

**CASE ANALYSIS ON DIAMOND v CHAKRABARTY AND DIMMINACO A.G v
CONTROLLER OF PATENTS AND DESIGNS**

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ABSTRACT

A landmark judgement can change the interpretation and working of a legislation. In the world of biotechnology innovations can help millions of people. Patents are granted to innovations which are novel, have industrial application and is non- obvious in nature. The question here comes whether living organisms can be patented or whether any kind of vaccine which included living organisms can be patented or not?

The two landmark case Diamond v Chakrabarty¹ and Dimminaco A.G v Controller of Patents and Designs², answer the question as to whether living organisms can be patented or not.

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¹ 447 U.S 303 (1980)

² (2002) I.P.L.R 255 (Cal)

INTRODUCTION

Patent is important for biotechnology as it gives the rights to the inventors to protect his innovation. It provides the way to the researcher or the inventor to invent more for the development. Patent motivates the inventor to invent more, without the patent protection it will be difficult for the inventor to spend time and money in an innovation. Patents are important in the biotechnology as it provides the exclusive rights to the inventor to protect his work which he has made by using his intellect and it also excludes the others from making that invention.

The importance of patent in biotechnology are as follows:

1. Encourage innovation
2. Protects investment
3. Attracts investor
4. Facilitates collaboration
5. Promotes competition

This research paper contains two cases: *DIMMINACO A.G V CONTROLLER OF PATENTS AND DESIGN*³, it is an Indian case and *DIAMOND V. CHAKRABORTY*⁴, it is a United States case which in detail will examine the importance of patent in biotechnology and how it has impacted the society, medical science, agriculture and forensics.

DIAMOND V. CHAKRABORTY⁵

Introduction

In this case, certiorari is filed to the United States courts of customs and patent appeal has been filed by the applicant. Here, respondent filed the patent application with regard to his new invention of a human-made genetically engineered bacterium capable of breaking down the crude oil, a characteristic which is possessed by no naturally occurring bacteria. Patent examiner has also rejected the application on the ground that living organism cannot be patent. The facts of this case have been divided into three parts.

Facts

Anand Mohan Chakraborty, a genetic engineer had invented a bacterium which is known as *Pseudomonas putida*, that is capable of metabolising the hydrocarbon which constitute as the crude oil. Facts of the case has been divided into three parts:

³ Ibid2

⁴ 477 U.S. 303 (1980)

⁵ 477 U.S. 303 (1980)

Part I

Mr. Chakraborty has filed patent application and stated 36 claims with regard to the invention. Chakraborty has the remarkable value for treatment of oil spills as the bacteria which has been invented has the characteristics of breaking down multiple components of crude oil. There are also certain types of the patent claims and they are as follows:

1. Process claims for method of producing bacteria.
2. Claims for an inoculum comprised of a carrier material floating in water, such as straw and new bacteria.
3. Claims to bacteria themselves.⁶

The examiner approves the first two claims but rejected the last one. The grounds for the rejection of the application have also been specified.

1. That micro-organisms are the product of the nature.
2. As living things they are not the patentable subject-matter.⁷

After that, Chakraborty appealed for the rejection of the claims and stated the history of plant patent act, and board concluded that section 101 was not intended to cover living things which includes laboratory created micro-organisms.

Part II

The constitution grants the congress board the power to legislate and promote and progress in science and useful acts.

Refer to the section 101 of the statute which states that “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”⁸.

And it was also said to determine whether the living micro-organisms are within the “manufacture” or “composition of matter”.

Part III

This part of the facts is related to the arguments which have been presented, but court did not find it compelling:

The first argument which has been put forward is with regard to the enactment of the plant patent act, 1930, which states the protection of the some asexually reproduced plant variety protection act, 1970 which also protects the asexually reproduced plant but it does not protect the bacteria.

⁶ 447 U.S. 303 (1980)

⁷ 447 U.S. 303 (1980)

⁸ 1930 Patent Act

Petitioner observed that “manufacture” or “composition of matter” did not include living organisms.

By rejecting the arguments, there were two reasons which have been given:

1. That the plants are the work of nature, they cannot be patented, even if there is the artificial plant but they are work of nature.
2. The second reason was that the plant cannot be influenced by something.⁹

The second argument which has been presented before the court was that the plant cannot be the subject-matter for the patent unless congress authorise it.

Issue

The issues of this case are as follows:

1. Does the respondent application shall consider as the patentable subject-matter.
2. Whether the living organisms can be patented or not or it shall be considered under “manufacture” or “composition of matter” with the law.

The issue of the case was examined by the U.S. court after two degrees of request with four-five choice holding that the living organism can be patented under 1930 patent act and it will be considered under the term “manufacture” or “composition of matter”¹⁰.

Judgement

The supreme court held that respondent application is maintainable as the living organisms can be patented under section 101 of the plant patent act, 1970 which states that “*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title*”¹¹. Living organisms will be considered as the patentable subject-matter as per the Supreme Court of the United States.

Supreme court also observed that technology is getting advanced day by day and patent act has the wider scope, any kind of technology which has been made through human intellect can be patented under 1930 patent act. However, law of nature, actual peculiarities and theoretical thoughts cannot be patented under the act but in the respondents case it will not consider as the law of nature or actual peculiarities in spite of that it will be considered as the non-living thing, where the human intellect was necessary. It will be contemplated as an invention by human resourcefulness.

⁹ Diamond v. Chakraborty available at <https://supreme.justia.com/cases/federal/us/447/303/> (last visited on 10.08.2023)

¹⁰ Case laws IP available at <https://lawessential.com/ip-case-laws/f/diamond-v-chakrabarty-447-us-303-1980/> (last visited on 15.08.2023)

¹¹ 1930 Patent Act

Court has also stated that 1930 patent act contains things which can be patented under the statute and that also includes the micro-organisms, which are made with the help of human intellect. Furthermore, section 101 of the 1930 patent act, which has the expression of “manufacture” or “composition of matter” excludes the living things. “Section 101 unmistakably stating completely acknowledges the respondent's innovativeness. Contentions restricting patentability under section 101 in light of likely dangers presented by hereditary examination ought to be coordinated to Congress and the Executive Branch, not the courts¹².

Analysis

As this case is considered as the landmark cases and this case has also changed the biotechnology environment in the United States by advancing the improvement in the life-saving technologies. The patent criteria was so unambiguous and simple and it was so reasonably implemented and perceived by the court that it had changed the whole biotechnology environment. In simple words, this case diamond v. Chakraborty had given new life to the biotechnology not only U.S. but also in other countries.

This case had also affected the new innovation and advancement in the life-saving technology. The impact on the biotechnology after this case are as follows:

1. Genetically modifies seeds¹³:

Genetically modified seeds are the seeds which have been modified to prevent the disease, pests or chemical treatment for example herbicides etc. they are different from the traditional breeding system as it contains the DNA from the organisms. They cannot be found naturally. As a result, they are regarded as the human made seeds which can be patentable under the statute.

In Dilip Shah case it has also been discussed about the patenting of the genetically modified organisms and because of the Chakraborty case on 2017 Monsanto earned \$10.4 billion yearly and it has also been surveyed that genetically modified seeds (GMO) increase 37% of the crop yielding.

2. Polymerase chain reaction¹⁴

Polymerase chain reaction is a method to rapidly boost the sequence of the DNA. It is exclusively used in laboratory research, medical diagnostics, forensic etc.

After this case Dr. Chakraborty had made it mandatory to invest in the new DNA purification procedure. As this will help in medical science and forensic science.

¹² Case laws IP available at <https://lawessential.com/ip-case-laws/f/diamond-v-chakraborty-447-us-303-1980> (last visited on 17.08.2023)

¹³ Mathew Jordan, Neil Davey, Maheshkumar P. Joshi, Raj Dave, Forty year since diamond v. Chakraborty: legal underpinning and its impact on biotechnology and society, page no. 3 (centre for protection of intellectual property rights)

¹⁴ Mathew Jordan, Neil Davey, Maheshkumar P. Joshi, Raj Dave, Forty year since diamond v. Chakraborty: legal underpinning and its impact on biotechnology and society, page no. 4 (centre for protection of intellectual property rights)

3. Monoclonal antibody therapy¹⁵

It is the part of the immune system to identify pathogens. They help the immune system to attack the potential pathogens.

This had helped the medical science improve more and without the Chakraborty case it wouldn't be possible.

The outcome of the case was licence for the heredity designed crops, DNA intensification innovation and monoclonal counter-acting agent therapy. And the biotechnology had also improved and wider its scope in the society.

Recently, covid has impacted the society however medical science and biotechnology made it easy for us to fight against the situation and live our lives easily. This is all because of the advancement in the medical science through biotechnology, by getting the new life in biotechnology people were able to cure from the disease. Chakraborty has made it easy for people to live, without him we wouldn't able to survive in this covid situation or any other situation.

DIMMINACO A.G V CONTROLLER OF PATENTS AND DESIGN¹⁶

Introduction:

The appellant (Dimminaco A.G) in the instant case is a company whose business line includes manufacturing of bulk organic and inorganic medicinal chemicals¹⁷. The appellant had filed for an appeal under section 116 of the Patent Act 1970 (hereinafter referred as "Act") against the order given by the Assistant Controller of patents and upheld the objections raised by the examiner, dated 27 December 1999 under section 15¹⁸ of the Act.

Facts of the Case:

The appellant had filed for a patent application for the invention relating to a process for preparation of infectious "*Bursitis Vaccine*". After the due application was filed with all the necessary procedure followed the examiner had examined the application under section 12¹⁹ of the Act and raised certain objections with regard to the invention. The examiner pointed out that the application does not constitute an invention as mentioned under section 2(1) (j) of the Act, furthermore, the application is filed for an invention which is one of the classes under

¹⁵ Mathew Jordan, Neil Davey, Maheshkumar P. Joshi, Raj Dave, Forty year since diamond v. Chakraborty: legal underpinning and its impact on biotechnology and society, page no. 5 (centre for protection of intellectual property rights)

¹⁶ Ibid 2

¹⁷ Dimminaco AG, available at <https://www.bloomberg.com/profile/company/0312086D:SW#xj4y7vzkg> (last visited on 20 August, 2023)

¹⁸ Patent Act 1970 (Act 39 of 1970)

¹⁹ Ibid 5

section 5 (a) and 5 (b) of the Act which states that “*substance prepared by the process is capable of being used as Food/ Drug*”²⁰.

Due to such refusal by the appellant filed an appeal with the controller and raised certain contentions to support the inventions which were as follows, the application was for process of preparation of infectious *Bursitis Vaccine* and the law does not state any bar against accepting the process for preparation of any product i.e. process patent is allowed. Moreover, the appellant also stated that granting of patent to an end-product and the manufacturing of a product which involves live virus cannot be denied on the basis of any administrative policy. Furthermore, the appellant argued that the objections raised by the examiner is not based on any reasons.

The assistant controller after hearing the contentions raised by the appellant held that the term “manufacture” has a very wide meaning and the process used for the preparation of the “*Bursitis Vaccine*” has living entity and hence it cannot be considered a manufacture. Furthermore, the controller also held that the definition mentioned under section 2(1) (j) is significantly similar with the definition which was recommended by Justice Rajagopalan Iyenger of the Patent Enquiry Committee²¹. Further it is pertinent to note that definition of the word “manufacture” which was provided under section 2 clause (i) of the Patent Bill 1953 was not credited by the Controller Assistant, as it was not accepted in the view of the recommendation of Justice Iyenger. Therefore, the assistant controller was not in favor of accepting wide meaning of the term “manufacture”. Another objection given by the assistant controller was that the subject matter of the specification does not constitute an invention and hence the controller had no other option but to reject the patent application. The controller also stated that vaccine with living organism cannot be considered substance and hence rejection of the application.

Due to the order passed by the assistant controller, the appellant filed for an appeal under section 116 of the Act. In the appeal the appellant had raised the following contentions which were as follows: -

- a. The contention which were raised by the assistant controller under section 2(1) (j) of the act, no rational reasons for such conclusion were given.
- b. The examiner did not make any investigation under section 13 of the Act, the only finding given by the examiner in his report were that the specification does not compose of invention and no proper reason was given about such refusal and hence such act should be termed as quasi- judicial.
- c. If the definition of given under section 5 of the act is read carefully, “*any new or useful art, process, method or manner of manufacture*”²² would be considered an invention. In the case the examiner will rejecting the application did provide any proper reasoning

²⁰ Ibid 5

²¹ *Dimminaco AG v Controller of Patents and Design & Other* (2002) I.P.L.R 255 (Cal), Pg 2

²² Ibid 5

and did not provide for questioning the usefulness of the end product which was arising out of the process.

- d. The claim of the appellant is for a patent of the process for the preparation of the vaccine.
- e. Furthermore, the main contention was that the patent is claimed for the process and hence it should come within the ambit of meaning of the term “manufacture” and even if the end product contain living organism it should be patentable.
- f. To support the contentions the appellant had also pointed several orders in which were filed in additional affidavit stating live cells, virus and micro- organism that were involved in the applications and patents were granted to such applications.

Decision:

The hon’ble High Court after considering all the contentions which were raised by the appellant, the court stated that the word “manufacture” has not been defined under the act and hence the dictionary meaning of the word. Furthermore, it was acknowledged by the court that there is no statutory bar to accept any manner of manufacture as a patentable even if the end product contains any sort of living organism.

Moreover, to decide the case “*vendibility test*”²³ was used by the court which states that if the invention results in the production of some sort of vendibility or it improves or restores former conditions of vendible item or its effect is the preservation and prevention form deterioration of some vendible product then such invention is considered patentable. In the following case the process for preparation of the vaccine involving chemical step under specific conditions and the vaccine is categorized useful for protecting the poultry against contagious Bursitis infection and due to such new process, it is apparently patentable under section 5 read with section 2 (1) (j) of the Act.

Court further was in the view that 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 appellant’s claim for patent should have been considered by the assistant controller on reading section 3 of the Act. The examiner did not take objections under section 3 of the act and hence the objections which were raised by the assistant controller were not principle based. The court further opined that the controller rejecting the application for the patent on the ground that process cannot be termed as manufacture because it involves a living virus in the end product did not act on correct principles of law and hence quashed the order given by the assistant controller dated 27 December 1999.

ANALYSIS

The instant case is said to be a landmark case as it deals with application of patent for the process of *Bursitis Vaccine*. The case can be divided into two parts, one part in which the assistant controller of the Patent did not allow for granting of patent and second part where the

²³ Ibid 8

hon'ble high court accepted the invention and granted the patent to the invention in which the living organism can be included in the invention.

To support their case the appellant had also mentioned few of cases through filing of additional affidavit, in the affidavit the appellant mentioned case as to "*an improved process for the production of penicillin V Acylase using B. Sphaericus*" ²⁴in which patent was granted by the patent office in the year 2000.

If we read the case carefully the main issue of the case was the meaning of the term "manufacture" which is not defined in the Patent Act and if the dictionary meaning of the term can be accepted in granting of the patent or not. The High Court used external aid of interpretation that is a dictionary to define the term "manufacture" to resolve the ambiguity and granted patent to the appellant. Another pertinent point to be noted in the judgement by the hon'ble High Court is that the court clearly disregarded the practice used by the assistant controller for refusing the patent as it had not provided for reasonable grounds of such refusal. Another pertinent point to be noted is that section 5 which was in question in the case, is now repealed after the Patent Amendment Act 2005²⁵.

Granting patent to such invention is a landmark move by the judiciary as it allows people to invent more innovational procedure for a vaccine furthermore the TRIPS convention clearly states that process patent can be granted. Granting of such patent to such invention helps the society to move forward and encourage more people in invention vaccines or products which have living organisms.

SIMILARITY BETWEEN THE CASES

Both the above-mentioned cases are said to be landmark judgement in the field of biotechnology and patent granting system. They are considered landmark for many reasons but one of them being that both grant patent to living organisms.

In *Diamond v Chakrabarty*²⁶ the United States Supreme Court in the year 1990 decided the case wherein the court held that invention whether or not it is living or non-living it can be patented under the law. Similarly, in *Dimminaco A.G v Controller of Patents and Design*²⁷ the hon'ble High Court of held that the process of producing the vaccine which includes living organisms is considered inventive and hence patent can be granted.

Furthermore, both the cases focused on granting of patent to inventive process and hence it can be seen that process patent was recognized by both the hon'ble courts. The main focus of granting for such patent was to encourage inventive measures in the field of biotechnology.

²⁴ Patent Application no. 1250/Del/95

²⁵ Patent (Amendment) Act 2005 (15 of 2005)

²⁶ Ibid 1

²⁷ Ibid 2

Another point of similarity to be noted that in both the cases, the question was the meaning of the term “manufacture”. The Hon’ble Supreme Court of United States of America held that *“live, human-made microorganism is patentable subject-matter under §101 and that the respondent's microorganism constitutes a "manufacture" or "composition of matter" within that statute”*²⁸.

The hon’ble High Court of Calcutta held that even if the term “manufacture” is not defined under the statute, dictionary meaning shall be acknowledged and hence the inventive process for the vaccine shall be accepted as invention and hence patent shall be granted.

CONCLUSION

To encapsulate, these two judgments are the landmark judgments. One is the India’s case and the another one is the United States case. These cases clearly state the importance of the patent in biotechnology and the living organisms can also be patent and it shall be considered as the subject-matter for the patent.

The analysis of these cases also states the importance of the biotechnology in our society, medical science, agriculture and forensics. This research paper also consists of the similarities between both cases. How patent is similar in India and united states and what are its impact.



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²⁸ Diamond v Chakrabarty (pp. 447 U.S. 308-318)

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