2023INSC794

REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 6791 OF 2013

Prakash Bang .... Appellant(s)

Versus

Glaxo Smithkline Pharmaceuticals Ltd. & Anr. .... Respondent(s)

J U D G M E N T

A.S. Bopanna, J.

1. The appellant is before this Court assailing the order dated 25.04.2012 passed by the National Consumer Disputes Redressal Commission, New Delhi ('NCDRC' for short) in Consumer Case No.178 of 1999. Through the said order the NCDRC has held that the complainant has miserably failed to establish his case in regard to either any defect in the drug in question or any negligence amounting

to deficiency in service on the part of the respondent who is the manufacturer of the drug. In that view, the complaint filed by the appellant was dismissed by the NCDRC.

2. The brief facts leading to the complaint is that the appellant in order to achieve immunity against contracting Hepatitis B, on 10.08.1998 approached his family physician Dr. Satyajit Pathak for administering the repeat dose of the vaccine Engerix-B, along with his family members. The appellant contended that he had purchased four single dose vaccines which were administered by Dr. Satyajit Pathak, one each to him, his wife and two sons. The family members of the appellant had no adverse reaction to the said drug but insofar as the appellant, after four days of being vaccinated, the appellant felt severe pain in his left shoulder at the site of the injection and he suffered pain while moving his shoulder. It was noticed that the skin at the place where he was injected was found shiny with a bit of erythema with local tenderness. The appellant took certain analgesics under medical advice and visited an orthopaedic

surgeon on 17.08.1998. The orthopaedic suggested certain radiological tests like X-ray and C.T. Scan of the left shoulder but no orthopaedic abnormality was detected.

3. The appellant thereafter contacted a general physician named Dr. Madan Phadnis and a general surgeon Dr. Makarand Paranjpe who examined the appellant had referred him to a neuro physician. After taking treatment from 13.09.1998 he was admitted in Ruby Hall Clinic where he was examined by neuro physician and the nerve conduction test was carried out and a dose of steroids was administered. The appellant contended that he developed sudden permanent disability in his shoulder which according to him was caused due to adverse reaction of the vaccine Engerix-B manufactured by the respondents and administered on 10.08.1998. The appellant was working as a Chief Executive of M/s Quicksel Communications, which effected his performance and as such he had taken up the issue with the respondent company. Since his grievance was not redressed but in the process since the appellant

learnt that the pain being suffered by the appellant was due to 'myositis' which is a condition occurring as an adverse reaction due to the administration of Engerix-B, he again contacted the respondents. Since the response of the respondents was not satisfactory and according to the appellant since the same amounted to deficiency due to negligence which had also caused suffering to the appellant, he filed the above noted complaint before the NCDRC claiming compensation of Rs,90,20,557/- (Rupees Ninety Lakhs Twenty Thousand Five Hundred and Fifty Seven Only).

4. The respondents appeared before the NCDRC and filed their version disputing the claim as put forth by the appellant. The very allegation of the purchase of the said drug or its administration was denied for want of knowledge and also since no proof in that regard had been produced along with the complaint. However, insofar as the very nature of the drug and about its quality and purity details, they were referred to. It was explained with regard to

'myositis', since it can occur for various reasons and in different circumstances. Hence it was contended that the appellant had failed to establish that he suffered with 'myositis' on account of any adverse reaction due to the administration of Engerix-B.

5. Before the NCDRC, though no documents were placed on record on behalf of the appellant with regard to the purchase of the vaccine or with regard to the nature of the treatment undergone by the appellant relatable to the shoulder pain experienced by the appellant immediately after being vaccinated so as to connect the two incidences and establish that the appellant had suffered 'myositis' due to the administration of vaccine, the appellant in addition to his own affidavit had also filed the affidavit of Dr. Satyajit Pathak who is said to have administered the vaccine as also the affidavit of Dr. V.L. Chandak who is the uncle of the appellant. The appellant is said to have consulted Dr. Satyajit Pathak and Dr. V.L. Chandak after suffering the discomfort due to the vaccination. The said affidavits were

filed in lieu of evidence. The respondents, apart from producing the certificate for release of the vaccine and the details thereof had filed the affidavit of Shri Ajay Nadkarni, the Company Secretary as also that of Ms. Catherine Ghislain, the Vice-President, Associate General Counsel of the respondent referring to details with regard to the procedure followed for manufacture and as also the certification of the drug.

6. In the above background, the NCDRC has considered the rival contentions in detail and on the aspect of the drug in question causing 'myositis' had taken into consideration that the same is an adverse reaction to the minimal level and not indicating the same as an adverse reaction in the literature accompanying the vaccination or on the 'vial' does not amount to deficiency. To arrive at such conclusion the relevant observations in the order of the NCDRC are as hereunder:-

> "On the basis of their worldwide safety database, the opposite parties could search out such nine cases involving four female and four male patients of the age

range of 23-51 years. Based on the number of doses distributed worldwide, the reported frequency of this adverse reaction could be calculated to a minimal incidence i.e. 0.02 per million doses. At the same time they explained that the relationship of such cases to the vaccine was difficult to establish. The opposite party therefore recommended that the complainant undergo muscle biopsy so as to establish the cause of his suffering with myositis. In this case the muscle biopsy was never sent to the opposite party. In any case, it is brought on record that there could be many other causes leading to the myositis. That apart there are several attenuating circumstances which would rather indicate that the alleged adverse reaction suffered by the complainant was not on account of the. administration of the above named drug. The circumstances are that before taking third repeat dose on 10.8.1998, the complainant and his family members had already taken two doses but neither the complainant nor his family members suffered with any such symptoms or reaction on those occasions. According to the complainant's own showing on 10.8.98 the other two family members of the complainant i.e. his wife and sons were also given the similar single dose besides to the complainant but neither the wife nor the sons of the complainant suffered any such adverse reaction. The drug used in all the cases was from the same batch. Had the drug of that particular batch had any such defect or deficiency, the reaction should have been common ·for other members also. Besides no other person from the city of Pune, who must have taken such injection have reportedly suffered from any adverse reaction as complained of due to the administration of the said drug."

"In any case, the opposite parties have put on record detailed analysis of the various kinds of examination/ tests conducted in the laboratory of the opposite party on the sample drug of the particular lot and found that all the values had passed the requisite standard and the drug of that lot suffered from no defect of any kind which could possibly lead to a reaction of the kind which the complainant had allegedly suffered."

> "That by not mentioning Myositis as one of the adverse reaction, which was too minimal i.e. 0.02 in one million, it was not necessary for the opposite parties to mention the same under the heading "Adverse Reaction". ln any case, despite such minimal incidences it was not established with certainty that myositis could be a direct cause arising out of the adverse reaction of the said· drug. We find force in this contention because the opposite party could not have mentioned myositis as one of the expected adverse reaction unless it was so established by Laboratory or other tests."

7. In that background we have heard Ms. Anita Shenoy, learned senior counsel for the appellant, Shri Ujjwal A. Rana, learned counsel for the respondents and perused the appeal papers including the records received from the NCDRC.

8. In that circumstance, what is necessary to be taken note and consider herein is as to whether the conclusion as recorded by the NCDRC and noted above can said to be erroneous or perverse so as to call for interference. Though the matter was heard at length, the position as it exists if taken into consideration, the aspect to be determined in the instant case, firstly is as to whether there is sufficient

evidence to establish that the appellant in fact had suffered 'myositis' and if so whether the cause for same was the vaccination Engerix-B being administered to the appellant. The second aspect is as to whether even if 'myositis' being a minimal cause is accepted, the non-mentioning of the same as an 'adverse reaction' in the literature or 'vial', if could be considered as 'deficiency of service', more particularly in the instant facts and circumstances of the case.

9. As noted, there is no documentary evidence placed on record to indicate the very basic issue of the purchase of the vaccine and the same being administered. Be that as it may, the fact remains that the family doctor of the appellant namely Dr. Satyajit Pathak has filed his affidavit stating that the Engerix B injection was administered by him to the appellant on 10.08.1998 at the deltoid muscle on the left arm. The said doctor has stated that the vaccine was a single dose adult vaccine bought from a chemist in Pune. There is no details indicated as to whether he had advised and on his prescription the said vaccine was purchased. In

a matter of the present nature where the appellant contends that he and his family members had taken the vaccination and his family members had no complaint whatsoever and also insofar as the appellant, since the earlier two doses had not caused any problem or discomfort but the pain was noticed only after final dose, the matter requires to be viewed with circumspection. Hence the onus to discharge the initial burden was heavy on the appellant to establish his case in a fact of the present nature. Except for the affidavit filed by the doctors known to the appellant, there is no other evidence available on record. The second witness on behalf of the appellant is his uncle who is stated to have been consulted by the appellant. The statements as contained in the said affidavit are more to refer with regard to the advice that they have tendered to the appellant and also to state with regard to similar complaint having come to their knowledge.

10. The learned senior counsel for the appellant in order to contend that the said affidavits would be sufficient for the

Court to come to a conclusion with regard to the case put forth by the appellant has relied on the decision of this Court in ***Malay Kumar Ganguly vs. Dr. Sukumar Mukherjee & Ors.*** (2009) 9 SCC 221 with reference to para 45 wherein it is observed that the opinions of the experts rendered on the basis of their expertise, which were notarised would be reliable more so when the respondents did not question the correctness thereof either before the Court or the Commission and when the respondents did not examine any expert to show that the opinions are not correct.

11. In our opinion, the said observation in the judgment cannot read as a provision in the statute but will be to assess the evidentiary value keeping in view the overall nature of the case and the evidence that is brought on record and if the affidavit is in support of such material. In the instant case, though in the summary procedure before the NCDRC the cross-examination in the nature as done in the Civil Court would not be followed, it is no doubt true

that in a normal circumstance it would be open to file interrogatories relating to the statements made in the affidavit. In the instant case it is true that no such effort has been put forth by the respondents but in our view it is not detrimental.

12. As against what was considered in the case which has been cited by the learned senior counsel for the appellant wherein it is clearly indicated that the medical records had been referred to in the affidavit filed by the doctor, a close perusal of the affidavit filed by Dr. Satyajit Pathak would indicate that he has stated only about administering the vaccine and the fact of the shoulder pain being reported to him subsequently. The advice he had given in that regard and the medication prescribed is also stated. He thereafter states the names of the doctors to whom he had referred the appellant for further treatment. Neither the affidavit of the doctors who had subsequently treated the appellant with specific reference to the shoulder pain has been filed nor has the said doctor who has filed the affidavit indicated any

reference in medical terms or with regard to his medical research on the subject to place it on affidavit that the vaccination was the cause due to which the appellant had suffered 'myositis' and had led to the disablement in the nature as stated by the appellant seeking for compensation. The only averment in this regard is contained in para 24 of the affidavit wherein he states that he being the family doctor of the appellant is of the opinion that it is nothing but the reaction of the Engerix-B vaccine because of which the complainant has suffered a lot. As already noted there is absolutely no material based on which such conclusion has been reached by the said doctor except to opine in that manner. In such circumstance, the non cross-examination or tendering interrogatories was wholly unnecessary in respect of the affidavit filed by him.

13. Insofar as the affidavit of doctor V.L. Chandak, admittedly he is the uncle of the appellant with whom the appellant has made certain correspondence about the pain suffered in his left arm. Though in the affidavit he refers to

one Dr. Sham Karwa, an Eye Specialist known to him having suffered a similar problem because of reaction on administration of vaccine Engerix-B and that he had suffered for about 2 to 3 months, the same can only be noted as hearsay since neither the affidavit of said Dr. Sham Karwa has been filed nor is there any material to indicate that the said doctor had taken vaccine and had suffered similarly. The other instance referred in the affidavit is also to the same affect. Therefore though the affidavit of doctors had been filed in the instant case, they are not of any evidentiary value whatsoever and the legally trained mind who was representing the respondents would well be aware that an affidavit of such nature did not warrant any cross-examination as the affidavit on the face of it had not indicated anything to establish the case of the appellant. The said doctors, except vaguely stating about the incident have not authentically provided any details based on their medical expertise or on their research on the subject from medical literature or commentaries about the adverse

reaction of the vaccine in question nor have they brought on record any authentic material. In the absence of such medical evidence, the Courts on their own will lack the expertise to come to a conclusion, more particularly in a case of the present nature where the cause itself is required to be unravelled.

14. If that be so, in our opinion, we find that the initial burden to be discharged by the appellant has not been discharged to substantiate the allegation which was made in the complaint. As already noted, the affidavit filed by the family doctor and the uncle of the appellant who is also a doctor, except referring to the fact of the vaccine being administered to the appellant and the appellant complaining of the discomfort subsequent thereto does not bring on record the aspect in medical terms or with reference to any medical records to co-relate that the pain suffered by the appellant was in fact 'myositis' and it was due to the vaccine being administered. The burden was on the appellant more particularly in a circumstance when all the

family members had got administered the same vaccination from the same source and the appellant himself did not undergo any difficulty when the first two doses were administered. In such circumstance the muscle biopsy not being furnished despite being asked to do so by the respondents should be held adversely against the appellant.

15. The next aspect for consideration would be as to whether the non-mentioning of 'myositis' being suffered as an adverse reaction in the literature accompanying the injection or on the 'vial' amounts to 'deficiency of service', more particularly when the adverse reaction was minimal only to the extent of 0.02 in one million. On this aspect, at the outset we note that the affidavit filed on behalf of the respondents would indicate the detailed procedure that is followed for certification of the drug. It is only after such certification the drug is available in the market. Nothing has been placed on record to indicate that this is a drug which was available 'of the shelf', without prescription. In the instant facts, the very affidavit filed on behalf of the

complainant by Dr. Satyajit Pathak, the family doctor refers to the purchase of the vaccine and the same being administered by him. The said family doctor also owed a duty to his patient and if he has prescribed the said drug it was incumbent on him to know more details about the vaccination before prescribing or administering the same. Further, if the same drug was administered to all the family members and after the third dose was administered to the appellant he had suffered the present discomfort complained of, it would also raise a question as to whether it had been administered in the manner and at this spot where it ought to be administered. If these aspects of the matter are kept in view, in fact the allegations as made by the appellant would also make the said family doctor responsible and ideally he ought to have been a party-respondent to the proceedings rather than filing his affidavit.

16. In that view of the matter, the judgment relied on by the learned senior counsel for the appellant in ***Jacob***

Punnen and Another vs. United India Insurance Company Limited (2022) 3 SCC 655 with reference to para 43 to contend that there was a deficiency on the part of the respondent would not be of any assistance. Further, in a circumstance as in the instant case, it is not just the manufacturer and the consumer are involved but the medical professional who ought to have knowledge of the product and before administering had an opportunity to advice the appellant on these aspects had not made any efforts. He cannot claim to become wise in hindsight. In any event, from the very details furnished by the respondents, the instance of 'myositis' being minimal to the extent of 0.02 in a million, to contend that there was negligence on the part of the respondent is also not acceptable. Hence the decision relied on by the learned senior counsel for the appellant in the case of ***Chanda Rani Akhouri and Ors. vs. M.A. Methusethupathi and Ors.*** (2022) SCC Online SC 481 with specific para 24 is also not of any assistance.

17. Therefore in the facts on hand, if the matter is looked at from its correct perspective it is seen that except for the appellant assuming that he has suffered 'myositis' and the cause for the same was the Engerix-B vaccine being administered, the same has not been established with the minimal required evidence to conclude even on preponderance of probability. That apart, as noticed, even muscle biopsy which was required by the respondents was not furnished so as to enable the respondents to take an ultimate decision in the matter. As such the appellant cannot be heard to complain that the respondents have not attempted to redress his grievance. Therefore, if all these aspects are taken into consideration we are of the opinion that the NCDRC has not committed any error so as to call for interference with the impugned order.

18. Accordingly, the appeal being devoid of merit stands dismissed with no order as to costs.

19. Applications if any pending are also disposed of.

.....J.
(A.S. BOPANNA)

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.....J.
(PRASHANT KUMAR MISHRA)

New Delhi,
September 05, 2023