(2009) 07 DEL CK 0064

In the Delhi High Court

Case No : Writ Petition (C) 8123 of 2008

Syngenta India Ltd. — APPELLANT

Vs

Union of India (UOI) — RESPONDENT

Date of Decision : 01-07-2009

Acts Referred:
Constitution of India, 1950 — Article 226
Essential Commodities Act, 1955 — Section 3
Insecticides Act, 1968 — Section 10, 14, 15, 5, 5(1)
Insecticides Rules, 1971 — Rule 4, 6

Citation : (2009) 161 DLT 413 : (2010) 7 RCR(Civil) 2322

Hon'ble Judges : S. Ravindra Bhat, J

Bench : Single Bench

Advocate : Raju Ramachandran, Ruchi Agnihotri Mahajan and Anushree Tripathi, for the Appellant; K.K. Sharma, for Resp. Nos. 1 and 2, Laliet Kumar and Santosh Sharma for Resp. No. 3, for the Respondent

Judgement

S. Ravindra Bhat, J.—The petitioner, in these proceedings, under Article 226 of the Constitution of India, impugns the decision of the Union Department of Agriculture, dated 5-11-2008, rejecting its appeal u/s 10 of the Insecticides Act, 1968 ("the Act") against the decision of the Registration Committee to granting for Emamectin Benzoate 5% SG to the third respondent, (hereafter "Jaishree") in its 293rd meeting held o 26.09.2008.

2. The facts necessary for deciding the case are that with the Act was brought into force with express the object of regulating the import, manufacture, sale, transport, distribution and use of insecticides with a view to prevent risk to human beings or animals, and for matters connected with it. Any prospective manufacturer or importer of any insecticide/pesticide in India is primarily governed by the regime of this Act. One of the areas of focus of the Act, is on import of insecticides and formulations, which it strives to regulate; the concern is enforcement of restrictions on rampant import of chemicals. The Act delegates the function to scrutinize, examine and analyze insecticides to the Registration

Committee ("the Committee", Respondent No. 2 in this case). Section 5 enacts for the constitution and functions of the committee, for enabling registration of insecticides on the receipt of applications, after enquiring into the safety and efficacy of the product (Section 5(1)). Rule 4 of the Insecticide Rules (hereafter "the Rules") elaborates on the functions of the Committee. u/s 5(5), the committee regulates its procedure and conduct of business, including the grant of registrations to parties desirous of importing or manufacturing insecticides, for which purpose it has formulated guidelines. It has apparently issued a check List specifying the various parameters on which data is required to be submitted by an applicant along with its Application for Registration.

3. Part B and C of the Checklist prescribe submission of data in respect of "Bio Efficacy and Residues" and "Toxicity". Form I of Schedule I under Rule 6 of the Rules provides the necessary contents of an Application seeking Registration of an insecticide. Clause 5 in Form I requires full disclosure of source of supply of the insecticide/chemical and its chemical composition, etc. Clauses 7 & 8 prescribe complete submission of data (as per details specified by RC) on Toxicity (interaction with soil, plant, animals and humans) and bio efficacy. All these, contends the petitioner, reveal that complete disclosure of information about an insecticide''s source as well as the submission of data are essential pre-requisites to be fulfilled by an Applicant before its request for registration.

4. Section 9 of the Act, relevant for the purpose of this case, provides for three kinds of registrations. The first, i.e provisional registration (Section 9(3B)) -is granted to an applicant for a period of two years when an insecticide is introduced for the first time in India. It can be granted pending an enquiry. It is contended that this provision pre- supposes insufficiency of examination of the data by the committee; a registration u/s 9(3B) is also granted in the event of agricultural exigencies, e.g. outbreak of an epidemic, etc. that may require taking emergency measures. The second category is regular registration, u/s 9(3B) - which is - granted only after submission of complete data by an applicant. The committee conducts a full and in-depth study of the data and has to ensure itself of the efficacy, toxicity and safety (for humans and other animals) of the insecticide before granting registration. The third category, u/s 9(4) is popularly known as a "Me Too" registration; it is on same conditions - and is only granted when there already exists a registration under S. 9(3) for a particular Insecticide. In such circumstances, any second or other person desiring to import or manufacture the insecticide can be granted registration on exactly the same conditions on which the insecticide was originally registered u/s 9(3). The petitioner contends that these "same" conditions necessarily mean and include the source of import also. It is stated that three kinds of certificates are granted u/s 9(3B), i.e. ''TIT'', ''TIM'', and ''FIM'' categories. The "TIT" signifies a New source; this and the FIT category applications can be made only u/s 9(4) and not u/s 9(3B). The registration certificate under ''TIT (New Source)'' category can only be given where there is a prior registration of the Technical i.e. ''active ingredient'' in place. It is contended that the registration for the technical

(i.e. active ingredient) of a particular Formulation granted u/s 9(3) of the Act brings the data submitted by the registrant (for the said Insecticide) into the public domain and the Registrant, thereafter, loses its exclusivity in respect of the said data. It is therefore argued that though registration is necessary (as no import or manufacturing licence, excise or customs approval, can be obtained without registration of the insecticide in favour of a party) it also destroys the exclusive rights which the registrant possesses for the data it has generated.

5. The petitioner alludes, in some detail, about vulnerability resulting from data disclosure, in the absence of a protection regime, and its utilization by applicants for the same product, for the purpose of their claim to registration. It is contended that the value in data protection is that it is the basis for the application (for registration) about the source, the raw materials, the nature of production of the insecticide, etc. Unless some measure of protection is afforded, the "data originator" would do all the toil and the "me too" applicant would reap the rewards. It is claimed that Article 39.3 of the TRIPS mandates protection for the test data submitted by the pharmaceutical and agro-chemical industries for market approval. It sets the minimum stands in this regard and reads:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure except where necessary to protect the public, or unless steps are taken to ensure the data are protected against unfair commercial use.

6. The petitioner argues that Article 39.3 of TRIPS, clearly recommends that protection be accorded to the data submitted by an Originator, against unfair commercial use and disclosure, meaning thereby that a Statutory Authority (in this case the Committee) cannot rely on the data submitted by the Originator for approving the second and subsequent applications for the same insecticide. This protection and data exclusivity, however, would be for a limited period and not in perpetuity. The petitioner also alludes to a "Reddy Committee" report, dated 31.05.2007 that endorses TRIPS'' recommendations concluding that the Act and the Rules should be amended to ensure that undisclosed test data of the originator is not put to unfair commercial use by others.

7. It is submitted that the Report''s recommendations and due to pressure from the indigenous lobby, the first Respondent issued a Directive dated 30.10.2007 in respect of "FIT" (Import of Formulation) registrations. The Directive introduced the concept of deemed registration of "Technical" i.e. in the category of ''FIT'' i.e. where formulation of a technical was registered and was being imported, the technical for the said Insecticide would also be deemed to be registered without a separate application for it. It was reiterated that there would be complete submission of data in respect of the "technical" even at the time that a registration was sought for the formulation. To grant some measure of protection

to the data originators, the Directive also stated that this registration of "technical" would come into force and would take effect after three years from the date of registration of the formulation without a separate application. It is submitted that this amounted to enforcement of an extremely limited period of data protection as opposed to the previously unlimited data protection being enjoyed by registrants in the category of FIT (import of Formulation). The directive, it is submitted, was effectuated through guidelines dated 30.10.2007 framed by the Committee on 13.12.2007. These according to the petitioner, made amply clear that the data on "Technical" must be complete while submitting an Application for registration of formulation.

8. In 2003 the petitioner filed application for registration u/s 9(3B) for import of technical (TIT) sourced from its parent factory in Switzerland, and for indigenous manufacture of formulation (FIM) for the insecticide, Emamectin Benzoate 5 % Soluble Granules ("Emamectin 5% SG"). The committee noted that its (the petitioners) data was incomplete on various parameters like toxicity and bio-efficacy, in its meeting held on 2.7.2004. The petitioner, therefore, could not be granted a registration u/s 9(3). The petitioner, however, was in the meanwhile, asked by the committee to convert its application to one u/s 9(3B), on account of an infestation of cotton crop by bollworm at the relevant time, as Emamectin is known to be effective in controlling such infestation Thus, a decision was taken by the Respondent No. 2 to grant a provisional registration u/s 9(3B) of the Act to the petitioner in the same categories of TIT (Import of Technical) and FIM (Indigenous Manufacture of Formulation). Accordingly, on 21.7.2004, certificates for provisional registration valid till 20.7.2006 were granted to the Petitioner in the categories of TIT and FIM under S.9 (3B), for Emamectin 5% SG. This provisional registration permitted commercialization of the insecticide (since the grant of provisional registration was only because of the demand expressed by the State Governments); but was subject to a limit of a total quantity of 5 (five) Metric Tonnes of Technical Emamectin permitted to the Petitioner during the period of 2 years. It is stated that from this 5 MT was indigenously manufactured by the Petitioner about 100 MT of formulation, and used it for commercialization as well as compilation and generation of exhaustive data.

9. The petitioner states that its provisional registrations in the categories of TIT and FIM lapsed on 20.07.2006. By that time it claims to have collated and completed its deficient data. On 11.09.2006, it applied afresh u/s 9(3) of the Act in the category FIT (Import of Formulation). On 24.7.2007, the petitioner was granted registration u/s 9(3B) of the Act in the category of FIT (Import of Formulation). It is claimed that as on that day, i.e 24.7.2007, there was no registration of the technical Emamectin, since the previous registration for technical (active ingredient) Emamectin granted on 21.07.04 was not u/s 9(3) but u/s 9(3B) of the Act, was provisional and based on insufficient data. On 27.07.2007, Jaishree applied for a registration in the categories of "TIT" (Import of Technical) and "FIM" (Indigenous Manufacture of Formulation) for Emamectin 5% SG u/s 9(3B) of the Act. The petitioner alleges that the said application

sought a grant of provisional Registration u/s 9(3B) of the Act since Jaishree''s data was incomplete and insufficient for grant of a Section 9(3) of the Act. Reliance is placed on the minutes of the 278th Meeting of the committee, held on 27.07.2007.

10. It is submitted that the committee directed Jaishree to apply u/s 9(3), instead of u/s 9(3B) of the Act. On 27.07.2007, itself, Jaishree requested the Committee to convert its Section 9(3B) Application to one u/s 9(3B) of the Act and grant it registration in the category of "TIT" (New Source) by placing reliance on the data already submitted by the Petitioner. It is argued that Jaishree also requested for framing and issuance of necessary guidelines by the committee, to accord propriety to the grant of such registration in its favour. Jaishree, says the petitioner, intended importation of the insecticide (technical Emamectin) from a completely new and distinct source i.e. China, which was different from the Petitioner''s source i.e. Switzerland.

11. It is submitted that the Directive dated 30.10.2007 and Guidelines dated 13.12.2007, could not aid Jaishree''s application since the Petitioner''s technical Emamectin would only be deemed be registered with effect from 24.07.2010, after lapse of three years of initial registration, i.e 24.07.2007. In this background, on 18.2.2008, a Clarification to the directive dated 30.10.2007, was issued by the first respondent, through an Office Memorandum. This had the effect of deeming that the Petitioner''s registration for technical Emamectin could be said to have come into effect on 21.07.2007 (3 years from the date of grant of provisional registration i.e. 21.07.2004). Thus, the registration fo the "technical" of the Petitioner, in terms of this OM would actually come into effect 3 days prior to the actual grant of registration to the Petitioner''s Formulation (Emamectin Benzoate 5%SG) in the category of "FIT". It is submitted that this Memorandum, dated 18-2-2008 was considered and acted upon by the committee, in its 293rd Meeting held on 26.09.08 when it granted registration to Jaishree u/s 9(3) of the Act.

12. The Petitioner opposed the grant of registration to Jaishree, which it (the petitioner) contends relied on its data, through a written representation. It later appealed u/s 10 of the Act to the Central Government, i.e the appellate authority highlighting the irregularity in granting the registration to Jaishree, based on insufficient and truncated data. The impugned Office Memorandum, dated 18.02.08 was also challenged.

13. The Central Government, by its impugned order dated 5-11-2008, rejected the petitioner''s appeal, and observed that:

M/s Syngenta India Limited (M/s Syngenta) have appealed against grant of registration to M/s Jaishree Agro Industries Ltd. (M/s Jaishree). They have mentioned that the Government had agreed to provide three years freeze on data submitted by the applicants for formulation import u/s 9(3) of the Act; that there is no technical Emamectin registered in the country u/s 9(3) as of how;

that in terms of the policy enunciated in 284th meeting of the Registration Committee, the technical would be deemed to be registered after three years form the date of formulation import; that as Emamectin Benzoate 5% SG formulation for import was registered in their favour on 26.07.2007, the technical can be deemed to be registered only after 3 years; that the grant of registration for technical to M/s Jaishree presumes registration of technical prematurely before the expiry of 3 years; that registration for import of technical from alternate source has been granted to M/s Jaishree based on truncated data requirement; that as per guidelines for registration the registrant u/s 9(3) is required to submit the complete data on its own which should be applicable for M/s Jaishree also who have relied on data furnished by M/s Syngenta instead as implied in their presentation made in the 278th meeting of the Registration Committee; that policy guidelines should be applicable prospectively and not retrospectively; that the decision of the Registration Committee taken in its 293rd meeting is contrary to the decision taken on 284th meeting; that equating registration u/s 9(3) with registration u/s 9(3B) for computing the 3 year period for effecting deemed registration of technical in contrary to the earlier decision and is arbitrary and illegal; that their provisional registration for Emamectin Benzoate u/s 9(3B) which expired on 20.07.2006 was restricted to import of 5 MT of technical grade material to deal with exigency of bollworm infestation in cotton at the request of State Governments; that the impugned decisions taken on 293rd meeting may be stayed till the matter is decided; that the impugned decision of 293rd meeting (agenda items 6.5 and 3.7) be quashed. In the hearing held on 04.11.2008, the representatives of M/s Syngenta elaborated on these points and also asserted that the letter dated 18.02.2008 of the Government was for formulations for import and not for indigenous manufacture and therefore the registration issued in 2004 for indigenous manufacture of the formulation to them did not come under its purview.

The Secretary, CIB&RC, vide letter No. 13-29/2008-CIR.I dated 30.10.2008, has questioned the locus standi of M/s Syngenta in the matter of grant of registration to another applicant as the matter is between the Registration Committee and another applicant. It has been stated that as per the directive of the Department of Agriculture & Cooperation dated 18.02.2008, the period of deemed registration is to be computed from the date of registration with commercialization u/s 9(3B), i.e. from 21.07.2004. The registration to M/s Jai shree, who have submitted requisite data under the relevant guidelines, has been granted as per the policy of the Government and the guidelines of the Registration Committee. The provisional registration was granted to M/s Syngenta in 2004 at their own request. In view of these averments, the appeal is liable to be set aside. These points were further elaborated by Secretary, CIB&RC in the hearing on 04.11.2008.

Section 10 of the Act provides that "Any person aggrieved by the decision of the Registration Committee u/s 9 may, within a period of 30 days from the date on which the decision is communicated to him, appeal in the prescribed manner..."

M/s Syngenta, already holding a registration of the insecticide in question, are an interested party in the matter. It would be too narrow an interpretation if the scope of Section 10 is confined to the applicant/registrant alone. The decision of the Registration Committee are in public domain and are displayed on the internet. It would not be fair to deny any person a change to appeal against a decision of the Registration Committee if he is aggrieved by that decision, provided the person has a clear interest in the decision.

Coming to the issues raised in the appeal, it is noted that the Government has been issuing directives from time to time for proper enforcement of the Insecticides Act, 1968 and the rules made thereunder, and in doing so it has been taking into account the views of the different sections of the pesticides industry. The letter dated 30.10.2007, issued in view of the instances where formulation had been registered for import without registration of technical u/s 9(3B) thus blocking registration u/s 9(4) and created a monopolistic situation, also took into account the industry''s concern to allow data protection for 3 years till suitable legislative changes are made. The letter dated 18.02.2008 included the category of registration u/s 9(3B) with commercialization in this dispensation with a view to remove the perverse tendency to continue with provisional 9(3B) registration with commercialization, thereby creating monopolistic situation. The data protection for 3 years is available to his category also. It would also be disingenuous to make a distinction between registration of formulation for import and registration of formulation for indigenous manufacture for this purpose as indefinite protection in either case would have the same consequence, i.e. existence of a monopolistic situation. Application received for grant of registration for the same product from any other source thereafter is treated under the category of new source and the data requirements for that category apply which have been met by M/s Jaishree. The registration u/s 9(3B) with commercialization was granted to M/s Syngenta at their own request in 2004. The Registration Committee has taken the decision in question (agenda items 6.5 and 3.7) in its 293rd meeting in line with the policy laid down by the Government. As such there is no reason to interfere with these decisions. The appeal is, therefore, dismissed.

14. The petitioner argues that the statutory intention is to ensure that insecticides approved for registration are safe, non-toxic and efficacious. These parameters can be verified only upon disclosure of comprehensive materials and data and its review in accordance with the parameters prescribed by the Committee. Any import or manufacture of insecticides is preceded by mandatory registration under the Act. In this context, it is submitted that the three classes of registration u/s 9(3B) presuppose that the intending manufacturer or importer should disclose most comprehensively the technical specifications u/s 9(3B). However, such disclosure is unnecessary u/s 9(3B) because it is granted for a limited period and subject to restrictions. The last category i.e. Section 9(4) on the other hand rides "piggyback" upon a registered insecticide.

15. It is submitted that insecticides are comprised of active ingredients which are termed technical that, after additives results in formulations. Whatever be the category in which a registration is sought i.e. TIT (import of technical); FIT (import of formulation); FIM (indigenous manufacture of formulation) and TIM (indigenous manufacture of technical), complete data on the technical or active ingredients of insecticide are submitted. The petitioner argues that the registration of active ingredients i.e. technical of insecticide results in the data disclosure in the public domain. This in turn implies that reliance can be placed upon it by the Committee and other applicants for registration. The registration of the "technical" resulting led to a demand for protection in accordance with Article 39.2 of TRIPS. After detailed consideration, a report was prepared and with the object of balancing the demands of indigenous manufacturers clamoring for registration of technical immediately on the issuance of the certificate itself. A balance struck by the authorities is guidelines contained in the directive dated 30.10.2007. This directive stated that the technical i.e. active ingredients of any insecticide, in the event of registration, would be deemed registered only three years after the registration of the formulation. Effectively three years'' data exclusivity and protection was granted to those who applied with complete specifications of the technical as well as formulation and upon registration of their insecticides u/s 9(3B).

16. It is submitted that the protection afforded by the guidelines dated 30.10.2007 recognized that first application u/s 9(3B) seeking to manufacture insecticide or more particularly import the insecticide not used in India so far are constrained to make full disclosure. Such data is compiled after investing and expending substantial amounts of money and resources, as well as time. Unprotected by any regulatory regime, the disclosure of such data can be exploited by a subsequent applicant, which merely would rely upon it. Feeling the need to assure applicants seeking registration of insecticide for the first time and in accordance with the commitment made under Article 39.3 of TRIPS, the directive of 30.10.2007, clarified that once registration is granted, the technical is deemed to be registered only three years after the first date of registration u/s 9(3). Having applied its mind and granted such protection based on a reasonable assessment of all the circumstances, there was no warrant or necessity to cut down its application by the subsequent impugned Office Memorandum dated 18.2.2008. In this regard, it is contended that though termed a clarification, the subsequent impugned order cut down the effect and virtually took away the benefit granted by the previous Memorandum dated 30.10.2007.

17. It is submitted that having conferred advantage by the guidelines of 30.10.2007 during the currency of the petitioner''s registration u/s 9(3B), such substantial benefit could not be taken away on entirely irrational considerations. Reliance is placed upon the decisions reported as Hiraji Tolaji Bagwan (since deceased by L.R''s) Vs. Shakuntala, ; Tata Cellular v. Union of India 1994 (6) SCC 65 ; Kumari Shrilekha Vidyarthi and Others Vs. State of U.P. and Others, and Bannari Amman Sugars Ltd. Vs. Commercial Tax Officer and Others, . It is

submitted that a citizen or commercial concern can base their expectations on the guidelines that confer benefits or advantages to them, which cannot be resiled from by the state agencies. An unexplained or unjustified departure from such guidelines would violate such legitimate expectations and would also be deemed arbitrary. It was also contended that the executive which is a policy maker as well as delegate of statutory power, cannot depart from the stated policy and adopt different interpretations to achieve the same objective. It is submitted that this Court should not overlook the Jaishree''s express statements, evident from the record through its letter dated 6.8.2007 and the Minutes of the 278th Meeting of the Committee dated 27.7.2007 which noted that reliance was placed upon the petitioner''s data. These clearly establish that barring the source of the two products which are different chemical compositions are the same. It is submitted that the exception to furnishing of data is enacted only u/s 9(4). In that situation alone is an applicant allowed to rely upon the previous registration.

18. The petitioner relies upon a decision of this Court in Coromandel Indag Products India Ltd. and Others Vs. Union of India and Others, . It is contended that the impugned Memorandum dated 18.2.2008 besides departing substantially and cutting down the protection granted by the previous guidelines is also unsustainable as it strikes at the root of the policy underlying the Act. The Act mandates, through the Rules, and guidelines framed by the Committee that toxicity, safety and efficacy of all substances sought to be registered as insecticides should necessarily be proved. This being mandated u/s 9(3B), registration without such data u/s 9(3B) is for a limited duration and carved out only as an exception. When the latter class of registration is granted with or without a pending application u/s 9(3B), in most circumstances, either the data is inadequate or there is no data at all to justify registration u/s 9(3B). In such circumstances, to deem protection for a data has commencing from the date of registration u/s 9(3B) would be arbitrary as it will amount to affording both kinds of registration the same legal sanctity - which is clearly impermissible in law.

19. The Central Government in its return resists the Writ Petition and contests the interpretation of the word "source" given by the petitioner. It is submitted that a source implies only a manufacturer and does not necessarily mean that the efficacy and safety of the product has not been established. That being the case, what has to be considered whether the manufacturer whose product is sourced by an applicant follows the same process as in the case of an existing applicant or registrant. Even by following different processes of manufacturing, the same product may be obtained. Similarly, the Central Government contends that applications under the FIT category can be made u/s 9(3B) of the Act, for which guidelines were framed by the Committee in its 198th, 199th and 201st meetings.

20. It is submitted that the petitioner''s data in support of its original application was found to be deficient in regard to toxicity. Consequently, it sought provisional registration u/s 9(3B) with commercialization; that request was granted on

2.7.2004. Consequently, a quantity of 5 MT of the product was allowed to the petitioner for which he manufactured 100 MT costing about 8 Crores for commercialization. In this context, it is contended that commercialization signals that the product is safe to the workers in the manufacturing process and farmers, who use it. It is contended that the chemical composition of the petitioner''s product and that of Jaishree are the same. That being the case and the petitioner having been permitted commercialization u/s 9(3B) based on certain data of efficacy and toxicity, the denial of Jaishree''s request would be arbitrary.

21. The Central Government, very crucially asserts as follows in the counter affidavit: -

To put the record straight, it is stated that the Respondent No. 3 had also applied for grant of registration of this product u/s 9(3B). However, they were not granted registration because the Petitioner was granted the registration u/s 9(3) before respondent No. 3 and the grant of registration u/s 9(3B) is only for the introduction of the product for the first time. This fact was intimated to Respondent No. 3 vide Secretariat of Central Insecticides Board & Registration Committee''s letter No. 1/TI/9 (3B)/2006-CIR.II dated 24.7.2007. Therefore, they requested that their application may be considered u/s 9(3B) for import of the product from a new (alternate) source, which is permissible under already existing guidelines of the Registration Committee requiring lesser data package because the efficacy and safety of the product had been established to the satisfaction of the Registration Committee (Respondent No. 2). Therefore, no separate or special dispensation of data was made in the process of granting registration to Respondent No. 3. It may also be mentioned that no verification of sources is done in any case including that of the petitioner. The Registration Committee verifies the claims of the applicants from the data submitted to it. It is pertinent to mention here that having attained some knowledge, the Registration Committee, or any one for that matter, can further use the knowledge in routine. It is due to this reason the Registration Committee had framed and adopted the guidelines for this category with this vision to avoid unnecessary repetition much before this case. It is more so because the chemical composition of the product of the Petitioner and that of the Respondent No. 3 are same. If the product of the Petitioner could prove efficacious and safe on certain minimum data, it is not understood as to how the product of the Respondent No. 3 would not be efficacious and safe with the same chemical composition. In fact, the Petitioner is unduly exaggerating the things to mislead this Hon''ble Court just to buy time to their advantage for business during the ongoing season for the product. And, it is due to all these reasons the Appellate Authority upheld the decision of the Respondent No. 2 in the Appeal filed by the petitioner earlier u/s 10 of the Act. It is, therefore, submitted that Respondent No. 2 have not gone beyond their mandate as given under the Act.

22. As far as the question of guidelines is concerned, the Central Government

relies upon the decision making process and refers to the meeting dated 30.3.2000 of the Committee which had recorded that

the Committee decided that the proposed guidelines should be harmonized with the existing guidelines for 9(3) and 9(3B). Besides, it was also decided that in import of formulation the technical grade of the same insecticide should also be registered simultaneously to the formulation.

It is also submitted that the subsequent meeting of 20.4.2000 and the 201st meeting, of the Committee, dealt with the same issue and had required simultaneous registration of the formulation and the "Technical". This decision was in fact in existence and was only modified after the petitioner was issued with registration on 24.7.2007. Such being the case, the question of unfairness in the clarification dated 18.2.2008 would not arise. The Central Government argues that the guidelines dated 30.10.2007 significantly mentions neither Section 9(3) nor 9(3B) and generally deals with the protection of interests of the applicants introducing new insecticides molecules for certain periods. If all these were kept in mind, the clarification dated 18.2.2008 is justified and reasonable.

23. Jaishree submits to having applied for registration of Emamectin Benzoate Technical Import (TIT) and 5% SG (FIM) formulation''s indigenous manufacture u/s 9(3B) on 20.02.2006 and also to having furnished complete data reports etc. in accordance with the prescribed checklist. It denies the petitioner''s contention about its placing reliance on the existing data and technical as incorrect. Had Jaishree relied upon petitioner''s data or technical, there would have been no necessity to submit its details and reports etc. In view of the grant of registration to the petitioner u/s 9(3), Jaishree requested consideration of its application u/s 9(3B), "TIT New Source", submitting all requisite data reports etc. Jaishree submits having invested approximately Rs. 50 lakhs for generation of such data and reports.

24. Jaishree makes a comparison of the petitioner''s data and its data to say that they were generated independently from different institutes and laboratories. It is submitted that the Committee, after detailed scrutiny and verification of the entire materials furnished by Jaishree with regard to the efficacy and safety, issued the certificate. Jaishree also relies upon Central Government''s return to say that its data was adequate and the insecticide, safe. It argues that the decision of an expert body cannot, save in exceptional situations be interfered with in judicial review. Reliance is placed on judgment of the Supreme Court reported as N.D. Jayal v. UOI AIR 2004 SC 867.

25. Jaishree next contends that the source of its products is different from that of the petitioner, which necessarily meant that the Committee had to adopt a stringent standard while considering the application u/s 9(3B). In this context, it is submitted that under the Act, what should be examined are the features and characteristics of the insecticide to ensure its efficacy and safety to human beings and animals. Their source only signifies the place of their manufacture; it,

therefore, does not make any difference if the chemical composition of the insecticide is the same and as long as the registrant complies with other conditions provided in the checklist. In this respect, it points to the fact that the Registration Committee has not made any mention of the source of manufacture in the petitioner''s case itself.

26. Jaishree contends that the question of protection to the "technical" afforded is not extended by provisions of the Act. They were also not in existence, when the petitioner was granted registration on 24.07.2007. In these circumstances, there can be no applicability of the principle of legitimate expectation. It is contended besides that in fact, the legislative policy, through the provisions of the Act and rules nowhere reflect the intention to confer data exclusivity or protection of the kind claimed by the petitioner. The guidelines were issued on 30.10.2007. The authority to do so was with the respondent who had previously determined that the technical would be deemed registered from the date of registration of the formulation. The same authorities were, after a consideration of all the circumstances is of the opinion that clarification was needed and issued it on 18.02.2008.

27. Reliance is placed in this regard on the judgment reported as Kuldeep Singh Vs. Govt. of NCT of Delhi, that the executive has right to formulate a policy and at the same time to vary, amend or rescind it. It is contended that the petitioner has not sought for quashing of the Office Memorandum dated 18.02.2008. In the absence of such relief, the decision to grant registration to Jaishree cannot be impugned on the ground of alleged duty exclusivity.

28. It is submitted that the petitioner has already enjoyed monopoly of the products since 2004 because it applied initially u/s 9(3B) in 2003. It was issued with the Section 9(3B) registration in 2004 without the necessary data generation. It has already enjoyed exclusive advantages to sell the insecticides, for about five years and earned profits of approximately Rs. 90 crores. Its petition challenging Jaishree''s registration conferred on the basis of independent data and materials furnished by it, should, therefore, not be entertained.

29. The preceding discussion would show that this Court has to decide on the legality of the registration granted to Jaishree in the context of the petitioner''s submission that reliance was placed upon its data or technical for which it was afforded protection for a three year period, ending on 23.07.2010. Though it does not expressly say so, the petitioner is also asking the Court to ignore the clarificatory guidelines dated 18.02.2008.

30. In the previous sections of the judgment, this Court had recounted the provisions of the Act, particularly Section 9 and discussed various categories of registration of insecticides as also the classes, i.e. the importation of formulation and manufacture of formulation and technical. Before a discussion of the merits of the rival cases, it would be necessary to extract the two Office Memoranda dated 30.10.2007 and 18.02.2008. The first one, of 30th October, 2007, is as

follows:

No.17-2/2006-PP.I

Government of India

Ministry of Agriculture

Department of Agriculture & Cooperation

****

Krishi Bhavan, New Delhi

Dated the 30th October 2007

To,

The Secretary (CIB&RC)

Directorate of PPQ&S

NH-IV, Faridabad

Subject:- Procedure for registration of "formulation" for import and its technical grade insecticide

Madam,

I am directed to refer to the subject cited above and to convey the approval of the Competent Authority that when a "formulation" is to be registered for import, where its "technical" is not registered, the "technical" shall be deemed to be registered. In such cases, since the evaluation of the "technical" is also done alongwith the "formulation", the "technical" shall get registered automatically, without separate application or evaluation. However, the registration of "technical" in such cases shall come into force only after expiry of 3 years from the date of registration of its "formulation" for import.

It is also decided that Secretary, CIB&RC will formulate the procedure/guidelines in consultation with Registration Committee for treating the "technical" also as deemed registered, after expiry of 3 years from the date of registration of its "formulation" for import. It is further informed that these norms will be applicable to all the "formulation" which are already registered for import, without registering the "technical".

Yours faithfully,

Sd/-

(NEERA SHARMA)

Under Secretary to the Government of India

The second notification, dated 18-2-2008 reads as follows:

F. No. 17-2/2006-PP.I

Government of India

Ministry of Agriculture

Department of Agriculture & Cooperation

(PP Division)

***

Krishi Bhawan, New Delhi

Dated 18.2.2008

OFFICE MEMORANDUM

Subject :- Procedure for registration of Formulation for import and its technical grade insecticide

***

The undersigned is directed to invite reference to this Department''s letter of even number dated 30.10.2007 on the above subject. It is further clarified that the period of three years for effecting the deemed registration of the "Technical", in cases where registration granted for formulations u/s 9(3B) with commercialization, will be computed from the date of issuing registration for formulation u/s 9(3B) with commercialization.

2. Secretary (CIBRC) is directed to take further action.

Sd/-

(Neeru Sharma)

Under Secretary to the Govt. of India

23387962

Dr. Sandhya Kulshreshtha,

Secretary (CIB&RC),

Dte. Of Plant Protection Quarantine

& Storage, Faridabad.

31. Section 9(3B), to the extent it is material for deciding this case, reads as follows:

Section 9(1) Any person desiring to import or manufacture any insecticide may apply to the Registration Committee for the registration of such insecticide and there shall be a separate application for each insecticide :

Provided that any person engaged in the business of import or manufacture of

any insecticide immediately before the commencement of this section shall make an application to the Registration Committee within a period of six months from the date of such commencement for the registration of any insecticide which he has been importing or manufacturing before that date.

(2) Every application under Sub-section (1) shall be made in such form and contain such particulars as may be prescribed.

(3) On receipt of any such application for the registration of an insecticide, the committee may, after such enquiry as it deems fit and after satisfying itself that the insecticide to which the application relates conforms to the claims made by the importer or by the manufacturer, as the case may be, as regards the efficacy of the insecticide and its safety to human beings and animals, register, on such conditions as may be specified by it and on payment of such fee as may be prescribed, the insecticide, allot a registration number thereto and issue a certificate of registration in token thereof within a period of twelve months from the date of receipt of the application :

Provided that the Committee, may, if it is unable within the said period to arrive at a decision on the basis of the materials placed before it, extend the period by a further period not exceeding six months :

Provided further that if the Committee is of opinion that the precautions claimed by the applicant as being sufficient to ensure safety to human beings or animals are not such as can be easily observed or that notwithstanding the observance of such precautions the use of the insecticide involves serious risk to human beings or animals, it may refuse to register the insecticide.

(3A) In the case of applications received by it prior to the 31st March 1975, notwithstanding the expiry of the period specified in Sub-section (3) for the disposal of such application, it shall be lawful and shall be deemed always to have been lawful for the Registration Committee to dispose of such application at any time after such expiry but within a period of one year from the commencement of the Insecticides (Amendment) Act, 1977.

Provided that nothing contained in this Sub-section shall be deemed to make any contravention before the commencement of the Insecticides (Amendment) Act, 1977, of a condition of a certificate of registration granted before such commencement, an offence punishable under this Act.

(3B) Where the Registration Committee is of the opinion that the insecticide is being introduced for the first time in India, it may, pending any enquiry, register it provisionally for a period of two years on such conditions as may be specified by it.

(3C) The Registration Committee may, having regard to the efficacy of the insecticide and its safety to human beings and animals, vary the conditions subject to which a certificate of registration has been granted and may for that purpose require the certificate holder by notice in writing to deliver up the

certificate to it within such time as may be specified in the notice.

(4) Notwithstanding anything contained in this section, where an insecticide has been registered on the application of any person, any other person, desiring to import or manufacture the insecticide or engaged in the business of, import or manufacture thereof shall on application and on payment of prescribed fee be allotted a registration number and granted a certificate of registration in respect thereof on the same conditions on which the insecticide was originally registered.

32. The crucial guidance, u/s 9(3B) is the satisfaction of the committee, that the insecticide "conforms to the claims made by the importer or by the manufacturer, as the case may be, as regards the efficacy of the insecticide and its safety to human beings and animals.." after inquiry into such claims, by applying prescribed parameters. This overbearing concern is underlined by the second proviso to Section 9(3B), ie. that:

...that the precautions claimed by the applicant as being sufficient to ensure safety to human beings or animals are not such as can be easily observed or that notwithstanding the observance of such precautions the use of the insecticide involves serious risk to human beings...

the committee can, in such circumstances, refuse registration. Section 9(3B) presupposes that the final opinion formation has not been arrived at; it is an exceptional power, enabling the committee, in the event the insecticide is being introduced for the first time in India, pending an enquiry to grant limited registration, on conditions that may be specified. This power, being an exception, would of course be exercised having regard to the overall policy of the enactment.

33. The facts here are that the petitioner had applied for registration u/s 9(1) in 2003; the data provided by it, was however insufficient, as to toxicity of the substance. This is an important aspect, since one of the non-derogable conditions under the provisions is the safety to human beings and animals; yet, pending supply of such data, its request for provisional registration, for commercialization was permitted, for two years, in 2004. Its application for registration, was finally accepted, u/s 9(3) on 24-7-2007. Significantly, at that point in time, there was no data protection regime of the kind brought in place through the guidelines of 30th October 2007, as effectuated on 13th December 2007.

34. So far as Jaishree is concerned, the application for registration was made for indigenous manufacture, u/s 9(3B) on 20.02.2006. It contends having furnished complete data reports etc. in accordance with the prescribed checklist. It sought to have the application, converted into one u/s 9(3B); later by its letter dated 6-6-2007, it requested the committee to process the application, u/s 9(3B), stating as follows:

We have applied for registration of Emamectin benzoate Technical Import and its formulation Indigenous manufacture u/s 9(3B) of Insecticides Act, 1968, in

February, 2006. As today, our both the applications are complete from all disciplines as per requirements of 9(3B).

With reference to your above said letter, we are requesting to consider our above applications u/s 9(3B) new source. As per the guidelines and requirements of 9(3) our both applications are completed from all disciplines except Toxicity and packaging.

Now we are submitting required information/data in both the disciplines i.e toxicity and packaging as per 9(3) New source.

Please find enclosed additional information for consideration of our applications of Emamectin Benzoate Technical for Technical Import u/s 9(3B) New Source and its formulation u/s 9(3).

So far as Emamectin benzoate formulation Indigenous Manufacturer is concern, the CIB & RC has already ensured efficacy and safety to human beings and animals about the insecticide and relevant data is already available with CIB & RC. Therefore, it is not required to submit repeated data on observation in man (Health record of spray operators) and toxicity to Livestock (field trials and observations) or may be submitted later on if required....

The subsequent letter of 14th August, 2007 by Jaishree to the committee enclosed further information on aspects such as bio-effectiveness, phytotoxicity and residue in plant. The official respondents categorically submit that the petitioner''s data was not used by Jaishree; it is also averred that independent testing is not done by the committee, which only goes through the claims, and co-relates with the data furnished to it. Its contention in this regard, inter alia, is that Jaishree

requested that their application may be considered u/s 9(3B) for import of the product from a new (alternate) source, which is permissible under already existing guidelines of the Registration Committee requiring lesser data package because the efficacy and safety of the product had been established to the satisfaction of the Registration Committee (Respondent No. 2). Therefore, no separate or special dispensation of data was made in the process of granting registration to Respondent No. 3. It may also be mentioned that no verification of sources is done in any case including that of the petitioner. The Registration Committee verifies the claims of the applicants from the data submitted to it. It is pertinent to mention here that having attained some knowledge, the Registration Committee, or any one for that matter, can further use the knowledge in routine. It is due to this reason the Registration Committee had framed and adopted the guidelines for this category with this vision to avoid unnecessary repetition much before this case. It is more so because the chemical composition of the product of the Petitioner and that of the Respondent No. 3 are same. If the product of the Petitioner could prove efficacious and safe on certain minimum data, it is not understood as to how the product of the Respondent No. 3 would not be efficacious and safe with the same chemical composition.

35. It is evident from the above extract, that the committee adopted, on a uniform basis, guidelines which had been evolved earlier that if the efficacy of a product is established, then, in the case of a different source, the authorities would only verify, on application of the prescribed parameters about the safety of such new source, to human beings and animals. The same yardstick was applied to the petitioners and Jaishree.

36. The above discussion should have been sufficient to deal with the petitioners'' contention that Jaishree used its data; however, since parties had urged factual contentions, in order to satisfy itself that the committee''s approach was correct, the court examined the materials. The petitioner, for bio-efficacy of emamectin benzoate 5% SF conducted six studies on Okra, three at University of Agricultural Sciences Dharwad, during different seasons; two at TN Agricultural University, Coimbatore, 2003-04 and 2006 and one at Punjab Agricultural University, Ludhiana. Jaishree, on the other hand, relied on TN Agricultural University study at Location Allapalayam, Season 2005-06 and location Maampali, season 2006. The four other studies'' locales were Malwa Plateau and Nimar Valley, for different seasons, through the Jawaharlal Nehru Krishi Vishwa Vidyalaya, Khargone. The petitioners'' cotton studies were from All India Co-ordinated Cotton Improvement Project, Coimbatore (two studies) and Tamil Nadu Agricultural University, Coimbatore (three studies). Jaishree''s studies, on cotton, on the other hand, were four studies from the Jawaharlal Nehru Krishi Vishwavidyala, during different seasons, two studies from the Indian Agricultural Research Institute, Delhi and two studies of the Tamil Nadu Agricultural University. It would not be necessary to go into greater details, save noticing that the Union''s stand is in support of Jaishree, and that the materials on record justify their position that the petitioner''s data was not used, in support of Jaishree''s claim.

37. The second, and important aspect to be considered is the soundness of petitioner''s contention about unfair dilution of data protection afforded by the notification of October, 2007. It would be relevant, at this stage, to notice that:

(1) No provision of the Act, or Rules, prescribe or enact data exclusivity, or postpone registration;

(2) The petitioner had applied u/s 9(3B) much before the notification of October 2007;

(3) The petitioner''s certificate was granted before the issuance of the notification of October, 2007.

(4) The existing regime, through guidelines and the minutes of meeting of 30th March, 2000 appear to suggest that registration of the formulation and technical, were effective simultaneously.

38. If one keeps in mind the above background of circumstances, what is apparent is that the October 2007 guidelines, directing a data exclusivity regime,

was brought into force after the petitioner''s registration certificate was issued. No doubt, it conferred a kind of right; perhaps the petitioner can even say that it was led to believe that this state would continue. However, the question is whether the continuation of this non statutory executive regime could be assured to anyone, indefinitely, and also mandated by courts.

39. Whilst there is no challenge to either of the circulars/ memoranda dated 30th October, 2007 and 18th February, 2008, the court cannot be unmindful of the fact that what is really being sought is a policy mandate. No doubt civil law assures a certain measure of protection to confidential data, and as between two parties, there may be situations where unlawful acquisition of such information by one of another''s may be fraught with serious commercial consequences, necessitating equitable remedies, what the court is confronted here is a policy issue. There is no statutory guidance, either in the substantive portion of the enactment, or under the Rules, enabling even the rule making authority to prescribe a period of limitation for "data exclusivity". It has been held AIR 1972 1935 (SC) that the rule making authorities, in the absence of an enabling power, cannot prescribe periods of limitation. Thus, under our Constitutional framework, prescribing of periods of limitation to do something, or confer a positive right, is an essential legislative function, not exercisable by the courts (Ref. Common Cause (A Regd. Society) Vs. Union of India (UOI) and Others, ; P. Ramachandra Rao Vs. State of Karnataka,). As noted earlier, though neither of the guidelines is in challenge, nevertheless the court cannot depart from these well established principles, while considering the petitioner''s claims about unfairness or arbitrariness by the official respondents. Absent a policy clearly discernable under the Act, dealing with data exclusivity, of the kind desired, this Court cannot hold that the clarification made through the guidelines of 18th February, 2008 is illegal. There is no basis, either under the Act, or the rules, in support of such a claim.

40. The next question is whether the clarification or the modification, made through the guidelines of 18th February, 2008 are arbitrary, as taking away something which vested in the petitioner. The jurisdiction under Article 226 concerns the correctness of the decision making process, rather than its merits. The administrative or statutory action of the executive government can be interfered with if it is vitiated by mala fides, illegality, "Wednesbury" unreasonableness, or exercise of power/ refraining from exercise of power, for purposes other than those authorized by law. The scope of such judicial review has been summarized was outlined in Tata Cellular Vs. Union of India, . In State of U.P. and Another Vs. Johri Mal, , the law was re-stated, and the scope of judicial review under Article 226 of the Constitution articulated in the following terms:

28. The scope and extent of power of the judicial review of the High Court contained in Article 226 of the Constitution of India would vary from case to case, the nature of the order, the relevant statute as also the other relevant

factors including the nature of power exercised by the public authorities, namely, whether the power is statutory, quasi-judicial or administrative. The power of judicial review is not intended to assume a supervisory role or don the robes of the omnipresent. The power is not intended either to review governance under the rule of law nor do the courts step into the areas exclusively reserved by the suprema lex to the other organs of the State. Decisions and actions which do not have adjudicative disposition may not strictly fall for consideration before a judicial review court. The limited scope of judicial review, succinctly put, is:

(i) Courts, while exercising the power of judicial review, do not sit in appeal over the decisions of administrative bodies.

(ii) A petition for a judicial review would lie only on certain well-defined grounds.

(iii) An order passed by an administrative authority exercising discretion vested in it, cannot be interfered in judicial review unless it is shown that exercise of discretion itself is perverse or illegal.

(iv) A mere wrong decision without anything more is not enough to attract the power of judicial review; the supervisory jurisdiction conferred on a court is limited to seeing that the Tribunal functions within the limits of its authority and that its decisions do not occasion miscarriage of justice.

(v) The courts cannot be called upon to undertake the government duties and functions. The court shall not ordinarily interfere with a policy decision of the State. Social and economic belief of a judge should not be invoked as a substitute for the judgment of the legislative bodies.

41. Judicial authorities, on the issue of whether administrative agencies, exercising powers, under statute can review their decisions, have dealt with the issue often. Talking of the power of "administrative review" the Supreme Court, held, in State of Uttar Pradesh and Others Vs. Maharaja Dharmander Prasad Singh and Others, , as follows:

53. It is erroneous to equate the powers under Sections 14 and 15 of the Act with judicial power which, in the absence of express provisions, could not enable the review of a judicial order after its exercise on the principle of functus officio. In Sardul Singh v. District Food and Supplies Controller, Patiala a statutory order, promulgated u/s 3 of the Essential Commodities Act, 1955, contained a provision enabling the cancellation of a "permit" under certain circumstances. The contention was that Section 3 of the parent "Act" itself did not delegate to the subordinate legislative authority to make such a provision for cancellation and, therefore, the provision for cancellation in the subordinate legislature was ultra vires. There was no provision in the Act expressly conferring the power to make a provision for cancellation of the permit. Section 3(2)(d) of the parent Act merely enabled the government to make orders "for regulating by licences, permits or otherwise, the storage, transport, distribution, disposal, acquisition, use or consumption of any essential commodity" and Section 3(2)(d) merely

enabled government to make orders for incidental and supplementary matters (emphasis supplied). The question arose whether provisions for cancellation of the permits envisaged in para 10 of the particular statutory order could be said to be relatable to or justified as a matter incidental or supplementary to regulation. This Court held that the power to cancel was an "incidental and supplementary matter.

In R.R. Verma and Others Vs. Union of India (UOI) and Others, , the position was formulated as follows:

We do not think that the principle that the power to review must be conferred by statute either specifically or by necessary implication is applicable to decisions purely of an administrative nature. To extend the principle to pure administrative decisions would indeed lead to untoward and startling results. Surely, any government must be free to alter its policy or its decision in administrative matters. If they are to carry on their daily administration they cannot be hidebound by the rules and restrictions of judicial procedure though of course they are bound to obey all statutory requirements and also observe the principles of natural justice where rights of parties may be affected. Here again, we emphasise that if administrative decisions are reviewed, the decisions taken after review are subject to judicial review on all grounds on which an administrative decision may be questioned in a court.

In M. Satyanandam Vs. Deputy Secretary to Government of A.P., General Administration (Accom. C) Department, Secretariat and Another, , it was held as under:

learned Counsel for the petitioner submits that the order of release was bad because the authorised officer had no power to review the previous order nor he had the power to release the property of the landlady without even giving an opportunity to the petitioner. In the facts of this case as noted by the High Court, we are unable to entertain these contentions. We are unable to accept the contention that the Government cannot review its own order.

42. The correct position therefore, is administrative or statutory powers, in aid of administrative functions, imply flexibility, and the need to review decisions taken. Unlike courts, administrators and administrative bodies have to take decisions on the basis of broad, general policy considerations. Review, as is understood in the functioning of courts, is an entirely different concept; importing elements from such concepts in administrative functioning, would inject an avoidable rigidity in administrative process. The correct position vis-?-vis administrative agencies may be stated as the power to make or change decisions, as the circumstances warrant, having regard to the nature of the power, and the purpose for which it is granted. If, while exercising such power of administrative review, the agency oversteps such limits, or acts illegally, or mala fides, arbitrarily, or its review or modification of a previous order is hit by Wednesbury unreasonableness, or other well established grounds, the court can judicially review it under Article 226 of

the Constitution. It may also be noteworthy that Parliament also empowered the executive to vary conditions for registration, having regard to the circumstances, as is evidenced by the power u/s 9(3C). Thus, even after registration, conditions may be varied, if the committee deems it appropriate, and in accordance with the statutory mandate. In the circumstances, the petitioner''s complaint of arbitrariness in the respondents'' approach in clarifying the scope of data exclusivity, cannot be accepted. The court discerns that the question of data protection was dealt with in one manner, for the period 2000 to October 2007; it was during that period that the petitioner''s registration was granted. The later clarification was made by the respondents; it is by way of a policy review. The petitioner, who does not have any indefeasible or vested right cannot therefore, complain that the policy originally declared in October, 2007, had to apply.

43. Now, the Petitioner''s contention regarding arbitrariness on account of not honouring its legitimate expectations. The court''s jurisdiction to reach out and cure any legality, in judicial review is no doubt wide. Its exercise is necessarily contextual to the facts and the rights asserted as well is found to be violated. The state is granted, in its legitimate executive sphere, "free play in the joints" to design and fashion policies, which best sub- serve larger public good, having regard to the nature of the activity. While judicial review concerns itself with fairness of procedure in decision-making, legality and regularity of proceedings, legitimately also enabling the courts to enquire whether the decision or decision-making was taken or arrived at in bona fide exercise of powers, it does not extend to arriving at value-judgments on the prudence, desirability or and wisdom of the executive measure complained of. If courts were to examine executive decisions from such standpoints, they would don the mantle of government agencies without the assistance of all those inputs which are vital for arriving at such executive decisions.

44. "Legitimate expectation", an argument put forward by the petitioners to challenge the impugned addendum, is concededly a dimension of fairness, which has to be considered by the decision maker. It is however, not "the key which unlocks the treasury of natural justice and it ought not to unlock the gate that shuts the court out of review on the merits" (Ref. Union of India and others Vs. Hindustan Development Corpn. and others,). It cannot inhibit the exercise of lawful executive power to make or change polices, in public interest or in furtherance of public policy; courts'' interference in such instances, was described by Brennan, J (of the High Court of Australia, in Attorney General for New South Wales v. Quin 1990 [64] Aust LJ 327) as too nebulous to form a basis for invalidating the exercise of state power, setting "the courts adrift on a featureless sea of pragmatism" (quoted in Dr. (Mrs.) Chanchal Goyal Vs. State of Rajasthan,). There is no statutory or overarching public policy compulsion binding the official respondents to their initial policy of 30th October 2007, or inhibiting their right to clarify or modify it. The petitioners cannot therefore, fall back on the principle of legitimate expectation as the sole basis for holding the registration granted to Jaishree, or invalidation of the clarificatory guidelines,

were framed in a bona fide manner, for valid and relevant considerations.

45. In view of the above discussion and findings, the petition has to fail. The court is of the opinion that this litigation was speculative, as the attempt was clearly to invite the court to make a policy declaration, which could not have been made under any circumstances. The pendency of this proceeding has also resulted in prejudice to the third respondent, who was constrained to give an undertaking not to give effect to its registration; that has subsisted all this while. The petition was heard finally, on five effective dates of hearing. The court is of opinion that the petitioner must bear the third respondents'' costs for those hearings, quantified at Rs. 75,000/- per hearing. The writ petition is, accordingly dismissed with costs quantified at Rs. 3,75,000/- to be borne by the petitioner, who shall pay it to the third respondent, within four weeks.

CM Nos. 15661/2008 & 15824/2008

Dismissed.

