



REPUBLIC OF KENYA
IN THE HIGH COURT OF KENYA
AT NAIROBI
CONSTITUTIONAL AND HUMAN RIGHTS DIVISION
PETITION NO.593 OF 2014
BETWEEN
CIPLA LIMITED.....PETITIONER
AND
PHARMACY & POISONS BOARD.....1ST RESPONDENT
LORDS HEALTHCARE LIMITED.....2ND RESPONDENT
RULING

1. This Ruling is in respect of the Application dated 1st December 2014 by the Petitioner, Cipla Limited, seeking interlocutory orders as follows;

“(i) ...

(ii) ...

(iii) This Honourable Court be pleased to grant an interim order of injunction directed at the 2nd Respondent restraining it whether by its directors, officers, employees, servants, agents or any person whatsoever authorized by it from importing, trading in, advertising or marketing any products covered by the drug registration certificates held by the Petitioner pending the hearing and determination of the Petition herein.

(iv) This Honourable Court be pleased to grant an order of mandatory injunction directed at the 1st Respondent requiring it whether by its directors, officers, employees, servants, agents or any person whatsoever authorized by it to quarantine and recall any products covered by the drug registration certificates held by the Petitioner in the Kenyan market pending the hearing and determination of the Petition herein.

(v) Costs of the application be in the Petition.”

2. In the Petition dated 1st December 2014, the following orders are sought:

“(a) This Honourable Court issues a declaration that by the failure of the 1st Respondent to act to halt or to respond to the complaints of Your Petitioner, the 1st Respondent has violated/infringed and/or limited the rights and fundamental freedoms of Your Petitioner under Articles 40 and 47 of the Constitution of Kenya;

(b) The Honourable Court issues a declaration that the unauthorized importation of the illegal products on the strength of Drug Registration Certificates held by your Petitioner, the 2nd Respondent has violated/infringed and/or limited the fundamental right of Your Petitioner to hold and own property of any kind under Article 40 of the Constitution of Kenya.

(c) The Honourable Court issues a judicial review order of mandamus directed to the 1st Respondent directing it to carry out its statutory and constitutional mandate to prevent the illegal and unauthorized importation and exploitation of medicines by the 2nd Respondent or by any person at all, on the strength of Your Petitioner’s Drug Registration Certificates;

(c) The Honourable Court issues a judicial review order of mandamus directed to the 1st Respondent directing it to carry out its statutory and constitutional mandate to prevent the illegal and unauthorized importation and exploitation of medicines by the 2nd Respondent or by any person at all, on the strength of Your Petitioner’s Drug Registration Certificates;

(d) This Honourable Court issues a judicial review order of mandamus directed to the 1st Respondent directing it to immediately carry out its statutory and constitutional mandate to recall and quarantine all products covered by the drug registration certificates held by your Petitioner in the Kenyan market to prevent the illegal and unauthorized importation and exploitation of medicine by the 2nd Respondent or by any person at all, on the strength of Your Petitioner’s Drug Registration Certificates;

(e) This Honourable Court issues a permanent order of injunction directed at the 2nd Respondent restraining it whether by its directions, officers, employees, servants, agents or any person whatsoever authorized by it from importing, trading in, advertising or marketing any products covered by the Drug Registration Certificates held by Your Petitioner;

(f) The Honourable Court issues an order of mandatory injunction directed at the 2nd Respondent requiring it whether by its directors, officers, employees, servants, agents or any person whatsoever authorized by it to quarantine and recall all products covered by the Drug Registration Certificates held by your Petitioner in the Kenyan market.

(g) The Costs of the Petition be borne by the Respondents.

(h) Such other Orders (s) as this Honourable Court shall deem just.”

3. From the above, it is alleged that the right to property under **Article 40** of the **Constitution** is in issue and in the Application, the Petitioner alleged that its proprietary rights to exploit the drug registration certificates that it holds has been infringed by the 2nd Respondent while the 1st Respondent has declined to take any administrative action to prevent the said infringement.

4. The Petitioner has stated in its Petition that is a pharmaceutical company established in India in 1935 and registered its trademark, **“CIPLA”** in 1945 and has registered and/or applied for its registration in more than 160 Countries worldwide. That it has had an agency relationship with the 2nd Respondent whereby the former would distribute its products and was also allegedly responsible for obtaining registration for the Petitioner’s products in the Petitioner’s name and not in its own name.

5. As regards the 1st Respondent, the Petitioner claimed that after confirming that the Petitioner had met all the conditions for registration including physical inspection of its manufacturing facilities, it issued

several Drug Registration Certificates in the name of the Petitioner and in accordance with the agency relationship it had with the 2nd Respondent, the Petitioner's products were then distributed into the Kenyan market.

6. What triggered the dispute before this Court is the allegation that upon the agency agreement aforesaid being terminated on 21st May 2014, it came to the Petitioner's knowledge that some of its products, and for which it holds Drug Registration Certificates, were being imported into Kenya without its knowledge, consent and/or approval.

Petitioner's case

7. By its Application aforesaid, Affidavits sworn on 1st December 2014, 4th December 2014, 16th December 2014 and 19th March 2015, by Nevin James Brandford (General Manager of Cipla Quality Chemical Industries Ltd and Regional Manager for East and West Africa of the Petitioner), as well as in an Expert Affidavit of William Mwangangi Kiamba Mwatu sworn on 15th December and in submissions filed on 19th March 2015 the Petitioner has stated its case in respect of the Application under consideration to be as summarized herebelow.

8. Firstly, that the applicable principles of grant of the orders elsewhere set out above have been addressed in *inter-alia* the following cases;

i. **Milca Jeruto Tallam t/a Milcah Faith Enterprises vs Fina Bank Ltd & Anor [2013] eKLR**;- that the purview of conservatory orders are limited to proceedings under **Article 22** of the **Constitution**.

ii. **AG vs Sumair Bans Raj (1985) 38 WIR 286** where the Privy Council defined a conservatory order as an order directed at both parties to undertake no action of any kind to enforce their respective right and that the status quo of the subject matter will remain intact.

iii. **Gatirau Peter Munya vs Dickson Mwenda Githinji & 2 Others [2014] e KLR**, where the Supreme Court of Kenya stated that conservatory orders are unlike injunctions and stay orders linked to private-party issues, such as "**irreparable harm**" or "**high probability of success.**"

iv. **Judicial Service Commission vs Speaker of the National Assembly [2013]eKLR** where the Court stated that conservatory orders are remedies in rem and not in persona and "**are meant to keep the subject matter of the dispute**" intact.

9. Secondly, in applying the above principles, the Petitioner submitted that it has established a *prima facie* case because whereas the registered trademark for the products in issue is disputed, as the owner of the Drug Registration Certificates, it was entitled to manufacture and market the said products. That the reliance on the trademarks and not the product registration was caused, deliberately, by the 2nd Respondent.

10. Further, that the registration of a party as the owner of a product registration certificate cannot be changed by another entity being shown as the holder of the market authorization in the retention certificate.

11. Thirdly, that the 2nd Respondent, at all times prior to 31st August 2014, was described and known as a mere distributor of the Petitioner's products within Kenya and had no ownership of those products. Its claim to ownership is therefore equivalent to illegal expropriation of property and has thereby breached the Petitioner's right to develop, register and commercialise a pharmaceutical product.

12. Fourthly, that the 1st Respondent failed to carry out its lawful mandate to resolve the dispute and refused to respond to correspondence from the Petitioner between April 2014 and October 2014. That it

also specifically allowed the 2nd Respondent to carry out the acts of alleged expropriation, the subject of these proceedings, and yet had it acted quickly, the 2nd Respondent would not have been able to import the products in question.

13. Fifthly and in addition, whereas the 1st Respondent issued a recall order of the said products, the same were still being sold in the Kenyan market by the 2nd Respondent and the action was in any event only taken after these proceedings had been filed.

14. Sixthly and on the prejudice to be suffered, it is the Petitioner's case that since the 1st Respondent has confirmed that the products had been imported into Kenyan illegally, it would be prejudicial to the Petitioner's interests if the interlocutory orders are not granted as the products may then be released unlawfully, to the market.

15. It is also the Petitioner's case that while the 2nd Respondent now purports to have licenses under which its new manufacturers have been authorized to undertake the manufacturing of the disputed products, there are serious and material discrepancies between the alleged licenses and in any event the inspection and certification of the 2nd Respondent's manufacturing sites was conducted in October 2014 well after the disputed products had been imported into Kenya.

16. Further, that the India FDA, the regulatory body in India's pharmaceutical industry has confirmed that Taj Pharmaceuticals is not licensed in India to manufacture the said products and that Vega Biotec whose license number is actually used on the packaging of the products has been ordered to cease production and its products seized by the Indian FDA.

17. Lastly, that on a balance of convenience, the orders sought should be granted.

1st Respondent's case

18. In a Replying Affidavit sworn on 24th February 2015, Dr. Kipkerich Koskei, Chief Pharmacist and Registrar of the 1st Respondent deponed that whereas the Petitioner is a foreign company, it entered into an agency agreement with the 2nd Respondent for importation and distribution of the Petitioner's products but the contents of that agreement are unknown to it.

19. Further, that the Petitioner, by a letter written sometime in May 2014 to the 1st Respondent, stated that the agency agreement would be terminated on 31st May 2014 and that Surgipharm Limited was its new local agent. The 1st Respondent acted on that request.

20. It also contended that prior to 31st May 2014, it issued certificates of registration to the Petitioner and the 2nd Respondent but only came to know of the alleged importation of illegal products by the 2nd Respondent when the Petitioner wrote to it on 22nd October 2014. It then responded to the Petitioner on 24th October 2014 and on 6th November 2014 seized the products in the possession of the 2nd Respondent and ordered the latter to recall all other such products in the Kenyan market.

21. Regarding Taj Pharmaceuticals which is alleged to have been the manufacturer of the seized products, the 1st Respondent stated that it has, pursuant to its legal mandate, inspected the said company's products and manufacturing site and a report is being prepared to ensure compliance with the law and quality standards.

22. In agreement with the Petitioner, the 1st Respondent admitted that the registered owner of a pharmaceutical product is the one who has the right to export such a product and commercially exploit it in a foreign County through its local agent but denied that the Petitioner has the mandate to determine what such product is safe for use in Kenya, a mandate reserved for the 1st Respondent only under **Cap.244 Laws of Kenya**.

23. Lastly, the 1st Respondent contended that the Petition does not disclose any cause of action against the 1st Respondent and is merely a commercial battle between two private companies and should be struck out for being frivolous, vexatious and scandalous.

24. I should state here that for some reason, although the matter under consideration is the Application dated 1st December 2014, the 1st Respondent's submissions are in respect of the Petition which is yet to be heard.

2nd Respondent's case

25. Lords Healthcare Limited, the 2nd Respondent, filed a Replying Affidavit sworn on 10th December 2014 by Stanley Waweru, its Ethical Business Manager. It also filed written submission on 23rd March 2015. Of relevance to the Application under consideration; it stated;

i. That whereas it had a business relationship with the Petitioner it was never one of Principal Agent as claimed.

ii. The 2nd Respondent had its own brands and trade marks exclusive to itself.

iii. Correspondences with the 2nd Respondent dated 28th November 2013, 29th January 2013, 16th July 2014 and 8th September 2014 led the 1st Respondent to believe that no change of registration of brands or marks as claimed by the Petitioner would be effected without its input.

iv. Despite the above expectations, the 2nd Respondent transferred the said brands and marks to the Petitioner between June and September 2014 hence the claims of ownership thereof by the Petitioner

v. Regarding registration of the products, while the same were registered by the 1st Respondent and manufactured by the Petitioner, the Petitioner never paid for the registration certificates as alleged and has no lawful claim to them.

vi. The trademarks belonging to the 2nd Respondent were also registered at KIPI and have never been challenged.

vii. The Petitioner was at all times only a manufacturer of products that belonged to the 2nd Respondent, the true owner of the products.

viii. Its new manufacturer has complied with all relevant laws and regulations and its sites have been inspected and approved by the 1st Respondent which has also granted it an importation license. It is for the same reason that the drugs seized by the 1st Respondent were allowed into Kenya.

ix. The presence of the products in issue within the Kenyan market cannot in the circumstances be unlawful.

26. It is in a nutshell the 2nd Respondent's case that it has suffered immense loss as a result of the actions of the Petitioner and the 1st Respondent and the Application should be dismissed with costs.

Determination

27. Two issues were raised by the Respondents which require a quick determination;

a. Whether the Petition raises any constitutional questions for determination and;

b. Whether the Petition was filed prematurely.

28. On issue (a), it was the Respondent's case that the issues raised are of a purely commercial nature and should be resolved as such and not as questions to be resolved under the Constitution.

29. In that regard, it is obvious that their contention is not that the High Court has no jurisdiction but that the resolution of the dispute should be in proceedings other than by invocation of the Constitution. My view is that it is indeed true that the dispute is one that relates to the breakdown of a business relationship between the Petitioner and the 2nd Respondent. The nature of that relationship is disputed but suffice it to say that the fact of reliance on **Articles 40 and 47 of the Constitution** does not negate that fact. I say so because the prayers in the Petition point to a purely commercial dispute and for avoidance of doubt, the Prayers have been reproduced elsewhere above.

30. I reiterate therefore that looking at the Petition, the dispute ought to be resolved in terms of ownership of the drug registration certificates, brands and marks and any constitutional question is purely peripheral to that singular issue. I will make necessary orders in that regard, at the end of this Ruling.

31. On issue (b) and whether the Petition was filed prematurely, I note that the 2nd Respondent, it is admitted, is the body statutorily mandated to determine at the first instance;

i. Who is the lawful holder of any drug registration certificate.

ii. Whether any manufacturer of drugs such as Taj Pharmaceutical and the Petitioner is complainant in that regard.

iii. Whether local agents of foreign manufacturing companies are properly appointed as such.

32. From the evidence before me, the 1st Respondent has taken action on part of the dispute and has categorically stated that it is yet to conclude its investigations on a number of aspects including who actually owns the brands and drug registration certificates in dispute.

33. In the circumstances, the law as I understand it is that where Statute or any other law has mandated a lawful body to undertake any function, the Court should be slow to intrude upon that mandate – See **Speaker of National Assembly vs Njenga Karume (2008) 1 KLR 245.**

34. In the circumstances, I am of the view that until the 1st Respondent has concluded its investigations into the present dispute, this Court should not intrude into its mandate.

35. What then should happen in the circumstances? I will not determine the Application in substance but would only state that when I issued interim orders in favour of the Petitioner, it was on my understanding that *prima facie*, it had established that being the holder of drug registration certificates, it was being prejudiced by the drugs named in those certificates being marketed and sold by the 2nd Respondent. I reiterate and confirm that finding pending orders to be made below.

36. The appropriate orders to make therefore are;

i. The first Respondent shall be given 30 days to resolve all aspects of the dispute between the Petitioner and 2nd Respondent and file a Report before this Court at the end of that period.

ii. The matter herein being a purely commercial dispute is transferred to the Commercial Division of the High Court for hearing and determination. The Report in (i) above shall be filed in that Division for appropriate orders thereafter.

iii. In the interests of justice, the interim orders granted on the 4th December 2014 in favour of the Petitioner are extended until further orders of the Commercial Division and in any event upon

receipt of the Report mentioned in (i) above.

iv. The Application dated 15th July 2015 by the 1st Respondent seeking vacation of the interim orders is stayed until further orders of the Commercial Division.

v. Each party is at liberty to apply and costs shall await the outcome of both Applications.

37. Orders accordingly.

DATED, SIGNED AND DELIVERED AT NAIROBI THIS 18TH DAY OF AUGUST, 2015.

ISAAC LENAOLA

JUDGE

In the presence of:

Muriuki – Court clerk

Miss Ibrahim holding brief for Mr. Njogu for Petitioner

Mr. Muturi for 2nd Respondent

Mr. Kibet for 1st Respondent

Order

Ruling duly read.

ISAAC LENAOLA

JUDGE

Further order

Mention before the commercial Division on 24/8/2015.

ISAAC LENAOLA

JUDGE