IN THE COURT OF APPEAL OF THE

DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In the matter of an Application for mandates in the nature of Writs of Certiorari, Prohibition and Mandamus in terms of Article 140 of the constitution

C A (Writ) Application No. 98/ 2016

1. F Haffmann-La Roche Ltd.
   Grenzacherstr.
   124,
   4058 Basel,
   Switzerland.
2. A. Baur & Co. (Pvt) Ltd.
   No. 05,
   Upper Chatham Street,
   Colombo 01
   and, of
   No. 62,
   Jethawana Road,
   Colombo 14.

PETITIONERS

-Vs-

1. National Medicines Regulatory Authority,
   120,
   Norris Canal Road,
   Colombo 10.

2. Director,
   Medical Supplies Division,
   Ministry of Health,
   No. 357,
   Rev. Baddegama Wimalawansa Mawatha,
   Colombo 10.

3. Director General of Health Services,

   Ministry of Health,
   No. 357,
   Rev. Baddegama Wimalawansa Mawatha,
   Colombo 10.

4. President
   College of Oncologists,
   Cancer Hospital,
   Maharagama.

5. Pharma Ace (Pvt) Ltd.
   No. 46,
   Galle Road,
   Dehiwala.

RESPONDENTS

Before: Vijith K. Malalgoda PC J (P/CA)

P. Padman Surasena J

Counsel: Manoj Bandara with Lakshana Perera for the 1st Petitioner

Dinal Philips PC with Ranil Premathillake for the 2nd Petitioner

Farzana Jameel SDSG with Arjuna Obeysekera DSG & Chaya Sri Nammuni SC for the 1st, 2nd and 3rd Respondents

Neomal Senathillake for the 4th Respondent

Ikram Mohamed PC with R Hettiarachchi & S Wadood for the 5th Respondent

Inquiry conducted on: 2016-05-17 and 2016-05-24

Decided on: 2016-06-22

ORDER PERTAINING TO THE OBJECTION FOR THE EXTENSION OF THE OPERATION OF THE INTERIM RELIEF

P Padman Surasena J

The Petitioners in this case having filed this petition in the registry of this court on 2016-03-21, supported it before this bench on 2016-03-28 without notice to the Respondents. This court, having heard, only the submissions of the learned counsel for the Petitioners, ordered

I. that notices be issued on the Respondents,
II. that the interim reliefs prayed for as per paragraph h(i), (iii) & (iv) of the prayers to the petition be granted for a limited period of 11 days, i.e. until 2016-04-08.

On the notice returnable date i.e. on 2016-04-08 learned counsel for the Respondents having appeared in court objected to the extension of the interim order issued ex parte by this court at the first instance.

Thereafter this court afforded the opportunities for all the parties to file objections and counter objections with regard to the limited scope of the inquiry, to be held to decide whether this court should extend the operation of the interim order, and then fixed the inquiry for 2016-05-17 and thereafter, further inquiry for 2016-05-24.

We heard the extensive submissions at length by learned counsel for all the parties on those two days. They thereafter, filed written submissions also and then concluded the said inquiry.

Learned Counsel who appeared for the Petitioners insisted that this court should extend the operation of the interim order until the final determination of this application while the learned Senior Deputy Solicitor General appearing for the 1st, 2nd and 3rd Respondents and the learned President's Counsel appearing for the 5th Respondent, vigorously argued that this court should not have granted the said interim reliefs in the first place.

It is the submission of the learned counsel for the 1st - 3rd and the 5th Respondents that this Court would never have made this interim order, if it had the benefit of hearing the opposing parties and that this court should vacate the said interim order forthwith.

As it stands at present, the task before this court is to decide whether this court should extend the interim orders it made ex parte until the final determination of this application or vacate the same forthwith.

Having the above task in mind it would be in order to first re-visit the grounds which a court should consider when it is tasked to resolve this type of problem.

It should be noted at the inception that the discretion to decide the granting of interim reliefs have been left to courts. However our courts

have at some occasions laid down broader guide lines to regulate the exercise of this discretion by courts.

One such judgment is Duwearachchi Vs Vincent Perera[1]. In that case this court has laid down three principles which courts should consider when they are called upon to decide the issuance or non-issuance of a stay order.

These principles are as follows:

(a) Will a final order be rendered nugatory if the petitioner is successful ?
(b) Where does the balance of convenience lie ?
(c) Will irreparable or irremediable mischief or injury be caused to either party ?

Learned counsel for all the parties have in principle agreed that the above judgment reflects the present legal position.

However the learned counsel for the Petitioner has advanced an argument that the ground namely, that there is a 'prima facie sustainable case' made out by the Petitioner for the issuance of a writ of Certiorari could also be considered as a basis for granting interim reliefs.

Learned counsel for the Petitioner in his written submission has quoted an extract from a judgment of this court in NatWealth Securities Ltd Vs The Monetary Board of the Central Bank, and five others[2] to advance the above argument. It is the submission of the learned counsel for the petitioners

[1] 1984 (2) SLR 94
[2] CA (Writ) Application No. 335/ 2015 CA Minutes of 2016-03-29

that the quoted extract of that judgment gives the impression that such an argument is possible, as this court in that judgment had considered the facts of that case also in the course of the inquiry relating to extension of the interim reliefs in that case.

It is convenient to reproduce the relevant paragraph in that judgment to show as to why it became necessary for this court to touch on major facts in that case. It is as follows.

" Although this court has to limit the scope of this order only to the question whether or not the interim order should be extended or not, it has become necessary for this court to touch on at least some of the major facts pertaining to this case as learned counsel for all the parties had not only extensively addressed this court but also heavily relied upon those grounds in this inquiry. Further, consideration of the above facts has become necessary particularly to find an answer to the question as to where the balance of convenience lies and also to ascertain whether there would be any irreparable loss and damage caused to any party in this case."[3]

The above paragraph is clear in its purpose and the consideration of major issues of facts was done for a particular purpose mentioned therein. That move was directed to find answers to the questions that this court had to answer when it applied the tests set out in the judgment of Duwearachchi's case[4]. Thus, while it is right to say that this court did touch on some of the major facts in that case, it is not right to say that this court considered

[3] (Ibid) at pages 6 & 7 of that judgment.
[4] Supra

whether or not there is a 'prima facie sustainable case' as a ground for the granting of interim relief.

If the argument of the learned counsel for the petitioners that court should extend the operation of the interim relief it had granted, on the basis that the petitioners have made out a 'Prima facie sustainable case', is to be accepted, this court will have to issue interim reliefs every time it decides to issue notices on the respondents. This is because court decides to issue notices on the respondents since it is satisfied that there is a prima facie case to be looked into.

Be that as it may, as has been done in the case of NatWealth Securities Ltd Vs The Monetary Board of the Central Bank[5], this court will albeit proceed to consider briefly some of the contested issues of facts in this case also to find out whether a final judgment in this case would render nugatory if the petitioner becomes successful or whether there would be any irreparable loss and or damage caused to any party in this case and also to find out as to where the balance of convenience lies.

The Petitioners' primary complaint in this application is the registration of a medicine by the 1st Respondent in violation of the law (substantive ultra vires), in violation of the procedure (procedural ultra vires), and contrary to established practice and the declared policies which have been consistently followed (unreasonableness and ultra vires).[6]

The legal position asserted by the Petitioners can be summarized as follows:-

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[5] Supra
[6] paragraph 12 of the written submission filed by the petitioners

a. All registrations of medicines should be done in compliance with the NMRA Act.
b. However, the NMRA Act is silent on the procedure to be followed on biological medicines. Although regulations are permitted to be made in this connection, no regulations have been framed. Thus, in terms of the existing legal frame work, no bio similar can be registered in Sri Lanka.
c. The respondents have issued the circular P 12 to examine a bio-similar candidate, to first establish that it is in fact a bio similar. There is no other regulation, circular or guidelines presently available. If it is established that it is in fact a bio similar, then it must be submitted for evaluation under the normal procedure set out in the NMRA Act.
d. Following the WHO guidelines on evaluation of bio similars marked P 11, and insisting on the approval from a WHO reference country is the declared and consistently followed policy of the 1st - 3rd Respondents in respect of a bio-similar.
e. Where an oncology medicine is concerned, the medicine should be evaluated by an oncologist, nominated by the College of Oncologists who is invited to the deliberations of the Medicines Evaluation Committee of the 1st Respondent.

In summary it is the position of the Petitioners, that any bio similar candidate of an oncology medicine should first establish that it is a bio-similar, by reference to the circular P 12, obtain approval from a WHO

reference country, and then undergo the evaluation under the NMRA Act, at which stage, an evaluation must be conducted by an Oncologist.

It is the position of the Petitioners that the establishing the proposed drug to be a bio similar, is an additional step in the process of drug evaluation; and not an alternative to drug evaluation.

The Petitioners' complaint is that none of the above processes was followed in the case of the medicine of the 5th Respondent, "Herticad".

On the contrary it is the argument of learned Senior Deputy Solicitor General appearing for the 1st, 2nd and 3rd Respondents and the learned President's Counsel appearing for the 5th Respondent that

i. the purpose of Medicine Policy of Sri Lanka and the NMRA Act is to encourage true and meaningful competition so as "to ensure the availability of efficacious, safe and good quality medicines to the public at affordable prices.
ii. the Petitioners have filed this application to preserve, what they consider to be their exclusive right to the drug "trastuzumab", and this is based on the premise and claim that the 5th Respondent's drug is not a bio similar of "trastuzumab". In doing this, they have collaterally challenged the registration process.
iii. what the Petitioners are seeking to do is to put in issue a question of fact, which can be effectively resolved only through a process that permits the calling of oral and documentary evidence, and clarifications and determinations based on real, expert evidence.

iv. Thus, although the Petitioners claim that the 5th Respondent's drug is not a bio similar, this is not a matter in respect of which the 1st to 3rd Respondents are entitled to presume that the information contained in the documentation (dossier) submitted by the 5th Respondent for evaluation and consideration for the purposes of registration, is false.

It would be appropriate at this juncture to proceed to consider whether the Petitioners have satisfied this Court with any of the grounds for the issuance of interim reliefs.

Will a final order be rendered nugatory if the petitioner is successful ?

The Petitioners' drug is 'trastuzumab' and the 5th Respondent's drug is 'Hertcad'. Both these drugs are being sold in Sri Lanka until the issuance of this stay order. As a result of this stay order the registration, importation, marketing, distributing and even administering to patients of the 5th Respondent's drug has been stopped. The sale of the Petitioners' drug is being continued. The only change, the vacation of the stay order will bring about, would be the resumption of sale of 5th Respondent's drug 'Hertcad'. Would such a move render a final order nugatory if the petitioner is successful ? The answer is obvious. It is in the negative form.

Where does the balance of convenience lie ?

It could be seen from the pleadings filed by the 3rd Respondent that since the granting of this interim relief it has become impossible to administer this drug on patients suffering from cancer both at the Cancer Institute Maharagama and other hospitals. The documents marked 3R4 and 3R6

have clearly shown the inconvenience that has caused to the general public. The affidavit filed on behalf of the 3rd Respondent setting out the statics in this regard demonstrates the need for affordable breast cancer drug particularly to the under-privileged segment of cancer patients of this country.

To the contrary what do the Petitioners achieve by the stay order being in place? Basically there are two things. They are as follows.

I. It stops the sale of the 5th Respondent's drug at the inconvenience caused to the general public.
II. It enhances the sale of the Petitioners' drug and would in the process establish a monopoly for it.

This shows that the balance of convenience of the parties to this dispute is clearly tilted in favor of the 1st - 3rd and the 5th Respondents. Indeed it is not a question of balance of convenience, it is just that the Petitioners cannot and should not be permitted to achieve the above results by an interim order issued by this court in a Writ application.

Will irreparable or irremediable mischief or injury be caused to either party?

The question that one should ask at this moment is whether an irreparable or irremediable damage would be caused to the Petitioners by not stopping the sales of the 5th Respondents drug? Answer is obviously no. Because a mere drop in sales of the Petitioners' drug cannot be taken as irreparable or irremediable mischief or damage caused to the Petitioners.

It is also relevant and is necessary to examine the interim reliefs that the petitioners have asked for, from this court in the light of the final reliefs they have claimed from this court.

The final prayers of the petitioners inter alia are as follows.

1. for a writ of Certiorari quashing the registration and/ or the decision of the 1st Respondent to register the product "Herticad" and/ or the license to import and market the same;
2. for a writ of Prohibition prohibiting the 1st Respondent from granting any extension of provisional registration and/ or granting a full registration for the product "Herticad" and/ or license to import and market the same;
3. for a writ of Mandamus directing the 1st Respondent to cancel the purported registration or provisional registration of the product "Herticad";
4. for a writ of Prohibition prohibiting the 1st Respondent from granting a provisional or full registration for the product "Avegra" and/ or a license to import and market the same;
5. for a writ of Prohibition prohibiting the 2nd Respondent from purchasing, or proceeding with any purported contract for purchasing, the product "Herticad" for administering to patients in Sri Lanka;

<u>The interim reliefs that the Petitioners have prayed for are as follows.</u>

I. staying and/ or suspending the registration and/ or the provisional registration and/ or any license to import and market the product "Herticad";

II. Preventing the 1st Respondent from registering the product "Avegra";

III. preventing the 2nd Respondent from purchasing, or proceeding with any purported contract to purchase the product "Herticad" for administering to patients in Sri Lanka;

IV. preventing the Respondents from importing and/ or distributing and/ or administering or causing to be administered, the product "Herticad" to patients in Sri Lanka;

As has been shown in the written submissions[7] filed by the learned Senior Deputy Solicitor General appearing for the 1st, 2nd and 3rd Respondents, it could be seen that the interim reliefs that the petitioner has prayed for, are similar to his final prayers. What the petitioners have done by obtaining the interim reliefs, has amounted to obtaining their final reliefs even without noticing the respondents from day one. This has never been, and should not ever be, the purpose which the Rules[8] are expected to serve.

Learned counsel for the 4th Respondent stated to this court that he is supporting the extension of the operation of the interim relief granted by this court. However the basis upon which he asserts that, has not been

[7]Pages 3 & 4 of the written submissions filed on behalf of the 1st, 2nd and 3rd Respondents
[8]Court of Appeal (Appellate Procedure) Rules 1990

made clear. The 4th Respondent has not filed any statement of objections. He has nevertheless filed written submissions. In that written submissions the 4th Respondent has stated inter alia,

I. that he is not an aggrieved party,
II. that he does not intend to oppose the interim order that has been issued,
III. that the Petitioner's drug is time tested and long used one,

He has stated in his written submission a considerable number of other facts as well.

It is strange that the learned counsel for the 4th Respondent has been able to narrate a series of facts pertaining to the issues under consideration as the 4th Respondent has neither filed a statement of objection nor filed any affidavit. It is to be observed that even the assertion that "the 4th Respondent or the College of Oncologists by no means is seeking to promote the Petitioners' drug Herceptin or encourage a monopoly for them" has not been supported by any affidavit and thus it is not difficult for this court to reject it totally. Similarly all those factual positions narrated by the learned counsel for the 4th Respondent must also be rejected as they clearly amount to either hearsay material or mere third party's opinions of a given set of facts. Such opinions should not have a place in these proceedings as this court is not interested in the opinions of third parties about the issues that it ought to consider in a case before it. The entitlement of 4th Respondent's counsel is only to represent his client and

act in court to safeguard his client's interests. He should not be entitled to either attack or assist any other party's factual position or interest without first taking up a position in that regard in his pleadings. Such a factual position has to be supported by an affidavit also. Further this Court cannot see any justification as to why the Petitioners have made the President, of the College of Oncologists, a party to this proceedings, in view of the statement by the learned counsel for the 4th Respondent that "it is not a party against whom relief has been sought and is not an agrieved party"[9].

It is the submission of the learned counsel for the 1st - 3rd and the 5th Respondents that the affidavit filed with the petition is not an affidavit of persons who could speak to the alleged material facts set out in the said affidavit from their personal knowledge. This issue has been raised by the learned counsel for the 1st - 3rd and the 5th Respondents as a preliminary objection and that issue, if proven, would go into the very root of this case as it is against Rule 3(1)(a) which has been held to be mandatory.

Further, the arguments advanced on behalf of the 1st, 2nd and 3rd and the 5th Respondent that

a. the Petitioners action amounts to a collateral attack on the decision to award the tender to the 5th Respondent but presented in the guise of a writ application
b. there is no legally protectable right that has been infringed by the 1st, 2nd and 3rd and the 5th Respondents in this case

[9] Paragraph 01 of the Written Submission filed by the learned counsel for the 4th Respondent.

appear to this court to be sensible arguments which this court will have to go into carefully. Although this court does not intend to make findings on all the arguments advanced by the parties it is appropriate to mention here the very presence of this type of arguments show that this is not a case in which the Petitioners should have obtained interim reliefs referred to above, exparte.

Having that in mind, it would be helpful for this court to look back, to identify the background in which this court had made an order granting the interim reliefs, at the first instance. This exercise must be done in the light of the legal regime governing the granting of such interim reliefs.

Rule 2(1) of The Court of Appeal (Appellate Procedure) Rules 1990 is the main rule deals with the granting of interim reliefs. It is as follows.

Rule 2(1)

"

a) Every application for a stay order, interim injunction or other interim relief (hereinafter referred to as 'interim relief') shall be made with notice to the adverse parties or respondents (hereinafter in this rule referred to as ' the respondents ') that the applicant intends to apply for such interim relief; such notice shall set out the date on which the applicant intends to support such application, and shall be accompanied by a copy of the application and the documents annexed thereto:

b) Provided that -

a) interim relief may be granted although such notice has not been given to some or all of the respondents if the court is satisfied that there has been no unreasonable delay on the part of the applicant and that the matter is of such urgency that the applicant could not reasonably have given such notice; and

b) in such event the order for interim relief shall be for a limited period not exceeding two weeks sufficient to enable such respondents to be given notice of the application and to be heard in opposition thereto on a date to be then fixed. ..."

In interpreting this rule, one must be mindful that Rule 2(1) has made it mandatory that,

a) all parties who would likely to get affected adversely by granting of such interim relief must be made respondents to the application,

b) every application for an interim relief shall be made with notice to the adverse parties or respondents.

c) the notice must communicate to the respondents the intention of the petitioner to support such application.

d) the notice must be accompanied by a full set of material that the petitioner intends to rely on.

It could also be seen that Rule 2(1) is a rigid one and that any petitioner supporting an application for interim relief must do so with notice to the respondents. This meaning could be gathered from the presence of the word 'shall' in Rule 2(1). It clearly indicates that giving notice to the

respondents is mandatory and stands as a pre requisite to supporting an application for interim relief. Any applicant for interim relief must therefore necessarily comply with it. It is not open for anyone to deviate from that provision.

There is however a proviso to this rule. It has to be borne in mind that Rule 2(1) is the rule proper and Rules 2(1)(a) and 2(1)(b) only serve as proviso's to the rule proper. The effect of the proviso is that court may grant interim relief "although such notice has not been given to some or all of the respondents" only when it is satisfied of the following two things. They are,

I. that there has been no unreasonable delay on the part of the applicant in giving such notice referred to in Rule 2(1)(a), and
II. that the matter is of such urgency that the applicant could not reasonably have given such notice

A closer look at the Rule 2(1)(a) shows that the presence of a solitary, yet important word 'and' therein, insists that a petitioner must satisfy both the above conditions.

It is the fervent wish and the right expectation of courts that the Petitioners filing applications for discretionary reliefs come to invoke the powers of court without ulterior motives on their part. This expectation assumes a greater importance particularly when a petitioner is seeking the court to invoke the extraordinary powers given to it in terms of Rule 2(1)(a).

Thus the Petitioners making an ex parte application, supporting it and obtaining interim reliefs in this case with a deliberate ignorance of giving notice to the Respondents in the circumstances of this case is definitely very much more than 'a reasonable delay' which is excusable under Rule 2(1)(a).

The Petiotioners had 07 days' time gap between filing of this case and the date on which it actually supported it in court. There was sufficient time for the Petitioners to give notice to the Respondents if they were seriously interested in complying with Rule 2(1). However the Petitioners have chosen not to comply with that Rule.

Brown & Co. Ltd. and another Vs. Ratnayake, Arbitrator and others[10] is a case where the dismissal by the Court of Appeal of an application for a Writ on the basis of a failure on the part of the petitioner in that case to annex to the petition, certified copies of relevant proceedings with regard to the particular dispute. The Supreme Court referring to Rule 46 of the Supreme Court Rules of 1978 which required the petition to be supported by affidavit and to be accompanied by original or duly certified copies of documents material to the case in the form of exhibits stated thus ".... The Rule itself is a commonsense response to litigants wanting the disturbance of an order or award. It is no more than a normal procedural step deemed necessary to inform both court and respondents of the matters of complaint. It is consistent with ordinary practice. One cannot claim a right

[10]1994 (3) SLR 91

to proceed to the next step without compliance with a valid invocation of jurisdiction in the first place. Such would lead to uncertainty, unreasonableness and oppressive results. In this sense the rule is mandatory. ..."[11]

Thus the message we could get from the above judgment in so far as we could apply to the circumstances of the instant case is that the Rules must be followed in order to avoid uncertain, unreasonable and oppressive results.

Subsequent to this inquiry it has now become clear that this is not an instance in which this court should have acted under the proviso to the Rule 2(1). In the face of severe criticism by the learned Senior Deputy Solicitor General appearing for the 1st, 2nd and 3rd Respondents and the learned President's Counsel appearing for the 5th Respondent, the Petitioners have not offered any explanation as to why they had chosen that path to obtain this order.

As has been shown before, Petitioners were duty bound to comply with the Rules particularly when they have asked for interim reliefs from this court. There is an additional burden on the Petitioners in this case to comply with these rules due to the hardships that an order for interim reliefs so widely drafted would cause to the patients in government hospitals suffering from cancer.

What has come to light now is that this court would never have granted this order if it had the benefit of an inter parte inquiry. In the absence of

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[11](Ibid) at page 100

any explanation by the Petitioners this court has no alternative but to conclude that the Petitioners have deliberately refrained from giving notice to the respondents about their intentions to apply for interim reliefs. Such conduct in the circumstances of this case amounts to a breach of uberimmae fides on the part of the Petitioners in their run up to achieving an order from this court for interim reliefs. This Court needs to stress that the requirement of uberimmae fides on the part of Petitioner has been recognized over and over again as being of paramount consideration when a court considers the granting of interim reliefs.

For the foregoing reasons we conclude that the interim order issued by this court as per prayer (h) of the Petition should not be extended. The said interim order must be vacated and dissolved forthwith. Registrar of this Court should take steps to inform this decision to the 1st,2nd, 3rd and 5th Respondents immediately.

JUDGE OF THE COURT OF APPEAL

Vijith K. Malalgoda PC J

I agree,

PRESIDENT OF THE COURT OF APPEAL