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

Date of Decision : 10.02.2020

+ W.P.(C) 6092/2013 & CM No.13395/2013

(6) W.P.(C) 5000/2018 & CM No.19269/2018

UNIKIL PESTICIDES PVT LTD Petitioner
Through: Mr.Aftab Rasheed, Adv.

versus

UNION OF INDIA & ANR. Respondents
Through: Mr.Kritiman Singh, CGSC,
Mr.Santosh Kr. Pandey, GP,
Mr.Rohan Anand and
Mr.Waize Ali Noor, Advs.
Mr.Sanjeev Uniyal and
Mr.Dhawal Uniyal, Advs.

CORAM:
HON'BLE MR. JUSTICE NAVIN CHAWLA
NAVIN CHAWLA, J. (Oral)

1. These petitions have been filed by the petitioner challenging the order(s) passed by the Registration Committee (Committee) and the Appellate Authority under the Insecticides Act, 1968 (hereinafter referred to as the 'Act'), rejecting petitioner's application under Section 9(4) of the Act. As both the petitions involve common question of law and facts, the same are disposed vide this common judgment.

2. It is the case of the petitioner that the molecule which is sought to be imported by the petitioner was already registered under Section 9(3) of the Act and therefore, petitioner's application was rightly filed under Section 9(4) of the Act. The learned counsel for the petitioner submits that the Appellate Authority has erred in placing reliance on the decision taken by the Registration Committee in its 229th Meeting held on 12.12.2002, implementing Guidelines for import of technical grade pesticides from additional sources under Section 9(3) of the Act. He submits that such decision was in derogation of Section 9(4) of the Act, making it otious and, therefore, *ultra-vires* the powers of the Registration Committee.

3. On the other hand, it is the case of the respondents that Section 9(4) of the Act would apply only where the import is to be from the same source. In the present case, as the petitioner was seeking to import the molecule from a source different from the one approved under Section 9(3) of the Act, the petitioner should have filed the application under Section 9(3) of the Act, with sufficient data to satisfy the Registration Committee as per the test laid down therein. In this regard, the learned counsel for the respondents has placed reliance on the judgment of the Punjab & Haryana High Court in ***Haryana Pesticides Manufactures' 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.

4. As far as the decision of the Registration Committee in its 229th Meeting, the learned counsel for the respondents submits that the same is, in fact, in accordance with Section 9(4) of the Act. He submits that ‘same conditions’ under Section 9(4) of the Act would also mean the same source and, therefore, where the insecticide is being imported from a different source, the applicant has to make its application under Section 9(3) of the Act.

5. I have considered the submissions made by the learned counsels for the parties. Sections 9(3) and 9(4) of the Act are reproduced hereinbelow:

“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 of 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.

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.

(emphasis supplied)

6. Under Section 9(3) of the Act, the Committee has to scrutinize the application and confirm to the claim made by the importer or by the manufacturer, as the case may, as regards the efficacy of the insecticides and its safety to human beings and animals and if satisfied, register the same. Under Section 9(4) of the Act, where an insecticide has been registered, any other person desiring to import or manufacture such insecticide or engaged in any business of import or manufacture thereof may apply for grant of a certificate of registration in relation thereof “on the same condition on which the insecticide was originally registered”.

7. 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.”

8. 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 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; 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)

9. In view of the above judgments, the plea of the petitioner that its case will fall under Section 9(4) of the Act, cannot be accepted. Similarly, its challenge to the decision of the Registration Committee in its 229th Meeting, also must fail. As held in the above judgments, where the source is changed, the application must be made under Section 9(3) of the Act *albeit*, while making such application, the applicant would not have to place on record the entire mass of material and data which was required to register the said insecticide originally. The requirement of submission of data would appropriately stand reduced, however, the application would still have to be tested on the touchstone of the conditions prescribed in Section 9(3) of the Act. This also flows from the object of the Act, which reads as under:

“An Act to regulate 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 therewith.”

10. Consequently, I find no merit in the present petitions. The same are dismissed. There shall be no order as to costs.

NAVIN CHAWLA, J

FEBRUARY 10, 2020/Arya

