IN THE HIGH COURT AT CALCUTTA

SPECIAL JURISDICTION ORIGINAL SIDE

A.I.D. No. 1 of 2001

Before: Hon'ble Ashok Kumar Ganguly J.

15th January 2002

Dimminaco A.G. ... Appellant/Petitioner

V/s.

Controller of Patents Designs & Ors. ... Respondents

Heard on: 13-9-2001, 20-9-2001, 26-9-2001 & 4-10-2001

Mr. Samaresh Chakraborty, Advocate &

Mr. P. Basu, Advocate appeared for Appellant/Petitioner

Mr I.P. Mukherjee, Advocate &

Mr. S.S. Sarkar, Advocate appeared for Respondent.

JUDGMENT

Asok Kumar Ganguly, J.

This statutory appeal under section 116 of the Patent Act, 1970 (hereinafter referred to as P.A.) was filed against the decision dated 27th December 1999 passed by the Assistant Controller of Patents and Designs under section 15 of P.A. By the said impugned decision dated 27th December 1999, the Assistant Controller of Patents & Designs exercising the delegated authority from the Controller under section 73(3) of P.A. refused to accept the patent application filed by the appellant and upheld the objection of the Examiner.

The material facts of the case are that the said Patent Application filed by the appellant involved, according to the appellant, an invention relating to a process

for preparation of infectious Bursitis Vaccine. The said Patent application was examined by the Patent Office Examiner under section 12 of P.A. On such official examination, the Examiner gave a finding that what is claimed in the said Patent Application does not constitute an invention under section 2(i)(j) of P.A. The said Examiner further stated that the invention is one of the classes as specified in section 5(a)/5(b) of P.A. as the substance prepared by the process is capable of being used as Food/Drug. However, the said examination report shows that the application of the appellant was rejected, inter alia, on the finding that the same does not constitute an invention under section 2(i)(j) of P.A. as noted above. In the said impugned decision under appeal, the authority concerned also proceeded on that decision of the examiner.

From the impugned order/decision under appeal, it appears that the Assistant Controller of Patents & Designs noted the contentions of the appellant that the invention relates to the process for preparation of infectious Bursitis Vaccine (hereinafter referred to as the said Vaccine) which is invented for protecting poultry against infectious bursitis. It was the contention of the appellant before the Assistant Controller of Patents & Designs that under the present sate of law in India, there is no bar against allowing the process for preparation of any product which is a patented commodity even if the process contains live virus. It was also the contention of the appellant that the objection under section 2(i)(j) of P.A. putforward by the Examiner is not based on any reason. It has also been contended that there is no bar under the present state of law against granting patent to an end-product, the manufacture of which involves the live virus and the grant of patent cannot be denied on the basis of any administrative policies. It was further stated that the administrative policies cannot be allowed to prevail over the statutory definition under the act as that will be a negation of a rule of law inasmuch as no administrative policy can override the statutory provision. In dealing with the said contention, the Assistant Controller of Patents & Designs held that the process for preparation of the said vaccine which has living entity cannot be considered a manufacture. It was held that in past the same was never

patented in India. The Assistant Controller of Patents & Designs was of the opinion that if the term 'manufacture' is to be given such a wide meaning, there will be further problems as ever going new process with foreign sophisticated technologies will have to be patented in India. The Assistant Controller of Patents & Designs, therefore, wanted to probe the intention of the Legislature is ascertaining the term 'Manufacture' and, as such, relied on the recommendation of Justice Rajagopalan Iyenger on the earlier Patent Bill, 1953 and held that the said recommendation of Justice Rajagopalan Iyengar was accepted by the framers of the present law. The Assistant Controller further held that the definition of 'Invention' under section 2(i)(j) of P.A. is substantially identical with the definition as recommended by Justice Rajagopalan Iyenger as published in 3rd paragraph of page 130 of the report of the Patent Enquiry Committee. The Assistant Controller of Patents & Designs further held that the original definition of manufacture as provided in clause (j) of section 2 of the Patent Bill, 1953 was not accepted in view of the recommendation of Justice Iyengar. The Assistant Controller of Patents and Designs was, therefore, also not in favour of accepting the wider meaning to the term manufacture. Therefore, the finding was reached by the said Assistant Controller of Patents and Designs that the process of preparing vaccine which contains the living virus cannot be considered manufacture.

The Assistant Controller of Patents and Designs further held that a vaccine with living organism cannot be considered a substance. The Assistant Controller further held that an inanimate object can be described as thing or item but not a living one and the specific finding providing micro-organism cannot be considered an inanimate such as it cannot converted physically or chemically to any other product. Therefore, in the impugned decision, the Assistant Controller held that the subject matter of the specification does not constitute an invention and the said patent application was, therefore, rejected.

The learned counsel appearing in support of the appeal has challenged those findings on various grounds.

First of all, the learned counsel challenged that no reason has been assigned by the Examiner in coming to the conclusion that the appellant's patent application does not constitute an invention under section 2(i)(j) of P.A. In support of this contention, the learned counsel referred to a text book.

Before considering the said authority, this court finds that the examination of the application for patent by the Examiner involves certain adjudicatory process. First of all, the Examiner has to find out under clause (a) of section 12 of P.A. whether application and the specification relating thereto are in accordance with the requirements of this Act and/or Rules made thereunder. Under clause (b) of section 12 it has to be found whether there is any lawful 'ground of objection' to the grant of patent under this Act and under clause (c) the report of investigation under section 13 is to be considered. Clause (d) of the said section is a residuary clause which provides for any other matter which may be prescribed, but is not covered under clauses (a), (b) and (c) of sub-section (1) of section 12 of P.A. Therefore, section 12 has a direct nexus with section 13. Thus sections 12 and 13 both constitute the Code for examination of the application. From the impugned report of the Examiner in this case, it does not appear that there has been any investigation made under section 13 of P.A. Apart from that, the main finding of the said Examiner is that the claimed specification does not constitute an invention. The reason for such finding has not been given. It appears that while giving his report, the said Examiner has to act in a quasi-judicial manner and it is well settled as a proposition of law that when an authority, acting in a quasi-judicial manner, passes an order which affects the right of the parties such order should be a reasoned order. In support of this contention, the learned counsel relied on Terrel on the Law of Patents. Terrell in the treaties on the Law of Patents (15th Edition) stated in paragraph 3.48 page 55. "The Examiner must invite his applicant to file his observations to any objections that the Examiner may have and such objection shall be contained in a reasoned statement".

Assailing the report of the Examiner, the learned Counsel for the appellant further submits that the process claimed in the original application of the

appellant and also in the amended form, after properly examined would meet the objection raised in the Examiner's report. The patent claimed is only for the process for preparation of the vaccine and not the vaccine itself. But for introduction of a new process for the preparation of a vaccine certain chemical steps have been taken under the specific scientific conditions. The said vaccine, end-product, is useful for protecting poultry against contiguous bursitis infection and the process contains a living virus as in any other vaccine. Therefore, it is a new process and such process for production of drug and pharmaceutical is patentable under section 5 read with section 2(i)(j) of the Act.

Under section 2(i)(j) of the P.A., expression 'invention' has been defined to mean as follows :

> "(j) 'Invention' would mean any new and useful -
>
> (i) art, process, method or manner of manufacture;
>
> (ii) machine, apparatus or other articles;
>
> (iii) substance produced by manufacturer and includes any new and useful improvement of any of them and an alleged invention"

Section 5 of P.A., is as follows :

> "**Inventions where only methods or processes of manufacture patentable** - (1) In the case of inventions -
>
> (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
>
> (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and intermetallic compounds),
>
> no patent shall be granted in respect of claims for substances themselves, but claims for the methods or processes of manufacture shall be patentable.
>
> (2) Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IV-A".

The learned counsel submitted that from a perusal of section 5 of P.A., it is clear that the claims for the method in the process of manufacture can be patentable. According to the learned counsel, if the definition of 'invention' is properly appreciated, it would mean that any new or useful art, process, method or manner of manufacture ought to be considered as 'invention' and the learned counsel submitted that in the report, the said Examiner has not cited any identical prior article or aspect of novelty comparable to the claimed process of the appellant, and no particulars have been given in the examination report questioning the usefulness of the end-product arising out of the said claimed process. On the other hand the learned counsel submitted that the claim process employed by the appellant's a novel one and the same constitute a manner of manufacture.

The learned counsel also by referring to the order of the Assistant Controller submitted that in the said order, arguments advanced by the appellant's agent have been noted in page 2 of the impugned order. But, the learned counsel pointed out that those arguments had not been dealt with in the alleged finding given by the Assistant Controller in pages 3 to 6 of the impugned decision. Therefore, the grievance is that the points raised by the applicant's agent had not been considered and dealt with of in the impugned order.

The learned counsel also submitted that the only reason on which the impugned order is based is that the process does not constitute invention without the meaning of section 2(i)(j) of P.A. The learned counsel further stated that in the impugned order, the reason assigned by the Assistant Controller in support of his refusal to accept the patent application of the appellant/petitioner is that 'the process has to result either in an article or a substance'. And a vaccine with the living organism has not been considered a substance. The further reason 'given in the impunged order is that an article according to the Webster New International Dictionary means 'material thing, item, a thing of a particular class or kind as distinguished from a thing of any class of kind. The Assistant Controller further held that an inanimate object can be donated as a thing or

item, but, not a living one. The further reason is that living organism cannot be considered an inanimate object and it cannot be converted to other product by any chemical or like process.

In assailing those findings, the learned counsel submitted that the expression 'substance' has not been defined under P.A. The Dictionary meaning of the word 'substance' is species of matter of a definite chemical composition or 'a solid or real thing as opposed to appearance or shadow'. It also means "the muscular tissue or fleshy art of any animal body". In support of the aforesaid meaning given to the word 'substance', the learned counsel placed his reliance on the Oxford Dictionary, Vol. XVII pages 64 and 65. The learned counsel further submitted that the said meaning of word 'substance' has also been mentioned in para 10 of the petition of appeal filed by the appellant. But, in the affidavit-in-opposition which has been used by the respondent authorities, the same has not been denied save and except stating that in India till date, no patent has been granted for any process of preparing a living organism, which undoubtedly a virus is.

The learned counsel asserted repeatedly that the claim of the appellant is for a patent of the process for the preparation of a vaccine. The other point which the learned counsel for the appellant/petitioner urged is that a wrong stand has been taken in para 5 of the affidavit-in-opposition that the definition of 'manufacture' does not mean and include a living organism and a substance as defined in the Act means and includes only non-living substance and does not include a living organism. The learned counsel for the appellant submitted that this is the main stand taken by the Assistant Controller in his order and also in the Affidavit. But, the said stand is not correct as the learned counsel submitted that in the absence of any statutory definition of either the 'substance' or 'manufacture' under P.A., the normal Dictionary meaning of substance and manufacture ought to be accepted. The normal meaning of manufacture is where whether the material in question after going through the process of manufacture has under-gone any change by the inventive process and it becomes a material which is different

from the starting material, it goes through a process of manufacture. On this aspect, the learned counsel relied on the decision of the Controller reported by the Patent Office Technical Society in the matter of an application for Patent No. 1354/Cal/73. The said decision was given under P.A.

Relevant portion of the said decision is extracted hereunder :

> "A method, process, art and manner under the Patents Act, 1970 would be considered as a patentable invention so long as they are new and useful and relate to 'Manufacture'. As the word 'manufacture' has not been defined under the Patents Act, 1970 it has to have the normal dictionary meaning. It may be pointed out that the word 'manufacture' gives the meaning of making from certain ingredients or starting materials, by some operation of industrial nature, manual, mechanical, electrical and chemical, an end product which will be useful that is suitable for human use. The end produce may be a useful article or a useful thing which can be perceived and gainfully used by humanity. Again the words Art, process, method and manner although varying slightly in degree convey the common idea of an 'artificial' process and not a 'natural' process. So, under Section 2(i)(j) the patentable invention as applied to a process, method, art or manner should be regarded as an artificial process or operation of an industrial nature where certain starting materials have been subjected to the said process or operation to convert the said starting material in such a manner as to produce a new and useful thing or product which may or may not be an article but can be perceived by humanity and may be applied for gainful use".

It also appears that in this proceeding, a supplementary affidavit was filed by the petitioner/appellant. In the said supplementary affidavit, it has been stated that several patent applications in the field of bio-technology, drugs and/have been accepted by various Branch Offices of the Patent Office other than the Patent Office at Calcutta. From those applications, it appears that live cells, virus and micro-organism were involved in those applications, but the patents have been granted in respect of those applications. It has been stated that those applications relate to diverse inventions in the field of bio-technology and many of them involve preparation of end-product containing living substances. In para 4 of the said supplementary affidavit, the particulars of such applications have been mentioned. Those particulars are as follows :

"Application Filing No.	Accepted Applicacation No.	Title	Branch of Patent Office accepting the application	Date of Notification of acceptance in Gazette
1250/Del/95	183925	An improved Process for the production of Pencilin V Acylase Using B. Sphaericus	New Delhi	May 20, 2000
1501/Del/95	183927	A Method of produce a Single-Chain form of a Glycoprotein Hormone	New Delhi	May 20, 2000
1662/Del/95	183928	Process for the preparation of very high purity Gamma Interferon	New Delhi	May 20, 2000
991/Del/94	183939	A Process for the preparation of pure Monospecific Polyclonal Abntibodies of Malarial lactate Dehydrogenase (LDH) useful for the Diagnosis of Malaria	New Delhi	May 20, 2000
1824/Del/95	184298	Process of preparing transfer vectors pCBTI to pCBT4 for the purpose of expressing proteins for commercial use.	New Delhi	July 29, 2000
2336/Del/95	184437	A process for producing and expressing DEVR Protein of Mycobacterium Tuberculosis.	New Delhi	August, 26 2000

Application Filing No.	Accepted Application No.	Title	Branch of Patent Office accepting the Application	Date of Notification of acceptance in Gazette
410/Bom/99	184510	A Process for isolation and purification of M. Tuberculosis excretory secretory M.tb ES 31 Petition for use in antibody based or antigen based assy for detecting the presence and monitoring of Of M. Tuberculosis infection.	Mumbai	August 26, 2000
2752/Mas/97	184620	A Process for the Preparation of Zeaxan Thin.	Chennai	September 9, 2000

465/Bom/96	185085	A Bifunctional or Bivalent antibody fragment analogue.	Mumbai	November 11, 2000
183/Bom/97	185409	A Process for preparing multivalent and multi-specific antigenbinding protein.	Mumbai	January 13, 2000

To the said supplementary affidavit, an affidavit-in-opposition has been used by the respondents. In the said affidavit-in-opposition, in para 5, the consistent stand of the respondents is that the process which is involved in the invention and is used for micro-organism has a living organism. But, the end-product manufactured out of the said process does not contain any living entity. So the patent was granted. Therefore, the stand of the respondents is that the process for which patent is claimed may involve living organism, but, the end-product produced by the process has to come within the meaning of manufacture and it cannot contain any living organism. So precise stand of the respondents is that the end-product must satisfy meaning of manufacture which rules out any living entity. But, the process for the end-product even if it contains any living organism is patentable.

It may be noted in this connection that in the course of hearing the learned counsel for the petitioner/appellant relied on a Gazette Notification dated 28-08-1999 and submitted that in respect of the three patents, viz., 183033, 183034 and 193035, it is clear that the end-product contains living organism. Since the said Gazette Notification was produced, which is otherwise admissible before in a Court producing this Court gave liberty to the respondents, in view of the prayer by their learned counsel, to file a supplementary affidavit dealing with the contents of the said Gazette Notification.

Pursuant to the said leave, a supplementary affidavit by the respondents was filed. In the said supplementary affidavit, it has not been disputed that those patent applications were accepted by the authorities concerned. The stand taken in the said affidavit is that the specification involved the process of lyophilizing the living organism. It was further stated that by the process of lyophilizing the department has understood the death of the living organism. In support of the

said stand that lyophillizing involves the death of the living organism, reliance was placed on Chamber's Dictionary of Science and Technology. From the said Dictionary, it appears that the lyophilizing is technical term and it means 'freeze drying'.

These are the rival contentions of the parties.

It is, therefore, clear from the aforesaid stand of the respondents that the patent applications have been granted in respect of some cases where even the end-product contains living substance. The said stand of the respondents is clear from the complete specification of the application in respect of serial numbers 183034 and 193035.

From the Indian patent Specification No. 183034, it appears as follows :

> "Lactobacillus return is the most commonly occurring Lactobacillus species found in the GL tract of human and animals. Like other Lactobacilli, L. reuteri produces acidic metabolic end-products which have considerable antimicrobial activity. Use of L. reuteri cell therapy for other than probiot purposes, i.e., benefiting the host by improving the indigenous mocroflora, or antibiotic purposes, is not known."

It is further clear from the following excerpts form the said specification :

> "A process of preparing the therapeutic preparations for reduction of acute diarrhea symptoms or for stopping dehydration of mammals and in particular young patients. Preferably at least above 10^7 cells of L. reuteri are administrated over period of at least one day, depending on the severity of the gastroenteritis. The result is a rapid, dramatic reduction in the animal's diarrhea and vomiting, previously not found using other therapies".

And also from the following excerpts :

> "From of Treatment with L. reuteri
>
> In addition to use of a liquid suspension of L. reuteri either freshly grown or as lyophilized cells resuspended in a chosen liquid, patients capsule, once a day".

From the aforesaid excerpts, it is clear that lyophilizing cells have been placed on the same footing with freshly grown living cells. Therefore, the presence of

the living organism in the end-product of the claim process is not ruled out.

Similarly, in respect of the Indian Patent specification No. 183035 it appears as follows :

> "The Invention is a method of reducing symptoms associated with cryptosporidia infection in mammals including humans in which L. REUTERI cells are administered to the mammal in an amount sufficient to reduce diarrhea in the animal to a normal level..... The cells may be administered suspended in a liquid or in dry form".

The following excerpts are also relevant :

> "Process of manufacturing cryptosporidium infection reducing therapeutic concentration, comprising,
>
> i) growing Lactobacillus reuteri cells
>
> ii) harvesting and concentrating said L. reuteri cells & finally lyophilizing the same.
>
> iii) Then suspending the said L. reuteri cells in a carrier medium in the ration equal to an amount of 10^8 - 10^9 cells per ml. In 100 ml. Carrier medium and,
>
> iv) Preferably diluted by fluid medium fit for oral admission".

It is clear from the aforesaid excerpts that the applicant for the patent Specification No. 183035 has claimed a process of manufacturing a therapeutic concentration, which is meant for reducing crypto sporidium infections in mammals resulting in diarrhea. For reducing the said infection the said cells of lactobacillus reuteri are grown and are harvested and concentrated and are finally lyophilized. Therefore, the end-product contains living organism.

It appears that in the instant case, the petitioner's application for patent has been refused mainly on the ground that the end-product contains a living organism. Therefore, it has been held that it cannot be called a manner of manufacture. It is an admitted position that the word manufacture has not been defined, in the Act. In such a situation since the word manufacture has not been defined the

dictionary meaning of this word or the meaning attributed to in the particular trade or business must be accepted if the end product is a commercial entity.

It is also admitted that there is no statutory bar to accept a manner of manufacture as patentable even if the end-product contains a living organism. It is of course, true whether a claim for grant of patent is an invention or not, has to be decided in the facts of each case. A new and useful are or process is an invention. In the instant case, the novel process claimed in the patent application in its original version and amended version is a new process for preparation of vaccine involving chemical steps under specific scientific conditions. The said vaccine is useful for protecting poultry against contagious bursitis infection. Therefore, it is a new process and such process is apparently patentable under section 5 read with section 2(1)(1) of P.A., Therefore, where the end-product is a new article, the process leading to its manufacture is an invention.

Judged in this context, the expression manner of manufacture is of special significance. To decide whether in a particular case, the process of manufacture involved in the invention ought to be patented or not, one of the most common test is the vendibility test. The said vendibility test is satisfied if the invention results in the production of some vendible item or it improves or restores former conditions of a vendible item or its effect is the preservation and prevention form deterioration of some vendible product. In other words, a vendible product means something which can be passed on from one man to another upon the transactions of purchase and sale.

Therefore, this Court is of the view that the controller erred himself in law by holding that merely because the end product contains a live virus, the process involved in bringing out the end product is not an invention. The dictionary meaning of the word manufacture does not exclude the process of preparing a vendible commodity which contains a living substance and in a case like this where there is no statutory meaning of manufacture, the dictionary must be accepted.

This court also finds that in the instant case, the appellant's claim for patent should have to be considered by the controller on the principle of Section 3 of P.A. No objection has been taken by the examiner under section 3 of the P.A.

This Court also find that the order passed by the controller that the claim process does not lead to the manufacture of a substance also cannot be accepted. Since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture. Reference in this connection may be made to the decision of the Supreme Court in the case of M/s. Bishwanath Prasad Radhey Shyam vs. M/s. Hindustan Metal Industries, reported in AIR 1982 SC 1444.

In that judgement the learned judges of the Supreme Court held that patent is granted only for an invention which must be new and useful, which means it must have novelty and utility. In para 17 of the said judgment the learned judges of the Supreme Court highlighted the object of patent law and said that the object of the law is encourage scientific research, new technology and industrial progress. In para 22 of the same judgment the learned judges also held that the law relating to patentable invention prevailing in Britain and the patent law in India is substantially the same. Keeping the aforesaid principle in mind, the court is of the opinion that the word manufacture which has been explained by the Chief Justice Abbott in R. vs. Wheeler should have been accepted by the Controller. In R. vs. Wheeler the Chief Justice Abbott has held "the word manufacture has been generally understood to denote either a thing made which is useful for its own shake, and vendible as such..... or to mean an engine or instrument to be employed either in the making of some previously known article.... or it may perhaps extend also to new process to be carried on by known implements or elements".

The Controller by rejecting the application for patent by the appellant's firm on the ground that it cannot called a manner of manufacture because it involves a living virus in the end-product has not acted on correct principles.

The Court has already referred to the patent application in the Gazette Notification and the materials disclosed by the respondent in dealing with those applications are already on record. From those record, it is clear that patent has been granted by the authorities in cases where end-product contains living virus. But the stand of the respondent is that by the process of lyophilizing the living cells will be killed.

However, the said explanation cannot be accepted by the Court. Even the dictionary meaning on which the respondent relied, shows that lyophilizing is meant for drying of materials in the frozen state. The same, is therefore, a preservation technique and by lyophilizing nothing is killed and destroyed. Reference in this connection be made to Willy's Encyclopedia of Food Science and Technology. Vol. II, pages 1106, 1107 and Vol. III of the same book at page 1633. Therefore, as a result of the said method, the biological activity of the material is retained and not wasted. In fact, freeze drying does not kill the mirco-organizm activity. On the other hand, the same is the best method to preserve the bacterial cultures.

The learned counsel for the respondent argued by way of desperation that if on investigation it is found that the end-product of those patent applications in respect of which patent has been granted contains a living virus, the Controller would initiate steps for revocation of the aforesaid grants of patent. In fact, the said stand is contrary to law. The revocation of grant of patent is governed under section 64 of P.A. Under the said section such revocation procedure can only be initiated on the petition of any person interested or on the basis of petition by the Central Government or on a counter-claim in a suit for infringement of the patent. There are certain grounds, which are mentioned, in the said patent for such revocation. There is nothing to show that any such step has been taken. Therefore, this submission is not acceptable to Court.

In that view of the matter and for the discussions aforesaid, this Court quashes the impugned order of the Controller dated 27th December 1999. The appeal is

thus allowed.

The patent application of the petitioner No. 135/Cal/98 is to be reconsidered for the grant of patent by the authority concerned as early as possible but, certainly not latter than two months from the date of production or service of this judgment on them. Such consideration must be made in the light of the observations made in this judgment and after hearing the parties.

There will be no order as to costs.

LATER:

Prayer for stay of operation of the judgment and order is considered and rejected. Let xerox certified copy of this judgment and order be given to the parties expeditiously, if applied for.