged by DGCI that if an attempt is made to link the requirement of information relating patent status to marketing, it would be *ultra vires* the Patent Act as well as the Rules. The DCGI says that it lacks institutional

expertise to deal with complex patent issues. It is argued that Indian statutory law does not permit the linking of the patent status of a drug to its marketing approval. The DGCI also urges that there is no administrative or regulatory scheme in India permitting the system of patent linkages. In fact, other developing countries such as the Philippines have specifically not allowed patent linkage through an administrative order.

30. The Indian Pharmaceutical Alliance (IPA), Applicant in CM.2346/2009 has intervened in these proceedings, and advanced submissions. Its position is supportive of the stand taken by the other respondents, ie. Cipla and the DGCI.

31. The preceding discussion would show that the following points have to be decided by the court:

(1) Whether a combined reading of the Drugs Act and the Patents Act lead to the conclusion that no marketing approval can be granted to applicants for drugs or formulations, of which others are patent owners, by reason of Section 2 of the Drugs Act, read with Sections 48 and 156 of the Patents Act;

(2) Whether drugs or formulations which infringe patents are "spurious drugs" under the Drugs Act.

Point No.1

32. Patents are monopoly rights granted to those who invent or discover new and useful processes, products, articles or machine of manufacture, or composition of matter, or any new and useful improvement of any of those. It is not an affirmative right to practice or use the invention; it is a right to exclude others from making, using, importing, or selling patented invention, during its term. They are property rights granted by states, to inventors in exchange with their covenant to share its details with the public. The Patent Act 1970 was preceded by an enactment of 1911, which had consolidated the pre-existing law. Section 2 of the Patent Act is the definition clause; it inter alia, defines, inventions, inventive step, new invention, and patent, as follows:

"2. (j) "invention" means a new product or process involving an inventive step and capable of industrial application;
(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;
(l) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art;
(m) "patent" means a patent for any invention granted under this Act;"

33. An inventor or applicant seeking patent has to apply with specifications which conform to what is prescribed under Section 10 (of the Patents Act). Claims for patents have to fully and particularly describe the invention, its operation or use and the method by which it is to be performed. It should also disclose the best method of performing the invention, which is known to the applicant and for which the applicant is entitled to claim protection; and they have to end with claim(s) defining the scope of the invention for which protection is claimed. The procedure for grant (of patent) involves the following steps:

a) Publication of the application under Section 11-A(3) subject to the terms of the Act and request for its examination under Section 11-B;

b) Examination of the application by the Patent Office, under Section 12, including search for anticipation by previous application, under Section 13 and report of the patent examiner;

c) Various steps that the Controller, can follow, under Sections 14 to 21.

d) Where an application for patent is published, any person may, in writing, oppose to the Controller against the grant of patent on the grounds specified under Section 25 (1) (a) to (k).

e) If the application is found to be acceptable and in order, the Controller can grant the patent, and enter it in the Register, under Section 43.

f) Within one year any "person interested" can give notice of opposition to the Controller in the prescribed manner about his opposition to the patent, under Section 25 (2) on any of the grounds mentioned in clauses (a) to (k). In such event, the Controller has to constitute an Opposition Board, and give notice to the patentee. The Board will then examine the opposition,

under Section 25(3). Under Section 25(4) the Controller shall order either to maintain or to amend or to revoke the patent, on the basis of the Board's recommendations.

g) Before the Appellate Board, or on a counter-claim in a suit for infringement of the patent, in the High Court, a patent granted under the Act can be revoked on any ground enumerated in Section 64 (1) (a) to (q). These grounds are similar to the grounds of pre-grant opposition (by any person) and grounds for post grant opposition (by persons interested).

34. Section 48 enacts *inter alia,* that subject to other provisions contained in the Act and the conditions specified in section 47, a patent granted shall confer upon the patentee, 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. Section 108 enables courts trying claims for infringement to grant injunctive, and suitable reliefs, appropriate in the circumstances. Under Section 105, notwithstanding anything contained in section 34 of the Specific Relief Act, 1963, any person can institute a suit for a declaration that the use by him of any process, or the making, use of sale of any article by him does not, or would not, constitute an infringement of a claim of a patent against the patentee or the holder of an exclusive licence under the patent, notwithstanding that no assertion to the contrary has been made by the patentee or the licensee, subject to certain conditions. Under Section 104-A, subject to a patentee or a person deriving title or interest in the patent from him first proves that the product is identical to the product directly obtained by the patented process, (where the subject matter of patent is a process for obtaining a product), the court may direct the defendant to prove that the process used by him to obtain the product, identical to the product of the patented process, is different from the patented process.

35. Inherent in the concept of patent is the grant of a property right to the inventor, by the state. The term of a new patent is 20 years from the date on which the application for the patent was filed. A patent right is the right to exclude others from making, using, offering for sale, or selling the invention; or "importing" the invention into the country. What is granted is not the right to make, use, offer for sale, sell or import, but the right to exclude others from making, using, offering for sale, selling or importing the invention. Patents are premised on

existence of a novel or inventive step, which is capable of industrial application. Such inventions or developments, being of immense potential for human progress, are granted monopolies traditionally, for limited periods; in India, the patents' tenure is twenty years. A trademark is a word, name, symbol or device (or their combination) used in trade with goods or services, to indicate the source of such goods or services and to distinguish them from others' goods. Trademark rights may be used to prevent others from using a confusingly similar mark, but not to prevent others from making the same goods or from selling the same goods or services under a clearly different mark. Trademarks, therefore, are based on distinctiveness of the mark, and its association with a product and the constancy of the *source,* or manufacturer. Here, there is no question of inventive step, or novelty. Copyright protection is provided to the authors of "original works" including literary, dramatic, musical, artistic, and certain other intellectual works, both published and unpublished. The Copyright Act, 1957 generally gives copyright owners exclusive rights to reproduce the copyrighted work, to prepare derivative works, to distribute copies or phono-records of the work, to perform the copyrighted work publicly, or to display the copyrighted work publicly. The important aspect here is that what is protected is the expression of the idea, and not the idea itself. For example, a description of a machine could be copyrighted, but this would only prevent others from copying the description; it would not prevent others from writing a description of their own or from making and using the machine. Copyrights have also been extended to computer software. Copyrights' tenure, in India, is sixty years; trademarks, however do not have any such limitation. It is not necessary that copyrights are registered; in the case of trademarks, their registration affords a greater protection, as registration results in a presumption. In the case of patents, however, the property owner does not, in the absence of a grant, (of patent) possess any right to prevent a rival from producing the same goods or products. Patents, unlike other intellectual property rights, are susceptible to challenge, at the "pre-grant" stage; later, at the "post-grant" stage; they can be questioned in proceedings before the Intellectual Property Appellate Board, and also challenged by defendants in suits; if such challenges are made in civil courts, the High Court assumes jurisdiction, and tries the action. Such multiple challenges to the intellectual property right are absent in the case of copyrights and trademarks.

36. The Drugs Act was enacted to regulate the import, manufacture, distribution and sale of drugs. The definition of drug, in Section 3(b) is as wide as it can be; and the sole exception relates to medicines and substances used or prepared for use exclusively in the Ayurvedic or Unani system. Chapter IV of the Act contains provisions relating to manufacture, sale and distribution of drugs. Section 16 provides that "standard quality" in relation to a drug means that it (the drug) complies with the standards set out in the Schedule. Section 17 relates to misbranded drugs; Section 17A deals with adulterated drugs. Section 18 prohibits manufacture and sale of sub-standard drugs including misbranded drugs. Sections 20 and 21 provide for the appointment of Government Analysts and Inspectors, the procedure to be followed by them and the reports of Government Analysts. Any person who manufactures for himself or by any other person on his behalf, manufactures for sale or for distribution, or sells or stocks or exhibits or offers for sale or distributes any adulterated, spurious or misbranded drugs shall be punished under Section 27; the punishments provided are severe.

37. A plain juxtaposition of the two enactments highlights distinct, even disparate objectives. The Drugs Act is a public regulatory measure, prescribing standards of safety and good manufacture practices which are to be followed by every pharmaceutical industry, or which are to be satisfied by the importer of a drug, to assure that what are marketed are safe. The provisions of the Act manifest Parliamentary concern with public health in ensuring standard practices, and that people do not fall prey to adulterated or spurious drugs. There is a general public policy interest in such regulation, just as in the case of other enactments which reflect societal concern in compliance with safety standards whether it is in buildings, equipment and machinery, licensing of medical practitioners and other professional service providers like chartered accountants, lawyers etc. Such concern may also be seen in regulatory enactments like Prevention of Food Adulteration Act, Standards of Weights and Measures Act, labour law enactments and provisions which provide for safety, hours of work, prevention of hazards at the workplace and public places (fire safety), etc. The Patents Act on the other hand, puts in place a *regime* containing standards for conferring private monopoly rights in favour of inventors. It requires that processes or products, to claim patents, should involve steps that are *"technical advance as compared to the existing knowledge or having economic significance or*

both"; or which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of the patent application. Of necessity, it covers a wider field than a regulatory law. The Controller of Patents and other officers are experts at judging whether claimed products or processes are patentable. This expertise is not only in respect of pharmaceutical products, but other specialized areas, such as engineering goods, components, accessories and other processes and articles that have industrial applications. This expertise depends upon adjudging, on an objective basis, whether a product or process is novel, or contains an inventive step. Such expertise does not necessarily exist in the case of officials under the Drugs Act, who are required to test the safety of the product, and ensure that it conforms to the therapeutic claim put forward. Whether it involves an inventive step, or is novel, is not within the domain of the Drugs Act authorities and officials. To invest these regulatory authorities with functions that are exclusive to other enactments would be beyond intendment of the Drugs Act. Conversely, the authority to police Patent standards is exclusively that of the authorities under the Patent Act; indeed at least two of them are quasi judicial or judicial (Intellectual Property Appellate Board, and the High Courts).

38. There are other problems in accepting Bayer's contentions. The existence of patent linkage standards in express legislation, in other parts of the world (like in China, which was relied on, and the "Orange Book" provisions, mandated upon the US Federal Drug Agency, through the Drug Price Competition and Patent Term Restoration Act, 1984, also known as the *"Hatch Waxman Act")* underscores that courts, in the absence of a Parliament mandated *regime*, should not blaze into an obviously legislative path. No doubt, courts can, through interpretive devices such as purposive interpretation, or for avoiding absurd results, at times "fill in" statutory gaps. But in every such instance, the courts further an explicitly discerned legislative intention. It would not be an exaggeration to say that what Bayer wants to achieve is not filling such a gap as much as establishment of an "air-link" where the gulf dividing what is sought for, and what exists on the statute, is of oceanic proportions.

39. The other problem to accepting Bayer's contention is that patent infringement is never assumed, at the askance of the patentee; it has to be established before a court of law, under the Patents Act. Such adjudication is unquestionably beyond the Drug agencies' jurisdiction, or

charter, under law. This court's accepting Bayers' position on the issue would crucially confer jurisdiction on one set of agencies, (under the Drugs Act) *who do not have it* and the wherewithal to exercise it, and simultaneously, denuding the powers, jurisdiction and meaningful role conferred lawfully on another set of specialized statutory authorities, under the Patents Act.

40. Bayer relies on Section 2 of the Drugs Act and Section 156 (of the Patents Act) to contend that statutory intention is clear that Drugs authorities are bound by patents, granted under the Patent Act, by virtue of Section 156 and therefore, they cannot, by conferring drug or marketing approval permit violation of patents validly granted. Facially, the argument is undoubtedly attractive. And yet, as discussed in the earlier section of this judgment, the disparate objectives of the two enactments, (both of which are complete and separate codes), undermine the contention. Section 156 is a clarification, that the Government, and its officials, as grantors, are bound by the patents. This means that they have to respect patents, and cannot infringe them, (except to the extent it is sanctioned by law). Ascribing anything more than this clear intention, would be to extend the boundaries of the patent standards and broadening the reach of Drug agencies, who cannot apply patent standards, in their legitimate scrutiny. 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.

41. The second serious concern why the "linear" argument (i.e. if patents are granted, by virtue of Section 2 of the Drugs Act, non-patentees' application cannot be scrutinized) cannot be accepted, is that the "non derogation" device, enacted does cannot subordinate an entire legislative scheme set up under the Patents Act. This aspect assumes importance, because the latter enactment was amended in 2005, when several important amendments were introduced, with the pharmaceutical sector in mind (Section 2(ta); Explanation to Section 3(d); Section 92, Section 92-A). Parliament never expressed any intention, significantly, to place patent superintendence, or policing powers, with Drug agencies. In fact, the placing of *non-obstante* clauses in Section 92 (3), and the imperative nature of the restrictions, under Section

3(d) as well as Section 92-A, underscore that Parliament was alive to pharmaceutical patents and made significant policy choices through these amendments. If the court were to establish or decree a patent linkage, desired by Bayer, it would not only be making a policy choice, avoided by Parliament, but overstepping its obvious interpretive bounds.

42. It is well settled that courts do not fill gaps in public policy spaces. In *Fertilizer Corpn. Kamgar Union* v. *Union of India* 1981 (1) SCC 468, the Supreme Court observed as follows:

> *'35. … We certainly agree that judicial interference with the administration cannot be meticulous in our Montesquien system of separation of powers. The Court cannot usurp or abdicate, and the parameters of judicial review must be clearly defined and never exceeded. If the directorate of a government company has acted fairly, even if it has faltered in its wisdom, the court cannot, as a superauditor, take the Board of Directors to task. This function is limited to testing whether the administrative action has been fair and free from the taint of unreasonableness and has substantially complied with the norms of procedure set for it by rules of public administration."*

Similarly, in *Premium Granites v. State of T.N.* 1994 (2) SCC 691 it was held that:

> *"54. It is not the domain of the court to embark upon unchartered ocean of public policy in an exercise to consider as to whether a particular public policy is wise or a better public policy can be evolved. Such exercise must be left to the discretion of the executive and legislative authorities as the case may be.'*
>
> ** * **
>
> *92. In a democracy, it is the prerogative of each elected Government to follow its own policy. Often a change in Government may result in the shift in focus or change in economic policies. Any such change may result in adversely affecting some vested interests. Unless any illegality is committed in the execution of the policy or the same is contrary to law or mala fide, a decision bringing about change cannot per se be interfered with by the court."*

The courts' avoidance, in judicial review jurisdiction of executive or legislative policy making was spelt out in *Directorate of Film Festivals v. Gaurav Ashwin Jain*,(2007) 4 SCC 737, as follows:

> *"The scope of judicial review of governmental policy is now well defined. Courts do not and cannot act as Appellate Authorities examining the correctness, suitability and appropriateness of a policy, nor are courts advisors to the executive on matters of policy which the executive is entitled to formulate. The scope of judicial review when examining a policy of the Government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary. Courts cannot interfere with policy either on the*

ground that it is erroneous or on the ground that a better, fairer or wiser alternative is available. Legality of the policy, and not the wisdom or soundness of the policy, is the subject of judicial review..."

Another established principle of statutory interpretation that where there is a seeming overlap between provisions in two enactments, the court should not do violence to one, and undermine its purpose; it cannot render such provisions into "useless lumber". The following observations in *State of Goa v. Western Builders,*(2006) 6 SCC 239 are apt, in this context**:**

"Whenever two enactments are overlapping each other on the same area then the courts should be cautious in interpreting those provisions. It should not exceed the limit provided by the statute. The extent of exclusion is, however, really a question of construction of each particular statute and general principles applicable are subordinate to the actual words used by legislature."

43. In the opinion of this court, Bayers' contentions would precisely achieve what the Supreme Court cautioned against – various provisions of the Patent Act would be reduced to "useless lumber". Those particularly relate to patent policing, such as enforcement of patent standards, in the context of infringement complaints, such as post grant oppositions, challenges before the Intellectual Property Board and suits in the High Court. Before each such body, the patentee has to establish and prove infringement, wherever alleged, and may, in some cases, face challenges to the grant of its patent. Such crucial provisions, conceived in public interest, would be rendered a dead letter, if the Drugs authorities, on a representation of the patentee were to refuse licenses or approval, to applicants who otherwise satisfy the requirement of the Drugs Act and its provisions, or even be precluded from examining such applications, on assumed infringement.

44. The third important reason why Bayer's argument of inferring Drug agencies role in patent policing or enforcement is unacceptable, is that some developed countries, and the European Union cautioned against patent linkages. A preliminary 400 page report dated 28-11-2008, by the competition authorities of the European Union, submitted last year, was based on a sample of medicines under investigation that faced loss of exclusivity in the period 2000 - 2007, and noted that it represented an aggregate post-expiry expenditure of about €50 billion over the period (in 17 member states). The report estimated that such expenditure would have been about €14 billion higher without generic entry. However, the savings from generic entry

could have been about €3 billion more, if generic entry had taken place without delay. The report suggested that to delay competition, originator companies had intervened before national authorities "other than patent offices" in a "significant number of cases," (much in the same manner as is sought in this proceeding):

> *"Originator companies claimed in their interventions that generic products were less safe, less effective and/or of inferior quality"*
>
> and also argued that marketing authorizations could
>
> *"violate their patent rights, even though marketing authorisation bodies may not take this argument into account."*

The EU Directorate General for Competition noted that

> *"Patent linkage refers to the practice of linking the granting of MA (market authorization), the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed to link marketing authorisation to the patent status of the originator reference product….*
> *…Since the status of a patent (application) is not included in the grounds set out in the Regulation and in the Directive, it cannot be used as an argument for refusing, suspending or revoking Marketing approval (MA).*
> *....patent-linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC)No.2001/83."*

(Ref.http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf accessed on 12-7-2009).

It is also a matter of concern that such patent linkage would have the following undesirable results:

(1) It clothes regulatory authorities, which are executive bodies solely concerned with scientific quality, efficacy and safety issues, with completely new powers, and into areas lack in expertise, i.e. patent rights policing.

(2) It transforms patent rights which are private property rights, that depend on the owners' promptitude and desire to enforce them, into public rights, whose enforcement is dependent on statutory authorities, who are publicly funded.

(3) Such linkage potentially undermines the "Bolar/Early Working" exception that encourage quick access to the post patent markets for generic medicines. This is a major public policy consideration in India, which faces a host of public health challenges.

(4) Article 27 of TRIPS requires that patents are made available without discrimination by field of technology. As the patent linkage system is not available outside of the pharmaceutical sector, or in the US, even for biologic products, extending it, as is sought, would potentially violate Article 27, without any debate, or mandate of law.

45. Bayers' reliance on *Hoechst,* in this context, is, in this court's opinion, inapposite. *Hoechst* was decided in the background of a rule framed by the Drugs authorities, which mandated generic description of products, and forbade use of lawfully acquired trademarks. The Division Bench, with respect, correctly, concluded that the writ petitioners, who were trademark owners, were held to:

> *"…have a right to sue their trademarks under the provisions of the Trade marks Act. Denying them this use not only puts their property rights into jeopardy but is in clear derogation of the rights guaranteed by the provisions of the Trade marks Act..*"

The court naturally held that the rule, framed under the Drugs Act, could not violate substantive trademark rights. There, the rules forbade use of trademarks. Here, what Bayer desires is that since the applications of Cipla *allegedly* infringe its patent, its (Cipla's) marketing approval application under the Drugs Act should not even be processed or entertained. Bayer seeks to achieve this objective, through of court interpretation, rather than a right achieved through the adjudicative process, testing Cipla's product as an infringing one. For these reasons, *Hoechst* is not an authority for mandating a patent linkage, sought in the case.

46. So far as the decision of the Allahabad High Court in *Cattle Remedies* is concerned, this court is unable to agree with the conclusions. The court there was not concerned with the interface between the Patents Act and the Drugs Act; it did not have the benefit of examining the nature of different intellectual property rights. It did not notice that patent infringements are not offences, unlike in the case of Trademarks and Copyrights, nor did it notice the multiple challenges that patents potentially have to face, and the specialized nature of enquiry which authorities under the Patents Act, and the courts have to conduct (these enquiries can be

complex; in the case of court proceedings, infringement and challenges to patents can potentially lead to specialist evidence, for which a separate provision, Section 115 of the Patents Act, has been enacted).

47. The court finds as insubstantial Bayer's argument that Rule 122-B(1) (b) of the Drugs Rules, read with Form 44 and the data required (Appendix 1 to Schedule Y) give an insight that patent linkage is intended by Parliament. Accepting that such patent linkage, achieved in all cited instances from other countries, through explicit legislation, in this inconsequential – even surreptitious manner- would unfairly ascribe a canny role to the lawmakers. Patent linkage is well known, thanks to multilateral trade negotiations; Parliament even amended the Patents Act, to comply with its TRIPS commitments. A known principle of statutory construction is that Parliament or the concerned legislature is deemed to be aware of existing laws when it enacts new legislative measures (*Syndicate Bank v. Prabha D. Naik,* (2001) 4 SCC 713). Its omission to establish a patent linkage on the lines of the US Hatch Waxman Act, significantly persuades this court to refrain from mandating it through judicial directive.

48. For the above reasons, it is concluded that Section 2 of the Drugs Act and Section 156 of the Patents Act do not establish the patent linkage, sought for by the petitioner.

Issue No. 2

49. Section 17-B of the Drugs Act defines spurious drugs as follows:

> *"**17B Spurious drugs** – For the purposes of this Chapter, a drug shall be deemed to be spurious, -*
>
> *(a) if it is manufactured under a name which belongs to another drug; or*
> *(b) 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; or*
> *(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or*
> *(d) if it has been substituted wholly or in part by another drug or substance; or*
> *(e) if it purports to be the product of a manufacturer of whom it is not truly a product."*

Bayer states that Cipla's generic version of Sorafanib, which, it is contended, is sold under the brand name "Soranib" would amount to a "spurious drug". If Bayer's contention were to prevail, every generic drug would ipso facto amount to a "spurious drug", since they are deemed substitutes of originator (patented) drugs. Such interpretation is facially untenable and contrary to the intent of the Drugs Act. The key elements of "spuriousness" are deception, in the manner of presentation of the drug concerned, in the sense that they imitate or represent themselves to be something that they are not.

50. Section 17-B was introduced when Parliament felt the need to address the serious challenge faced by adulterated drugs. The Statement of Objects and reasons for the Drugs and Cosmetics (Amendment) Act, 1982, clarify that the definition of "spurious drugs' was introduced because of the problems of adulteration of drugs and production of spurious and sub-standard drugs, as posing a serious threat to the health of the community. The *regime* for enforcement of these provisions, essentially penal in nature, presupposes that samples of offending or suspected drugs, placed in the market, or offered for sale, are drawn by inspectors and enforcers (Section 23); they are sent for testing. If they are determined to be contrary the prescribed standards, the offender can be prosecuted, and found guilty, under Section 27. The line of authorities who police these standards are entirely different; they are drug enforcement officials, inspectors, sample testing institutions, public prosecutors, and criminal courts. Being penal provisions, the standard of proof to establish guilt, and the resultant consequences, is different from the standard of proof required of in civil cases.

51. A declaration by the drug agency entrusted with the task of deciding applications seeking marketing approval that someone not holding a patent is attempting to get clearance for a "spurious drug" would be pre-emptive, and would negate the provisions requiring that enforcers should follow certain mandatory procedures, and prosecute potential offenders. Such a declaration would be startlingly preclusive, even drastic, whether given by the Drug

Controller, or this court. For this reason alone, the court should desist from making it, as it would be arriving at findings, contrary to procedure established by law.

52. For the above reasons, it is held that this court cannot conclude that that unpatented drugs are "spurious drugs".

53. This court is constrained to observe that the present litigation was what may be characterized as a speculative foray; an attempt to "tweak" public policies through court mandated *regimes.* The petitioner, doubtless is possessed of vast resources and can engage in such pursuits. Yet, often, these attempts, even unsuccessful in the ultimate analysis, achieve short term goals of keeping out competitors, through interim orders. That short term objective has been achieved, and the petitioner has successfully stalled an independent examination of Cipla's application. Even though the writ petition cannot succeed, it would be a travesty of justice if the court does not direct realization of realistic costs, in this case. The court is reminded of the observations in *Ashok Kumar Mittal v. Ram Kumar Gupta*,(2009) 2 SCC 656 where the system of awarding costs, usually resorted to by Indian courts, has been characterized as *"wholly unsatisfactory and does not act as a deterrent to vexatious or luxury litigation."* There were six hearings in this case, of which three were for final hearing dates. The petitioner had engaged a senior counsel, for each hearing. In the circumstances, the court deems it appropriate that the costs for each "miscellaneous" hearing should be Rs. 75,000/- and for each final hearing date, it should be Rs. 1,50,000/-.

54. In view of the above discussion, the writ petition fails; it is dismissed with costs, quantified at Rs. 6,75,000/- payable in equal shares to the Union of India, and Cipla. The amounts shall be paid by the petitioner within four weeks.

August 18, 2009 (S.RAVINDRA BHAT)

JUDGE