Sanotize Research And Developement ... vs Lupin Limited And 2 Ors on 6 October, 2021

Author: G.S. Patel

Bench: G.S. Patel

17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-20
LPETNL22809-202

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IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION
IN ITS COMMERCIAL DIVISION
INTERIM APPLICATION (L) NO. 22810 OF 2021
IN
COMMERCIAL SUIT (L) NO. 22803 OF 2021
WITH
LEAVE PETITION (L) NO. 22807 OF 2021
AND
LEAVE PETITION (L) NO. 22809 OF 2021

SaNOtize Research and Development Corp. ...Pla
Versus
Lupin Ltd & Ors ...Defend

Mr Janak Dwarkadas, Senior Advocate, with Vehnkatesh Dhond, Senior Advocate, Rohan Kelkar, Amol Bavare, Krishna Baruah, & Vrushali Pokharna, i/b Pragnya Legal, for the Plaintiff.
Mr Dinyar Madon, Senior Advocate, with Hamshed Master, Raj Panchmatia, Pranav Sampat, & Bhann Chopra, i/b Khaitan & Co., for Defendants Nos. 1 and 3.
Mr Atmaram Patade, for Defendant No. 2.

CORAM: G.S. PATEL, J

DATED: 6th October 2021

PC:-

1.

Heard Mr Dwarkadas for the Plaintiff, Mr Madon for Defendants Nos. 1 and 3 and Mr Patade for Defendant No. 2. Defendant No. 2 is the manufacturer for Defendant No. 1. Defendant No. 3 is a US-based entity. The Plaintiff is a Canadian company.

2. The dispute in this case relates to an Ayurvedic product very recently put into the market by the 1st Defendant, Lupin Limited, the Indian arm of the 3rd Defendant, Lupin Inc. The Lupin product in question is called NOXGUARD. It is said to be a 'Nitric Oxide Deliverable'. It has a special product delivery system: a nasal spray. The suit is framed as an action in breach of confidentiality and for infringement in copyright.

3. There are pending Petitions for leave under Clause XII of the Letters Patent and leave under Clause XIV of the Letters Patent. I will grant the Petition under Clause XII. The Petition for leave under Clause XIV is served on the Advocates for the 1st and 3rd Defendants in Court today. That now having been done, I am granting leave under Clause XIV.

4. When we deal with cases involving what is commonly called "breach of confidentiality", what is actually meant is a breach of a contract of confidentiality. It stands slightly apart from considerations in copyright infringement. For the latter cause of action, there are the usual considerations of the extent of copying, the kind of use and so on. For the former, i.e. a breach of confidentiality, the legal considerations are rooted in contract law.

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5. The Plaintiff (" SaNOtize") describes itself as a growing pharmaceutical company. In the recent past, it has focused its attention on certain therapeutic targets, including SARS-COV-2 or the COVID-19 virus, influenza and some other. One of the Plaintiff's founders is Dr Gilly Regev, an experienced biotech executive with a track record in drug development, intellectual property development and clinical trials. The other founder is Dr Chris Miller, a pioneer in the nitric oxide technology that is central to this case. He says he has 25 years' experience in this field.

6. Between 2009 and 2017, SaNOtize developed a proprietary method for the treatment of a range of diseases using different formulations. One of these was a proprietary method for delivering a specific formulation and a calibrated dose of Nitric Oxide by a special delivery method. SaNOtize calls this its Nitric Oxide Releasing Solution or NORS. In the suit, this is called "the Plaintiffs proprietary method". SaNOtize has a trade mark protection over the expression NORS.

7. With the onset of the COVID-19 pandemic, SaNOtize turned its attention to developing a NORS technology application to control or attenuate the effects of the SARS-COV-2 virus. It says it developed a novel and unique application of its proprietary method NORS in what is called a Nitric Oxide Nasal Spray or NONS. This was called "ENOVID" in markets in Israel.

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8. The product, said to be a proprietary formulation, uses citric acid and sodium nitrite to produce gaseous nitric oxide or gNO. The delivery mechanism is this. The formulation is packaged in a dual-chamber container. This facilitates the administration of a precisely calibrated dose of gNO directly into the nose, such that it can act as a barrier preventing a target virus penetrating the host's (human's) cells.

9. SaNOtize also claims some level of patent protection internationally and in Canada. But that is not the frame of the suit. SaNOtize says that NONS is unique because it delivers a precise quantity of citric acid and sodium nitrite combined to form gNO at a specific point, at specific pressure and in specific doses directly into the nose. SaNOtize says that an arbitrary or random variation in the composition or formulation would not serve the purpose. The dual- chamber container -- evidently one that combines the two elements to produce gNO at the very instant, or fractionally before, it is administered is SaNOtize's proprietary delivery system.

10. In April 2020, SaNOtize began clinical trials in Canada and UK. Those were encouraging. In January 2021, SaNOtize began applying for regulatory approvals for the marketing and sale of NORS, including under the mark ENVOID. It received some authorizations in Europe in June 2021. Sales in Israel were approved in February 2021, in April 2021 in Baharain and in July 2021 in Thailand. SaNOtize also sought emergency use authorization in Canada.

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11. In May 2021, Lupin Inc approached SaNOtize and said it was interested in taking NONS to market as rapidly as possible across various territories. Over the next few months, the parties at the most senior level engaged with each other. Obviously, India was one of the markets in contemplation.

12. SaNOtize says that to carry these discussions further, SaNOtize needed to share proprietary, confidential and sensitive information, data, trade secrets and know-how with Lupin Inc. This is the

subject matter of the confidential information described in paragraphs 18 and 19 of the plaint. Broadly, this was divisible into three. There was material that was entirely confidential and a trade secret but in which SaNOtize claims no copyright; then there was material that was both confidential or secret and also subject to a copyright claim. Finally, there was material that was not confidential but capable of copyright protection. This is shown in a table at Exhibit 'F2' at pages 224 to 226.

13. Also in May 2021, a representative of Lupin Inc visited SaNOtize's laboratory in Vancouver. Employees of Lupin India were introduced (on email, I believe). Some of the emails annexed indicate that, at least at this early stage, Lupin said that it was interested in looking for partners in India to manufacture and distribute SaNOtize globally: see page 234.

14. There were various areas of discussion, including the necessary regulatory information that would be required.

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15. Obviously, this information flow needed some protection and, therefore, the parties entered into a confidentiality agreement on 17th May 2021. A copy of this is at Exhibit 'I', pages 231-232. It is between SaNOtize and Lupin Inc. The agreement has the usual clauses: the obligation by either party to the other in anticipation of a possible business transaction involving sale or licensing to keep this information strictly confidential and not to use the other party's confidential information for any purpose other than the 'stated purpose'. On a plain reading of this, nothing disclosed by SaNOtize could be used by Lupin in any manner except for the purpose stated in the confidentiality agreement. It is equally clear that the confidentiality agreement could not extend to matters already in the public domain or not covered by the confidentiality agreement, nor to any purpose that was not the subject matter of the confidentiality agreement. That is not even SaNOtize's case today.

16. While I am on the confidentiality agreement, I need to note paragraphs 6 and 12 at pages 232A and 232B. I do so because Mr Madon raises a threshold argument that this Court has no jurisdiction. He bases this argument on clause 12m saying parties agreed to the exclusive jurisdiction of court in Vancouver, British Columbia, Canada. But this completely ignores the provisions of clause 6, which clearly allows parties to move a court of local jurisdiction. It is difficult to say unequivocally, especially at this very early ad-interim stage, that this Court does not have jurisdiction.

17. I need not consider the details of what followed in the email exchanges because I propose to grant only a time-limited order until Affidavits in Reply are filed. Once that is done, the matter can be 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC taken up again for further ad-interim reliefs or for continuation of the relief that I am inclined to grant today. I am, therefore, not considering all the material that is before me.

18. Mr Madon's argument is that though the confidentiality agreement was of 17th May 2021, Lupin was by then already working on a very similar product, also a nitric oxide nasal spray delivered by a slightly different two-cannister system. Lupin says sought permission from the Drug Controller for this on 16th April 2021, received the permission on 19th April 2021 and went to testing on 24th April 2021.

19. Mr Madon also says that the confidentiality agreement was only for marketing the SaNOtize's allopathic formulation, while Lupin has put into market an entirely different product, an Ayurvedic formulation.

20. Prima facie, these submissions do not commend themselves. There are emails at pages 245, 250 and 261 that indicate that Lupin's involvement was much wider than it currently contends.

21. I also do not know -- and in fairness Mr Madon has not been able to take any instructions on this -- whether Lupin ever informed SaNOtize, and if it did so, how and when, that it was working in parallel on a very similar product even while it was in discussions with SaNOtize. If Lupin did not disclose its parallel development of a very similar product, that has the most serious ramifications, and raises more questions than it answers. If it did make this disclosure, 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC then I would expect it to be part of the email correspondence. But it is not.

22. The Confidentiality Agreement is clearly bi-directional. Each party is to keep confidential certain proprietary information disclosed by the other. The Confidentiality Agreement per se does not carry an obligation to disclose; it only controls the conduct of a party after a disclosure is made. But the Confidentiality Agreement is clearly a step in aid of a stated purpose. It is one component, perhaps a very early-stage component, of attempts by the parties to arrive at some more solid agreement. The obligation to disclose must, prima facie, be held to begin to arise when one party obtains access to the other party's confidential information but then withholds or suppresses its own confidential information that has a direct bearing on the intended stated purpose. I do not think that is possible in circumstances of commercial confidentiality for one party to say, "I will gain access to your confidential information, but I will not disclose mine, although my information is in conflict with, and directly affects, your information and your enterprise." That is, unfortunately, the effect of Mr Madon's submission that even before it entered into the Confidentiality Agreement, Lupin had plans afoot to bring to market a competing product.

23. To be plain about one central aspect of this case, Mr Dwarkadas for SaNOtize claims no monopoly on the use of nitric oxide for any purpose whatsoever. Nitric oxide occurs naturally. It is a common chemical reaction between citric acid and sodium nitrite. Its delivery mechanism, precise formulation and the dosage needed for any efficacy at all are what are proprietary to SaNOtize and 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC constitute its confidential information, or copyright, or both. There is presently enough to show that Lupin had access to SaNOtize's material. The reverse -- Mr Madon's case of Lupin developing a rival product in parallel -- is not at all evident.

24. The immediate cause for the present suit and the urgent application was that while discussions were continuing even until as recently as August 2021 and beyond, and while there was still a pending application for emergency use of the SaNOtize product in India, on 1st October 2021 SaNOtize learnt that Lupin had introduced in the market a product called NOXGUARD. SaNOtize manage to obtain a bottle. The packaging described this as an "Advanced Nasal Spray of Nitric Oxide" that supposedly kills 99.99% viruses in two minutes. Now whether this claim is puffery or correct is not my concern today. If the advertising or packaging is inaccurate, there are other regulatory bodies and authorities that will take up the issue. What is important however is that Lupin said that this was an Ayurvedic proprietary medicine combining Bijora Nimbu (citrus lemon), Fr. Satva and Samudra Lavana with an added preservative. Whether or not this is actually an Ayurvedic product is also not my concern at this stage although there is a frontal assault on this in the plaint.

25. The only question before me is whether it can be said that there has been prima facie breach of the confidentiality agreement and infringement of SaNOtize's copyright.

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26. To complete this narrative, I must note that Lupin India has filed an application for registration of a trade mark in Lupin's NOXGUARD. It did so on 30th July 2021 and there seems to be no indication that it told SaNOtize that it had done so. That application has been advertised.

27. In paragraph 48 at page 41 SaNOtize relies on the Affidavit of one Thomas Abraham, an expert chemist. His Affidavit will of course be put to the test later. I am referencing it only for a limited purpose --an understanding of the ingredients that Lupin says are contained in its rival product, i.e. Bijore Nimbu and Samudra Lavana. These are said to be citric acid and sodium chloride or sea salt. According to the expert, no combination of these can ever produce nitric oxide. As I have noted earlier, whatever be the claim and whether it is true or not is a matter for another day and perhaps another proceeding. The question is whether it can be prima facie said that the NOXGUARD delivery system violates the confidential information that is the subject matter of the confidentiality agreement and SaNOtize's copyright. Images of the Lupin's product are at pages 269 to 271. There is no doubt that this is also a direct nasal spray. There is also no doubt that this seeks to combine two elements at the point of delivery and to deliver what it claims is nitric oxide specifically targeting a certain class of virus.

28. Exhibit 'F2' is a tabulation of confidential information at pages 224-226. It contains a list of the various items of confidential information. These are the subject matter of the confidentiality agreement and at least one of them is the mechanism of the action. This confidential information is available to me in Court and 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC undoubtedly will be made available to Lupin's lawyers. I do not see how Lupin can say that it never received this. The logical consequence of accepting that argument from Lupin (that it was never shown any of this information) would be that the confidentiality agreement is an empty formality, for there was no sharing of confidential

information under it. The emails that I have referred to do not support of any such theory of non-disclosure or non-sharing at all.

29. Every case of breach of a contract of confidentiality has certain essentials. First, it must be shown that the information is indeed proprietary, that is to say, covered by confidentiality. Second, the opposite party must be shown to have been afforded access to that information. Third, there is the obligation governed by the agreement to keep that information confidential and not to use it except for the 'stated purpose'. Not all confidential information need be copyright-protected. Some might be, some might not. The existence or absence of copyright protection does not render the confidentiality agreement and its obligations otiose. It is entirely possible for a defendant to say that there was no information that was proprietary or confidential, that is to say it was all in the public domain; or that it was never given access; and therefore there was no obligation to keep it confidential or to refrain from using it.

30. All three aspects are, I believe, prima facie shown to be answered by the emails and the statement at Exhibit "F-2". There is nothing to indicate that Lupin said that any information was not proprietary. If it was, it would not have sought it. I do not suggest that it is conclusively shown that all confidential information was 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC disclosed, but I find no material to buttress Mr Madon's case that no confidential information was shared. Indeed, as I have noted, that is simply not credible because it reduces the Confidentiality Agreement to a nothingness. There is not a single email from Lupin complaining that it had been promised information covered by the Confidentiality Agreement but had not received it. The emails indicate sharing of information, and therefore the question of access is answered. Immediately, this brings to bear the obligation of confidentiality and the in-built restraint from using that information for other than the stated purpose.

31. Lupin's case that, even before the Confidentiality Agreement, it had already begun work and sought permissions for a nitric oxide product seems to me smoke and mirrors at this stage, an attempt at dissembling, misdirection or obfuscation. The defence attempts to portray SaNOtize's case as a claim for monopoly over nitric oxide and its application to the SARS-COV-2 virus. That, as I have noted, is clearly incorrect. Mr Dwarkadas's submission, as I understand it, does not centre around monopoly or exclusivity over a chemical compound or the form that it takes, whether gaseous or otherwise. He says the precise formulation, dosage and the delivery mechanism at a specific calibrated point of time is what is proprietary to and the copyright of the Plaintiff. Some use or application of nitric oxide may well have been the subject of Lupin's efforts and applications. The question is whether it sought permission and had done any work for the production of nitric oxide in this particular manner and for delivery or administration in this particular fashion. For, conspicuous by its absence in this entire chain of events is any information from Lupin informing SaNOtize that it had in the pipeline, so to speak, a 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC competing product with a very similar name and a very similar delivery mechanism. "Nitric oxide" on its own is neither case nor defence.

32. Therefore, once there is a prima facie finding that there has been a disclosure, a rival product from Lupin will fall afoul of the confidentiality agreement. When it comes to copyright, the question is of the extent and the degree to which the Lupin product can be said to be a copy of Sanotize's. Both claim to deliver the same end product. Both claim to deliver it in the form of nitric oxide. Both say they have either a dual chamber or dual canisters, a distinction without a difference at this stage. It is SaNOtize's case that it was the forerunner in developing this technology and formulation.

33. Also, from this it is difficult to accept the argument that no confidential information was shared or that it did not relate to this product or that it was limited to only marketing and did not extend to manufacturing.

34. As to whether or not there is copyright in the items listed at Exhibit 'F2', this is to be gauged from the averments and assertions made in paragraphs 20(b) and 20(c) of the plaint. As an example, I find that at page 245 there is an email from Lupin to Dr Gilly Regev asking to see a CAD drawing of the bottle. That is clearly copyright- protected material. There is some issue about access to BOX, a secured digital file sharing/ storage system, but that is not relevant. The same email speaks of pump priming and filling; again, copyright-protectable material. At page 251 is another email from 6th October 2021 17-IAL22810-2021 IN COMSL22803-2021 WITH LPETNL22807-2021 AND LPETNL22809-2021.DOC Lupin to Dr Regev saying that Lupin's interests were aligned with SaNOtize because this relate to "leveraging the platform and delivering the products more globally". A third email at page 261 ask for details of technical files, safety performance, risk assessments and the material relating to other regions. At the very least, the technical materials would be potentially covered by copyright. SaNOtize's case on copyright, given its past development and work in other territories, cannot be so lightly defeated. Again, saying simply 'nitric oxide' is no answer.

35. I believe these reasons are sufficient to grant a time-limited injunction in terms of prayer clause (a)(iv) of the Interim Application, which reads thus:

> "(a) That pending the hearing and final disposal of the present Suit, this Hon'ble Court be pleased to issue orders and temporary injunctions (prohibitory or mandatory, as the case may be)--
>
> (iv) Restraining Defendants No. 1 and 2, and (as the case may be) their directors, employees, contractors, agents, business partners and affiliates from in any manner manufacturing, marketing, selling, offering for sale or otherwise dealing in or with the impugned Product, NOXGUARD;"

36. Mr Madon says that the words 'dealing in' are too wide. I do not think so. The relief is against Lupin dealing in a rival product, one that is said to be in contractual breach and infringing copyright. The injunction is intended to restrain the Lupin' s Indian arm and its manufacturer from in any manner transacting or trucking in the rival product until the next date.

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37. I will give Mr Madon time until 13th October 2021 to file and serve an Affidavit in Reply. At this stage, no Rejoinder without prior leave of the Court.

38. List the matter for further ad-interim reliefs including a confirmation of this order on 14th October 2021.

39. This order will continue only until 14th October 2021.

40. All concerned will act on production of a digitally signed copy of this order.

(G. S. PATEL, J) 6th October 2021