

**IN THE SUPREME COURT OF THE DEMOCRATIC
SOCIALIST REPUBLIC OF SRI LANKA**

In the matter of an appeal under and in
terms of Article 128 (2) of the Constitution of
the Democratic Socialist Republic of Sri Lanka.

SC / CHC / APPEAL / 38 / 2022

CHC / 425 / 2017 / MR

B.J. International Pvt Ltd,
“Vijitha”, Kahatapitiya,
Hanwella and

No. 375/B,
Malamulla,
Panadura.

PLAINTIFF

-Vs-

**National Medicines Regulatory
Authority,**
No. 120, Norris Canal Road,
Colombo 10.

DEFENDANT

AND NOW

B.J. International Pvt Ltd,
“Vijitha”, Kahatapitiya,

Hanwella and

No. 375/B,
Malamulla,
Panadura.

PLAINTIFF – APPELLANT

-Vs-

National Medicines Regulatory Authority,
No. 120, Norris Canal Road,
Colombo 10.

DEFENDANT – RESPONDENT

Before: A.H.M.D. Nawaz, J

Achala Wengappuli, J &
Sobhitha Rajakaruna, J

Counsel: Varuna Nanayakkara instructed by Ms. Suneetha Nanayakkara for the Plaintiff – Appellant.

Sumathi Dharmawardena, ASG with Mihiri De Alwis, SSC for the Defendant – Respondent.

Argued and decided on: 21.05.2025

A.H.M.D. Nawaz, J.

1. The Plaintiff – Appellant, *a corporate entity*, instituted this action in the Commercial High Court against the Defendant – Respondent, the *National Medicines Regulatory Authority* (NMRA), averring delay in the issuance of the certificate of registration and the subsequent licences required for importation of medical devices.
2. In other words, this was a suit against the *National Medicines Regulatory Authority* for damages in a sum of Rupees 497,700,000 (Four Hundred and Ninety-Seven Million Seven Hundred Thousand). The Plaintiff – Appellant (the Plaintiff) claimed that the failure of the Defendant-Respondent (the Defendant) to issue, or to timely renew, the licences during the periods 2013-2014, 2014-2015, 2015-2016, 2016-2017, and 2017-2018 caused substantial financial loss.
3. The Plaintiff alleged that this loss directly resulted from the malicious and wrongful conduct of the Defendant in negligently delaying the grant of the required licences.
4. Following the settlement of issues at a pre-trial conference, the matter proceeded to trial in the Commercial High Court.
5. The learned Commercial High Court Judge by his judgment dated 11/11/2021 dismissed the Plaintiff's action. The reasons given by the learned Commercial High Court Judge is that the delay in renewing the licences was caused not by the Defendant but by the Plaintiff Company itself. The learned High Court Judge states that the Plaintiff made belated applications for renewal of the licences and it was itself at fault for not furnishing the required documents for the purpose of obtaining the subsequent licences.
6. It is quite apparent from a perusal of the record that the licences are given by virtue of the National Medicines Regulatory Authority Act No. 05 of 2015.

There was also a Gazette Notification that had been issued prescribing the procedure for the grant of licences. The overriding and pervasive allegation against the Defendant is one of *malicious* and *mala fide* conduct in prolonging the grant of licences. It has to be borne in mind that the Defendant (NMRA) is a statutory body or a legal entity which is created as a body corporate by the aforesaid legislation.

7. Taking a look at the plaint and the issues, I would classify this action as having been premised on malice (*dolus*). The action based on malice is founded upon the basis that the NMRA maliciously delayed the grant of licenses so as to contribute to the economic loss of the Plaintiff Company. In other words, the NMRA is vested with a statutory discretion to grant or refuse a license and the exercise of the discretionary power that took place in this case is alleged to be malicious and *mala fide*. Simply put, the crux of the complaint before the Commercial High Court was that while licenses for four years were given belatedly, a license for the year 2017 - 2018 was not granted at all.
8. On the question of the availability of actions founded upon negligence (*culpa*) and malice (*dolus*) in relation to the exercise of statutory power, I observe that Sri Lankan jurisprudence recognizes the concurrent availability of both causes of action under the principles of the *Lex Aquilia* - see **David v. Abdul Cader**¹. For causes of action founded upon malice or mala fides in the case of an invalid exercise of discretionary power - see **Corea v. Corea**².
9. Certainly the case filed by the Plaintiff in the instant appeal was **not based on negligence** and I hasten to point out that Section 143 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015 **impliedly takes away the right of a person to file an action in negligence** against the NMRA.

¹ (1971) 77 NLR 18 - The Plaintiff succeeded in being awarded damages by the then Supreme Court on May 30, 1971. H.N.G. Fernando, C.J (p.23) said: "Wille (Principles of South African Law, 5th ed., 502) states that, 'legislation, by imposing a duty, positive or negative, on one person, may impliedly confer a right on another person ...and if the person subject to the duty commits a breach of the duty, his act or omission is equivalent to *culpa* and is an infringement of the right.'

² (1925) 27 NLR 328

Section 143 of the NMRA makes this position patently clear and I will revert to this matter more fully after having alluded to the facts immanent to this case.

10. There is incontrovertible evidence before this Court that the Defendant Authority was unable to issue the relevant licenses on the stipulated dates, owing to the Plaintiff's failure to furnish all requisite information as called for by the Authority. The testimony of a witness whose evidence remained uncontested established that the Plaintiff, in submitting annual applications, consistently failed to comply with the documentary requirements in a timely manner. Such conduct amounted to a breach of the gazette notifications issued under the Cosmetic, Devices and Drugs Act, No. 27 of 1980. While these notifications stipulated a time period for applications to be made, a belated application outside the time limit causes administrative inconvenience and it has to be borne in mind that the time limits for making the applications are given so as to enable officials in a department or authority to process the application and any applicant for a license who falls foul of the time limits cannot complain of negligence or malice on the part of officials dealing with such applications.
11. The substance of the testimony thus clearly indicates that the delays in the issuance of licenses were directly attributable to the Plaintiff Company's own omissions.
12. The non-issuance of the import license for the year 2017/2018 has also been satisfactorily explained. Evidence has been led to demonstrate that the Defendant Authority had, in response to concerns regarding price disparities of medical devices in the market, introduced regulatory requirements mandating that applicants submit proof of pricing. The testimony of a key witness established that the Plaintiff failed to comply with this requirement. Further, there is unchallenged testimony that the Plaintiff had not obtained a Taxpayer Identification Number (TIN), giving rise to a reasonable inference

that the relevant imports had not been processed through official customs procedures but through alternative channels. On the totality of the evidence, it appears that this non-compliance on the part of the Plaintiff constituted the basis for the Defendant Authority's refusal to issue the license for the said period.

13. As I stated before, it is apposite now to draw attention to Section 143 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015 which reads as follows:

No civil or criminal proceedings shall be instituted against a person for any act which in good faith is done or purported to be done by him under this Act or any regulation made thereunder.

14. In terms of the aforesaid provision, it is manifestly clear that only actions founded on *mala fides* (i.e *malice or bad faith*) are maintainable against the NMRA, whilst any other action, including one predicated on negligence, is by necessary implication excluded. Section 143 (2) further stipulates that in order to succeed in an action grounded on malice (*dolus*), the Plaintiff must establish that the impugned act was committed by a person with the requisite intent of malice.

15. In other words, in the case of an invalid exercise of discretionary power, the person who so acted wrongfully could be liable in delict only if he is proved to have acted *mala fide*. Following the English Law, it has been held that,

"As a rule when the discharge of a public duty imposed by statute upon a person or bodies of persons involves the exercise of a discretion which is not a merely ministerial act, if the discretion

has been exercised erroneously, no action lies except upon proof mala fides or indirect motive".³

“.....If a man is required in the discharge of a public duty to make a decision which affects, by its legal consequences the liberty or property of others, and he performs that duty and makes that decision honestly and in good faith, it is, in my opinion, a fundamental principle, of our law that he is protected. It is not consonant with the principles of our law to require a man to make such a decision in the discharge of his duty to the public, and then to leave him in peril by reason of the consequences to others of that decision, provided that he has acted honestly in making that decision.”⁴

16. The word *person* in Section 143 (2) specifically imports the requirement of identification of such a person in the plaint and proof of that person as having acted in bad faith. A legal person, like a natural person, can be held to have acted with malice, and could therefore become liable in damages or *injuria* under the *Actio Injuriarum*;⁵ or in the alternative it can become vicariously liable for an *injuria* committed with malice by its agent or servant. The issue raised on malice against the NMRA has been answered in the negative and that finding cannot in any way be struck down as perverse.

17. In *Singer Sewing Machine Company v. Bowes*⁶, it was held that where malice is averred, it must be pleaded with particularity; the Defendant must be identified with reasonable certainty, and malice must be specifically alleged and proved against that Defendant. In the present matter, the allegation of malice is directed *ipso facto* against the juridical person, namely, the National

³ See Jayawardene A.J., *Corea v Corea* (1925) 27 NLR 228 at 335.

⁴ Lord Moulton in the House of Lords, in *Everett v Griffiths* (1921) AC 631, 695-696, cited by Jayawardene A.J., in *Corea v Corea* (1925) 27 NLR 328, 335.

⁵ *Kandasamy v. Municipal Council of Colombo* (1905) 1 ACR 90.

⁶ 4 CWR 78

Medicines Regulatory Authority, but no such mental element was established against the NMRA or any of its servants, let alone their identification with certainty.

18. No averment has been made in the pleadings, nor has any issue been raised, identifying any particular individual within the Defendant's legal entity as having maliciously or wrongfully caused the alleged delay in the grant of licences. A bare allegation of malice directed at a corporate entity, without specifying the individuals - the directing minds or agents who are said to have committed the impugned acts, is insufficient. In the absence of such identification and without establishing a delictual nexus between those individuals and the statutory body, the claim cannot be sustained.
19. The learned Judge of the Commercial High Court, in addressing the issue of malice and mala fides, correctly concluded that malice had not been established. As I said before, that finding in the absence of an error of law, must dispose of the allegation of malice. This Court finds no material on record that specifically identifies or accuses any individual within the National Medicines Regulatory Authority of having maliciously withheld or delayed the grant or renewal of licences. In such circumstances, the imputation of malice to the statutory body becomes unsustainable, as the requisite nexus between any particular individual conduct and institutional liability has not been demonstrated.
20. This is a case where malice and mala fides were directly attributed to the statutory entity itself. The question is whether the alleged delay in granting the licenses is referable to malice or mala fides of the Defendant Authority. In other words, even though the Defendant issued licenses for the years ranging from 2013 / 2014, 2014 / 2015, 2015 / 2016 to 2017 to import medical devices, the Plaintiff averred that the delay contributed to the damages. In regard to the year 2017 / 2018 the Defendant failed to issue any licences at all.

21. It would appear that this case suffers from want of a cause of action against the statutory body and I see no reason to interfere with the finding and conclusion of the learned Commercial High Court judge. De Sampayo, *J.* articulated the following view in ***Lowe Vs. Fernando***⁷

*"The expression 'cause of action' generally imparts two things, viz, a right in the plaintiff and a violation of it by the defendant, and cause of action means the whole cause of action i.e. all the facts which together constitute the plaintiff's right to maintain the action, (Dicey's parties to an action Ch. XI Sec. A) or, as it has been otherwise put, the media upon which the plaintiff asks the court to arrive at a conclusion in his favour (Lord Watson's judgement in ***Kaur vs Singh***)*

22. This was also emphasized in ***Narendra Vs. Seylan Merchant Bank***⁸ and reiterated by *Dheeraratne, J.* in ***Eksith Fernando Vs. Manawadu and Others***⁹.

23. No such person, as we have observed in the course of this judgment, has been identified or established to have been the wrong doer in this case. It has to be borne in mind by all trial judges that one cannot open the flood gates for litigation in respect of allegedly incorrect or invalid administrative decisions unless *malice and mala fides* are particularized with definite certainty. This would be the effect of Section 143 (2) as aforesaid. Section 143 (2) predicates only an action based on *dolus* and not an action premised on *culpa*.

24. In the circumstances, this Court holds no *mala fides* or bad faith has been established and there is no evidence to counter the strong and compelling case that it is the Plaintiff Company that contributed to the delay in the grant of

⁷ 16 NLR 398

⁸ 2003 2 Sri.LR 01

⁹ 2001(4) Sri.LR 95

the licenses which it applied for. Accordingly, I affirm the judgement of the Commercial High Court dated 11 November 2021 and proceed to dismiss this appeal.

JUDGE OF THE SUPREME COURT

Achala Wengappuli, J

I agree

JUDGE OF THE SUPREME COURT

Sobhitha Rajakaruna, J

I agree

JUDGE OF THE SUPREME COURT