Syngenta India Ltd. Vs Union of India (UOI) and Others

Court: Delhi High Court

Date of Decision: Aug. 11, 2009

Acts Referred: Insecticides Act, 1968 â€" Section 10, 5, 5(5), 9, 9(3)
Insecticides Rules, 1971 â€" Rule 4

Hon'ble Judges: A.P. Shah, C.J; Manmohan, J

Bench: Division Bench

Advocate: Mukul Rohatgi and Ruchi Agnihotri Mahajan, for the Appellant; A.S. Chandhiok, ASG, Gaurav Duggal, Ritesh Kumar, Sandeep Bajaj for R-1/UOI and S. Ganesh, Sudhir Nandrajog, Laliet Kumar and Santosh Sharma for R-3, for the Respondent

Final Decision: Dismissed

Judgement

@JUDGMENTTAG-ORDER

1. The appellant Syngenta India Ltd. has preferred this appeal against the judgment and order dated 1.7.2009, passed by S. Ravindra Bhat, J. in

W.P(C) No. 8123/2008. In the writ petition the appellant impugned the decision of the Department of Agriculture, Government of India, dated

5.11.2008, rejecting its appeal u/s 10 of the Insecticides Act, 1968 (""the Act"") against the decision of the Registration Committee (''Committee''

for short) for granting registration for Emamectin Benzoate 5% SG to the third respondent - M/s Jaishree Agro Industries Ltd. in its 293rd meeting

held on 26.9.2008. The learned Judge came to the conclusion that the 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 and the pendency of this proceeding had 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.

Consequently, the learned Judge dismissed the petition with heavy costs.

2. The facts necessary for deciding this appeal are as follows:

In 2003 the appellant filed an application for registration u/s 9(3) of the Act 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 (appellants'') data was incomplete on various parameters like toxicity and bio-efficacy, in its meeting held on

2.7.2004. The appellant, therefore, could not be granted a registration u/s 9(3) of the Act. The appellant, however, was in the meanwhile, asked

by the Committee to convert its application to one u/s 9(3-B), 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 Committee to grant a provisional registration

u/s 9(3B) of the Act to the appellant 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 appellant in the categories of TIT and

FIM u/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 appellant during the period of 2 years. It is stated that from this 5 MT the appellant indigenously

manufactured about 100 MT of formulation, and used it for commercialization as well as compilation and generation of exhaustive data. The

provisional registrations granted to the appellant in the categories of TIT and FIM lapsed on 20.07.2006. By that time the appellant claims to have

collated and completed its deficient data. On 11.09.2006, the appellant applied afresh u/s 9(3) of the Act in the category FIT (Import of

Formulation). On 24.7.2007, the appellant was granted registration u/s 9(3) of the Act in the category of FIT (Import of Formulation).

3. On 27.07.2007, the respondent No. 3, 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. However, the respondent No. 3, was not granted registration because

the appellant was granted the registration u/s 9(3) before respondent No. 3 and the grant of registration u/s 9(3B) is only for introduction of the

product for the first time. This fact was intimated to the 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, the respondent No. 3 requested that its application may be

considered u/s 9(3) for import of the product from a new (alternate) source, which is permissible under already existing guidelines of the

Committee requiring lesser data package because the efficacy and safety of the product had been established to the satisfaction of the Committee.

Accordingly, an application was submitted by the respondent No. 3 on 7.8.2007 for registration as TIT(new source) u/s 9(3). Along with the

application required information / data was also submitted by the respondent No. 3, as was applicable and required in respect of application u/s

9(3) for TIT (new source). The data submitted comprised more than 4000 pages of detailed technical studies, analysis, reports and other data,

including reports of numerous studies conducted by Jawaharlal Nehru Krishi Vishwa Vidyalaya, Indian Agriculture Research Institute, Tamil Nadu

Agriculture University etc. which are well known institutions in the field of agriculture. The Committee verified the claims of the respondent No. 3

from the data submitted to it and granted the registration to the respondent No. 3 u/s 9(3) of the Act in its 293rd Meeting held on 26.09.2008.

4. The appeal preferred by the appellant u/s 10 of the Act to the Central Government, i.e the appellate authority, came to be dismissed by order

dated 5.11.2008, which interalia reads as follows:

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. 1329/ 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(3) 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.

5. After a very elaborate and detailed consideration of the facts and law, the learned single Judge dismissed the writ petition challenging the order

of the Central Government passed in appeal u/s 10 of the Act.

6. Mr. Mukul Rohatgi, learned senior counsel appearing for the appellant, inter alia raised the following four submissions before us:

(i) that though the respondent No. 3 was effectively seeking registration on parameters / criterion applicable to registrations u/s 9(4) of the Act

(""Me Too"") by placing substantial reliance on data of the appellant, the Committee erroneously granted to the respondent No. 3 registration u/s

9(3) of the Act;

(ii) that in any event the data submitted by the appellant pertained to a technical / active ingredient having a purity of minimum 95% whereas the

maximum purity available with the supplier of the respondent No. 3 is 90%. Thus, the data submitted by the appellant was for an entirely different

product and there could be no reliance whatsoever on the appellant''s data;

(iii) that the order of the Committee granting registration to the respondent No. 3 amounts to unjustified dilution of the data submitted by the

appellant which is liable to be protected under the guidelines issued by the Government vide circular dated 30.10.2007;

(iv) that Office Memorandum (OM) dated 18.02.2008 purportedly clarifying the circular dated 30.10.2007 is arbitrary and illegal.

7. Before adverting to the submissions made by Mr. Mukul Rohatgi, we may briefly refer to the scheme of the Insecticides Act, 1968 (''The Act''

for short). The Act was brought into force on 2.9.1968 with 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 connected there with.

Any prospective manufacturer or importer of any insecticide / pesticide in India is primarily governed by the regime of this Act. No insecticide can

be imported into India / manufactured indigenously, unless the prospective importer / manufacturer has obtained registration u/s 9 of the Act. An

insecticide contains an active ingredient or the raw material called the technical and after adding certain additives, these result in formulation. For

each activity, there has to be an approved registration of the formulation and/or technical as the case may be. A desirous party can either import

the technical of an insecticide and manufacture the formulation indigenously or import the formulation of the insecticide for direct marketing and use

in India upon obtaining the approval of the Committee.

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. u/s 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 be 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 u/s 9(4) is granted on same conditions and is only granted when there already exists

a registration u/s 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 u/s 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 u/s 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 u/s 9(3) of the Act

but if applicable, from the grant of provisional registration u/s 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 u/s 9(3) and not u/s 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 u/s 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 u/s 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 u/s

9(3) of the Act. Further, the record of the proceedings before the Committee also makes it clear that the application of respondent No. 3 for

registration was only u/s 9(3) and was under the head ""Technical import from new source"" i.e. TIT (new source). The data submitted by

respondent No. 3 comprises more than 4000 pages of detailed technical studies, analysis, reports etc. It is also seen that in the 293rd meeting of

the Committee the data was verified by the Committee u/s 9(3) and on satisfaction about the data the registration came to be granted in favour of

the respondent No. 3 u/s 9(3). The Central Government has also in its counter affidavit filed before the learned single Judge clearly stated that the

data submitted by the respondent No. 3 was more than adequate for grant of registration as TIT (new source). It has been further stated in the

counter affidavit of the Central Government that chemical composition of the insecticide of the appellant and that of the respondent No. 3 are the

same.

13. Learned single Judge has minutely examined the records and has recorded the following findings:

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(3); later by its letter dated 6-6-2007, it requested the committee to process the application, u/s 9(3), 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(3) 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(3)

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(3) 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 Coordinated 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.

14. In our opinion therefore submissions (i) & (ii) are without any merit. Submissions (iii) & (iv)

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.

16. We dismiss the appeal with costs of Rs. 1 lac, which will be paid by the appellant to the respondent Nos. 1 and 3 in equal proportion.