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IN THE HIGH COURT OF DELHI AT NEW DELHI

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Date of Decision: 09.05.2023

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LPA 530/2022

UNIKIL PESTICIDES PVT. LTD.

..... Appellant

Through: Mr. Aftab Rasheed, Advocate.

versus

UNION OF INDIA & ANR.

..... Respondents

Through: Mr. Kirtiman Singh, CGSC with
Mr. Waize Ali Noor, Ms. Shreya V.
Mehra & Mr. Madhav Bajaj,
Advocates for Respondents No.1/
UOI.

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CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE SUBRAMONIUM PRASAD

SATISH CHANDRA SHARMA, CJ. (ORAL)

LPA 530/2022

1. Regard being had to similitude in the controversy involved in both the LPAs, they were heard together and a common judgment is being passed. The facts of the LPA 530/2022 are being dealt with as under.
2. The Appellant before this Court has filed this present Appeal under Clause 10 of Letters Patent being aggrieved by an order dated 10.02.2020 passed by the Learned Single Judge in W.P.(C.) No. 6092/2013 titled ***Unikil Pesticides Pvt. Ltd. Vs. Union of India & Anr.***
3. The facts of the case reveal that the Writ Petition was preferred under Article 226 of the Constitution of India by the Appellant herein being aggrieved by an order dated 10.07.2013 and a prayer was made to issue Registration Certificate to the Appellant for “Imazathapyr molecule” under Section 9(4) of the Insecticides Act, 1968 (hereinafter to be referred as ‘Insecticides Act’).
4. The facts of the case further reveal that the Appellant, as stated by him, is a leading manufacturer/ formulator of pesticides, insecticides, weedicides and other biocides in the State of Madhya Pradesh having a factory situated at Industrial Estate Vidisha, Madhya Pradesh.
5. The undisputed facts of the case reveal that the Petitioner preferred an Application under Section 9(4) of the Insecticides Act for registration of molecule, which was already registered under Section 9(3) of the Insecticides Act, and, the claim of the Appellant was rejected.
6. The facts further reveal that the Petitioner (Appellant herein) in the

Writ Petition has stated that there is another Company namely BASF India Ltd. which has registered the molecule in question under Section 9(3) of the Insecticides Act, and, in those circumstances, the molecule was already a registered molecule. The Appellant applied for grant of registration for importing molecule under Section 9(4) of the Insecticides Act.

The Appellant, thereafter, as stated by him, carried out necessary tests in respect of the molecule and the same was to be imported from China.

7. The facts further reveal that an order was passed on 02.06.2011 informing the Appellant cancellation of the registration application. The Appellant, thereafter, submitted a representation on 20.12.2012, and as nothing was being done, he preferred a Writ Petition before this Court i.e. W.P.(C.) No. 2319/2013 and the Writ Petition was disposed of by an order dated 12.04.2013 directing the Respondent to decide the representation of the Appellant.

8. The Registration Committee has thereafter decided the representation of the Appellant by an order dated 05.05.2011, and Appellant has again filed a fresh Writ Petition before this Court i.e. W.P.(C.) No. 6092/2013, and the Learned Single Judge has dismissed the said Writ Petition.

9. The Appellant's contention is that he is importing molecule from China, and it is already registered under Section 9(3) of the Insecticides Act, hence the application preferred by the Appellant was rightly preferred under Section 9(4) of the Insecticides Act, and, therefore, the rejection is bad in law.

10. The Respondent before this Court had defended the order passed in the matter, and it was argued before the Learned Single Judge as well as before this Court that Section 9(4) is applicable only when the import is from the same source.

11. The Learned Single Judge placing reliance upon a judgment delivered in the cases of *Haryana Pesticides Manufacturers' Association and Ors. V. Central Insecticides Board & Registration Committee and Ors.*, MANU/PH/0222/2015, and of this Court in *Syngenta India Ltd. V. Union of India (UOI) and Ors.*, MANU/DE/1955/2009 has dismissed the Writ Petition.

12. This Court has carefully gone through the order passed by the Learned Single Judge, and heard Learned Counsel for the Parties at length. Section 9 of Insecticide Act reads as under.

“9. Registration of insecticides.—(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 such 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 2 [seventeen months] from the date of such commencement for the registration of any insecticide which he has been importing or manufacturing before that date:

[Provided further that where any person referred to in the preceding proviso fails to make an application under that proviso within the period specified therein, he may make such

application at any time thereafter on payment of a penalty of one hundred rupees for every month or part thereof after the expiry of such period for the registration of each such insecticide.]

(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 it [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 day of March, 1975, notwithstanding the expiry of the period specified in sub-section (3) for the disposal of such applications, it shall be lawful and shall be deemed always to have been lawful for the Registration Committee to dispose of

such applications at any time after such expiry but within a period of one year from the commencement of the Insecticides (Amendment) Act, 1977 (24 of 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 (24 of 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 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.”

13. Section 9(3) and 9(4) of the Insecticides Act read together provides that in case an Application is made for registration of molecule under Section 9(3), the Committee has to scrutinize the Application and confirm to the claim made by the importer or by the manufacturer, as the case may be, as regards to efficacy of the insecticides and its safety to human beings and

animals, and if satisfied, it can be registered. Section 9(4) of the Insecticides Act, which is a me-too registration, categorically provides that in case the insecticide is already registered and any other person who wants to import or manufacture such insecticide, is entitled to apply for grant of certificate of registration on the same conditions on which the insecticide was originally registered.

Meaning thereby, if a molecule/ insecticide has to be registered under Section 9(4), it has to be from the same source as held by Coordinate Bench of this Court in the case of *Syngenta India Ltd.* (Supra).

14. The issue involved in the present case is no longer *res integra*.

15. The Punjab & Haryana High Court in Haryana Pesticides Manufacturers' Association and Ors. (supra) on considering the two provisions, has held as under:

“7. This sub-section, it can be noticed provide for a fast track where the insecticide has been registered on the application of a person. It contemplates therefore that a person who applies for certificate on a 'me-too basis' merely falls in the line to claim the registration because the insecticide is already registered on assessment of the formulation, its efficacy and safety. Though sub-section 4 does not make any reference to the registered insecticide of a particular technical manufacturer, I will understand that every registered insecticides is of a formulation brought through unique process. Same compound formulations may come through different processes. The product through different processes may not necessarily have same safety or efficacy. There may be impurities in one process which may not be in another registered insecticides brought through a technical manufacturer tested before registration under Section 9 (3) ought to be qua the said manufacturer only. To that extent source of supply becomes very relevant. Another

technical manufacturer having the same formulation may still have a different efficacy for the product which is brought through another process. Indian patent law protects not merely process patent but also product patent. The end product may enjoy some protection so that the registered insecticide of the manufacturers shall not be replicated by another manufacturer even through a different process. Consequently, it is perfectly tenable to put a 'me-too' application of a technical manufacturer through a different source is treated as an application under Section 9 (3) for consideration. The registration is to the products, namely, of the insecticide in its particular formulation and not the registration of a product of the particular manufacturer, who is identified supplier from a particular source. Consequently, any other person desiring to import or manufacture insecticide cannot be compelled to show anything more than he is importing a registered insecticide.”

16. This Court also in Syngenta India Ltd. (supra), placing reliance on the Checklist issued by the Committee observed that the same condition as mentioned in Section 9(4) of the Act would necessarily mean and include the same source of import also. Relevant findings of the Court are reproduced hereinbelow:

““8. Section 5 of the Act vests the power / function to scrutinize, examine and analyze insecticides as to their safety and efficacy on the Committee. Section 5 makes elaborate provisions 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. Under Section 5(5), the Committee regulates its procedure and conduct of business, including the grant of registrations of parties desirous of importing or manufacturing insecticides, for which purpose it has formulated guidelines. It has also issued a Checklist specifying the various parameters on which data is required to be submitted by an applicant along with its application for registration. Rule 4 of the Insecticides Rules

elaborates on the functions of the Committee. Section 9 of the Act provides for three kinds of registrations: (i) Section 9(3-B) – a provisional registration which 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 and also in the event of agricultural exigencies. This section presupposes insufficiency of examination of data by the Committee; (ii) Section 9(3) – regulation registration – The regular registration is granted only after submission of complete data by an applicant. The Committee conducts a full and indepth 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; and (iii) Section 9 (4) provides for what is popularly known as a “Me Too” “registration”. The registration under Section 9(4) is granted on same conditions and is only granted when there already exists a registration under Section 9 (3) for a particular Insecticide. It is obvious that these “same” conditions necessarily mean and include the same source of import also.

9. At this stage, we may refer to the guidelines framed by the Committee for the registration of insecticides and parameters / criterion fixed by it to effectuate verification of the efficacy and safety of the insecticides. The Committee has issued a Checklist specifying the various parameters on which data is required to be submitted by an applicant along with its application for registration – like Chemistry; Bio-efficacy, toxicity, etc. The Checklist has enumerated categories under which the registration of an insecticide can be sought, the relevant categories (for the present Appeal) are :

- (a) TIT – import of technical*
- (b) FIM – indigenous manufacture of formulation.*
- (c) FIT – import of formulation.*
- (d) TIT (new source) – import of technical from a different / new source.*

10. *The Checklist framed by the Committee is at pages 151 – 156 of the compilation and the Checklist for TIT (new source), which is at page 151, makes it clear that the Committee has laid down that in the case of registration of an insecticide which has already been permitted by the Committee in the past under Section 9(3) of the Act, and which is now proposed to be procured from a new source, only the attenuated or reduced data, material evidence specified under column no. 12 of the Checklist is required to be furnished and if such data is furnished then the applicant will be entitled in law to registration under Section 9(3) of the Act. We may also mention that the Central Government has issued the circular dated 30.10.2007 introducing a concept of deemed registration of the technical/active ingredient of the formulation without a separate application being made for the same. The circular also provides for data protection for three years from the date of registration of the formulation. By OM dated 18.2.2008 the Central Government has clarified that the period of three years is to be reckoned not from the date of the grant of registration under Section 9(3) of the Act but if applicable, from the grant of provisional registration under Section 9(3B), if previously granted with permission to commercialize.*

11. *In the above background of the provisions of the Act, rules and the relevant guidelines, we may now proceed to deal with the submissions made by the learned senior counsel appearing for the appellant. Submissions (i) & (ii)*

12. *We have gone through the entire records and it is absolutely clear to us that in the present case, the registration which was granted to respondent no. 3 was under Section 9(3) and not under Section 9(4) of the Act. It is also seen from the records that for the purpose of taking the decision to grant registration to respondent no. 3 under Section 9(3), the Committee has followed the standard guidelines and criteria which are set out in the Checklist framed and issued by the Committee, in exercise of its statutory powers under Section 5(5) read with Section 9(3) of the Act, under which it is the prerogative of the Committee to decide the criteria, material,*

evidence and data on the basis of which the Committee would take a decision to grant registration under Section 9(3) of the Act.....

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15. Insofar as the allegation of dilution of data is concerned it is required to be noted that no provision of the Act, or Rules, prescribe or enact data exclusivity or protection. The October 2007 guidelines, directing a data exclusivity provision, was brought into force after the appellant's registration certificate was issued. As per the circular dated 30.10.2007, as amended by OM dated 18.2.2008, the exclusivity is only for a period of three years from the date of the provisional registration. Thus the period prescribed under the circular had already expired before the registration granted to the third respondent. It is also pertinent to note that no challenge has been raised to the OM dated 18.2.2008 in the writ petition though submission appears to have been raised across the Bar questioning the OM on the ground of the arbitrariness. In any event, we find that the submission regarding the data protection is completely misconceived. It is not the case of the appellant that the respondent no. 3 in importing its "TIT" has in any way violated the confidentiality of appellant's data. Mr. Ganesh, appearing for the respondent No.3, submitted and in our opinion, rightly, that in a case of registration of "TIT" (new source) it is not as if the applicant is utilizing the materials or the intellectual property of the earlier applicant. The correct position is that since the Committee has, on an earlier occasion after fully and carefully studying all the relevant and applicable materials, approved a particular insecticide there is no need thereafter for another applicant who wishes to import the same insecticide albeit from a different source to reinvent the wheel as it were and to place on record the entire mass of material and data which was required to register the said insecticide originally. In such a situation that the Committee, which is a high powered technical body, has considered it appropriate to issue a Checklist providing that when a person desires to import the same insecticide, but from a different source, the requirement of

submission of data are appropriately reduced. The respondent no. 3 has fully complied with the guidelines of the requirements of the Checklist issued by the Committee. In our opinion, therefore there is no illegality in the action of the Committee in granting registration in favour of the third respondent. In our opinion, the whole object of initiating these proceedings is to somehow continue the monopoly of the appellant in the product and sale of the insecticide in question. It is pertinent to note that now the third respondent is selling the same insecticide approximately at the rate of Rs.5,000 per kg. which has been all along sold by the appellant at the rate of about Rs.9,000/- per kg.” (emphasis added)”

17. In the considered opinion of this Court, the Learned Single Judge was justified in holding that the Petitioner’s (Appellant herein) case does not fall under Section 9(4) of the Insecticides Act as the Petitioner was not importing the molecule from the same source, and, therefore the Registration Committee in its 229th Meeting has rightly declined the Petitioner’s claim for registration under Section 9(4).

18. The Statutory Provisions governing the field, as contained under Section 9 of the Insecticides Act, makes it very clear that in case a person wants a registration of a molecule/ insecticide and the source is changed, the Application has to be made under Section 9(3) of the Insecticides Act, 1968.

19. This Court does not find any reason to interfere with the order passed by the Learned Single Judge. Accordingly, the present Appeal i.e. LPA 530/2022 stands dismissed.

LPA 536/2022

In light of the order passed in the LPA 530/2022, this Appeal i.e. LPA 536/2022 which is connected with the said LPA, and also is a case of me-too registration deserves to be dismissed. Accordingly, this LPA also stands dismissed.

SATISH CHANDRA SHARMA, CJ

SUBRAMONIUM PRASAD, J.

MAY 09, 2023

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