



[2017] JMSC Civ. 162

**IN THE SUPREME COURT OF JUDICATURE OF JAMAICA**

**IN THE CIVIL DIVISION**

**CLAIM NO. CL. 2002/P.00040**

<b>BETWEEN</b>	<b>PFIZER LIMITED</b>	<b>CLAIMANT</b>
<b>AND</b>	<b>MEDIMPEX JAMAICA LIMITED</b>	<b>1<sup>ST</sup> DEFENDANT</b>
<b>AND</b>	<b>NMF PHARMACEUTICALS LIMITED</b> <b>(t/a Mac's Pharmaceuticals)</b>	<b>2<sup>ND</sup> DEFENDANT</b>
<b>AND</b>	<b>LASCO DISTRIBUTORS LIMITED</b>	<b>3<sup>RD</sup> DEFENDANT</b>

**IN OPEN COURT**

**Mrs. Denise E. Kitson QC, Mr. Kevin A. Williams, Mr. David Ellis and Ms. Khian Lamey instructed by Grant Stewart Phillips & Co. for the Claimant**

**Dr. Lloyd G. Barnett and Mr. Ian H. Robins for the 1<sup>st</sup> Defendant**

**Mr. Vincent A. Chen, Mr. Leonard S. Green, Ms. Sylvan N. Edwards and Ms. Nicole-Anne Fullerton instructed by Chen, Green & Co. for the 3<sup>rd</sup> Defendant**

**Heard: 26<sup>th</sup>, 27<sup>th</sup>, 28<sup>th</sup>, 29<sup>th</sup>, 30<sup>th</sup> September, 21<sup>st</sup>, 22<sup>nd</sup>, 23<sup>rd</sup>, 24<sup>th</sup>, 25<sup>th</sup> November 2016, 23<sup>rd</sup>, 24<sup>th</sup>, 25<sup>th</sup>, 26<sup>th</sup> January, 19<sup>th</sup>, 20<sup>th</sup>, 21<sup>st</sup> April & 3<sup>rd</sup> November 2017**

**Damages – Assessment of damages based on undertaking given on obtaining an interlocutory injunction – Whether damages are to be awarded for post-injunction period**

**COR: V. HARRIS J**

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## **INTRODUCTION AND BACKGROUND**

- [1] The claimant, Pfizer Limited ('Pfizer'), is a well known international manufacturer and exporter of pharmaceuticals. One of Pfizer's products is the besylate salt of amlodipine ('amlodipine'), a pharmaceutical marketed as Norvasc. This preparation is a calcium channel blocker ('CCB'), utilised in the treatment of hypertension. Pfizer entered the Jamaican market in 1994 and had a monopoly on the sale of drugs containing the besylate salt of amlodipine, owing to its patent.
- [2] The monopoly was broken in or about 2001. Clearly in recognition of the demand for such a product in Jamaica, the 1<sup>st</sup> defendant ('Medimpex'), entered the market and began trading in its own generic version of the product which they marketed as Normodipine whereas the 3<sup>rd</sup> defendant ('Lasco') began trading on the 9<sup>th</sup> of January 2002, and marketed its version as Las Amlodipine. The 2<sup>nd</sup> defendant ('NMF') also entered the market in or around 2002 selling its own brand of generic amlodipine called Amlopres.<sup>1</sup>
- [3] Pfizer's sales were affected by the competing products and in June 2002, it instituted proceedings against the defendants alleging that its patent for amlodipine had been infringed. NMF ceased all dealings in amlodipine at some time prior to the 18th of June 2004 and since then it has not participated in the ensuing proceedings.
- [4] On the 29<sup>th</sup> of March 2005, Pfizer sought and obtained an interlocutory injunction restraining, *inter alios*, Medimpex and Lasco from selling or trading in products containing amlodipine. The injunction was granted on the basis that Pfizer had a patent for the said product and Pfizer provided the usual undertaking as to damages.

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<sup>1</sup> See: paragraph 4 of the witness statement of Basil Wright filed on June 26, 2016.

- [5] At trial, Pfizer's patent was ruled invalid by Jones J on the 30<sup>th</sup> of April 2009. Accordingly, Jones J refused the applications for declarations, a permanent injunction and other orders sought by Pfizer and gave judgment for Medimpex and Lasco with costs to be agreed or taxed. At the time of judgment the court also ordered an enquiry as to the damages suffered by the defendants as a result of the interlocutory injunction granted to Pfizer under its undertaking in damages.
- [6] The Court of Appeal (Panton P, Harrison and Dukharan JJA) affirmed the decision of Jones J on the 31<sup>st</sup> of May 2012 and similarly ordered an *'inquiry to be conducted as regards damages payable to the Defendants consequent on the undertakings given for the grant of the injunction against them.'* The inquiry was delayed by virtue of Pfizer's appeal to the Judicial Committee of the Privy Council ('UKPC'), which advised that the appeal should be dismissed on the 2<sup>nd</sup> of July 2014.
- [7] The matter was remitted to this court for an enquiry to be conducted as to the damages suffered by Medimpex and Lasco as a result of the injunction. Accordingly, this judgment relates to the assessment of damages, in furtherance of the orders of Jones J and the Court of Appeal.
- [8] I wish to thank all the Attorneys in this matter for their hard work, industry and assistance to the court. I want to make it known that I have carefully considered all the submissions and authorities in this matter whether they have been referred to or not.

## **THE UNDERTAKING**

[9] Where a litigant applies for an interlocutory injunction, it is the usual practice not to grant it unless the claimant gives an undertaking in damages. The rationale is that the proceedings are interlocutory and the issues have not been finally determined. As such, the interlocutory injunction is therefore granted to preserve the status quo until the determination of the issues. Should the claimant eventually fail, fairness dictates that he should undertake to compensate the defendant(s) for any damage suffered by reason of the injunction having been granted (see: the dicta of Lord Diplock in ***F. Hoffmann-La Roche & Co. A.G. and others v Secretary of State for Trade and Industry*** [1975] AC 295, 360; ***Smith v Day*** (1882) 21 Ch. D. 421, 429 and ***Griffith v Blake*** (1884) 27 Ch. D. 474).

[10] With regards to the instant case, Pfizer in obtaining the interlocutory injunction provided the usual undertaking as to damages. The specific wording of the undertaking given by Pfizer was as follows:

*“The Claimant gives the usual undertaking in damages should it become necessary.”*

[11] The undertaking was in keeping with rule 17.4 (2) of the **Civil Procedure Rules** (‘the CPR’) 2002 which provides:

*“Unless the court otherwise directs, a party applying for an interim order under this rule must undertake to abide by any order as to damages caused by the granting or extension of the order.”*

[12] Counsel for Lasco submitted that the words ‘*caused by*’ in rule 17.4(2) are in line with the development of the law which permits flexibility in the assessment of losses.

## **THE LEGAL PRINCIPLES**

### **Summary of the parties' submissions**

[13] It was accepted by Pfizer that the interlocutory injunction was in force from the 29<sup>th</sup> of March, 2005 to the 31<sup>st</sup> of May, 2012. It is Pfizer's position that the court should determine the losses incurred by the defendants by reason of them having been restrained from making sales in the market during this seven (7) year period. Counsel for Pfizer further submitted that the enquiry as to damages in this matter should be based purely on contractual principles. Accordingly, the general rules of causation, remoteness, foreseeability and mitigation are live and should be applied to the assessment undertaken at the instance of Medimpex and Lasco. Reliance was placed on the oft-cited dictum of Lord Diplock from **F. Hoffmann-La Roche v Secretary of State for Trade** (supra) at 361D-F:

*"The court has no power to compel an applicant for an interim injunction to furnish an undertaking as to damages. All it can do is to refuse the application if he declines to do so. The undertaking is not given to the defendant but to the court itself. Non-performance of it is contempt of court, not breach of contract, and attracts the remedies available for contempts, but the court exacts the undertaking for the defendant's benefit. It retains a discretion not to enforce the undertaking if it considers that the conduct of the defendant in relation to the obtaining or continuing of the injunction or the enforcement of the undertaking makes it inequitable to do so, **but if the undertaking is enforced the measure of the damages payable under it is not discretionary. It is assessed on an inquiry into damages at which principles to be applied are fixed and clear. The assessment is made upon the same basis as that upon which damages for breach of contract would be assessed if the undertaking had been a contract between the plaintiff and the defendant that the plaintiff would not prevent the defendant from doing that which he was restrained from doing by the terms of the***

*injunction*: see *Smith v. Day* (1882) 21 Ch.D. 421, per Brett L.J., at p. 427.” (Emphasis added)

- [14] Further, learned counsel for Pfizer has submitted that it would be unreasonable to award the defendants damages for the post-injunction period. In respect of this submission, the court was asked to have regard to the evidence that after the injunction was discharged Medimpex made a decision not to return to the amlodipine market. Lasco, on the other hand returned to the market in September 2012 and went on to sell a greater volume of its product than it did prior to the injunction.
- [15] In essence, counsel for Pfizer contends that it is not permissible in law to award damages for a period where, (a) the injunction was not in place; (b) the losses claimed cannot be substantiated by evidence; and (c) such a claim for losses would represent future profits, which would not be reasonably foreseeable and/or too remote especially where the defendants never notified the claimant of any such likely losses. Reliance was placed on ***Les Laboratoires Servier v Apotex Inc*** [2008] EWHC 2347 (Ch), ***Richard John Hone and others v Abbey Forwarding Ltd. (In Liquidation) and another*** [2014] EWCA Civ 711, ***Smith v Day*** (supra), ***Schlesinger v Bedford*** [1893] 9 TLR 370, and ***Hadley and Another v Baxendale and Others*** (1854) 9 Ex. 341.
- [16] It is Medimpex’s position that the losses recoverable are not limited to the period for which the injunction was in effect but includes losses which continued as a result of the injunction, that is, losses which are subsequent to the discharge. Reliance was placed on ***F. Hoffmann-La Roche v Secretary of State for Trade***, ***Les Laboratoires Servier v Apotex Inc***, ***Tharros Shipping Co. Ltd v Bias Shipping*** [1994] 1 Lloyd’s Rep 577 (‘the ***Apotex*** case’), ***Algonquin Mercantile Corporation v. Dart Industries Canada Limited*** (1996) 12 CPR (3d) 299 (Federal Court of Canada), and ***Gee, Mareva Injunctions and Aston Piller Relief*** (4th ed.), p. 166.

- [17] Learned counsel for Medimpex submitted that even though the evidence indicates that Medimpex was unable to re-enter the market, the demand for amlodipine products continued to be robust and as such there is an inference that, but for the injunction, Medimpex would have continued to experience profitable sales of its Normodipine after May 2012. Meximpex is claiming damages up to 2021, nine (9) years post injunction.
- [18] Counsel for Medimpex also asked the court to have regard to the 'first mover advantage' and to apply a 'liberal assessment' as Sales J did in **Astrazeneca AB and another v KRKA, dd Novo Mesto and another** [2014] EWHC 84 (Pat), which was endorsed on appeal [2015] EWCA Civ 484 (the '**Astrazeneca AB** case').
- [19] Further, on the liberal assessment point, counsel has asked the court to have regard to paragraphs [15] and [16] of the **Astrazeneca AB** case where the Court of Appeal endorsed the third clarification by Norris J:

*"[15] Reverting to Servier, Norris J then went on to clarify the approach to be adopted in these terms:*

*"7. ...*

*8. ...*

*9. Third, whilst it is for Apotex to establish its loss by adducing the relevant evidence, I do not think I should be over eager in my scrutiny of that evidence or too ready to subject Apotex' methodology to minute criticism. That is so for two reasons, quite apart from an acceptance of the proposition that the very nature of the exercise renders precision impossible. (a) Whilst, in order to obtain interlocutory relief, Servier will not have had to persuade Mann J that it was easy to calculate Apotex' loss in the event of the injunction being wrongly granted, it will have had to persuade him that that task was easier than the calculation of its own loss in the event that the injunction was withheld. The passages I have cited from its skeleton argument and evidence show that it did so. Having*



*obtained the injunction on that footing it does not now lie in Servier's mouth to say that the task is one of extreme complexity and that the court should adopt a cautious approach. Having emphasised at the interlocutory stage the relative ease of the process, it should not at the final stage emphasise the difficulty. (b) In the analogous context of the assessment of damages for patent infringement, in General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd [1975] 2 All ER 173 at 177, [1976] RPC 197 at 212 Lord Wilberforce said:*

*"There are two essential principles in valuing the claim: first, that the plaintiffs have the burden of proving their loss: second, that the defendants being wrongdoers, damages should be liberally assessed but that the object is to compensate the plaintiffs and not to punish the defendants."*

*The principle of "liberal assessment" seems to me equally applicable in the present context. Although a party who is granted interim relief but fails to establish it at trial is not strictly a "wrongdoer", but rather one who has obtained an advantage upon consideration of a necessarily incomplete picture, he is to be treated as if he had made a promise not to prevent that which the injunction in fact prevents. There should as a matter of principle be a degree of symmetry between the process by which he obtained his relief (an approximate answer involving a limited consideration of the detailed merits) and that by which he compensates the subject of the injunction for having done so without legal right (especially where, as here, the paying party has declined to provide the fullest details of the sales and profits which it made during the period for which the injunction was in force)."*

*[16] The first and second of these clarifications have no bearing on this appeal and I shall say no more about them. However, the third is relevant and again I would endorse it..."*

- [20]** Similarly, Lasco is claiming that it is entitled to damages for the period up to 2022, that being for a period of ten (10) years after the injunction was discharged. One of its main arguments is that during the life of the injunction several other parties entered the market and started to deal in generic products containing amlodipine. Lasco claims that this was brought to Pfizer's attention but

no effective steps were taken to either similarly restrain the third parties or to have the injunction discharged. According to Lasco, the effect of Pfizer's inaction had a profound negative effect on their ability to regain its market share on the lifting of the injunction. The court has been invited to follow the reasoning from the recently decided case of **Astrazeneca AB**.

[21] Learned counsel for Lasco accepted that the traditional approach to the assessment was as stated by Lord Diplock in **F. Hoffmann-La Roche v Secretary of State for Trade**<sup>2</sup> namely that the assessment is akin to the one done for damages for breach of contract. However, it was submitted that there is authority for the proposition that damages can be assessed on a wider basis. Reliance was placed on the dicta of James LJ in **Graham v Campbell** (1878) 7 Ch D 490 at page 494 and Aicken J in **Ansett Transport Industries (Operations) Pty Ltd. v Halton** (1979) 25 ALR 639<sup>3</sup>.

[22] Further, reference was made to the dicta of Norris J in the **Apotex** case. It is Lasco's position that this summarises the modern principles in relation to damages payable in cases where an undertaking is given pursuant to an injunction. In particular, counsel for Lasco is submitting that, *'It is to be noted from Servier that the remedy under a cross-undertaking in damages is by way of equitable compensation rather than common law damages, so the defendant has to show the damage would not have been sustained but for the injunction and not that the injunction was the sole cause.'*<sup>1</sup> Reference was also made to the case of **Lilly Icos LLC et al v. 8PM Chemists Limited et al** [2009] EWHC 1905 (Ch).

[23] On the point of remoteness and foreseeability, counsel for Lasco contends that the principle as stated by Lord Diplock in **F. Hoffmann-La Roche v Secretary of State for Trade** has been subsequently expanded upon by cases such as

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<sup>2</sup> See: paragraph [13] above

<sup>3</sup> This case was appealed **Air Express v Ansett Transport Industries (Operations) Pty. Ltd** [1981] HCA 75; it was from this case that the dictum which is being relied on came.

**Richard John Hone and others v Abbey Forwarding Ltd. (In Liquidation) and another and Fiona Trust & Holding Corporation v Yuri Privalov & Others** [2016] EWHC 2163 (Comm) to include recoverability for matters that might not necessarily have been in the parties contemplation at the time of the granting of the injunction. McCombe LJ and Males J, respectively, both expressed the view that Lord Diplock's analogy with breach of contract is not exact as such and that there has to be some flexibility and/or room for exception.

[24] In the **Astrazeneca AB** case, the trial judge (Sales J) referred to the dicta of Norris J from the **Apotex** case, as explaining the general principles to be applied by the court when assessing the damages payable under a cross-undertaking. The England and Wales Court of Appeal endorsed this statement of the principles. Kitchin LJ at paragraph [12] of the judgment stated:

*"[12] The parties were agreed before the judge and before this court that the general principles to be applied in assessing the damages payable under a cross-undertaking given in respect of the grant of an interim injunction are those explained by Norris J in **Les Laboratoires Servier v Apotex Inc** [2008] EWHC 2347 (Ch), [2009] FSR 220, [2009] IP & T 600. In that case Norris J said this:*

*"[5] The principles of law sufficient to enable me to quantify compensation in this case may be shortly stated:*

*(a) The undertaking is to be enforced according to its terms. In the instant case (as in many others) it is that Servier will comply with any order the court may make 'if the court ... finds that this order has caused loss to the Defendants'. The question for me is therefore: what loss did the making of the order and its continuation until discharge cause to Apotex?*

*(b) The approach is therefore essentially compensatory and not punitive;*

*(c) The approach to assessment is generally regarded as that set out in the obiter observation of Lord Diplock in **Hoffmann-La Roche v Secretary of State for Trade** [1975] AC 295 at 361E namely:*

*'The assessment is made upon the same basis as that upon which damages for breach of contract would be assessed if the undertaking had been a contract between*

*the Plaintiff and the Defendant that the Plaintiff would not prevent the Defendant from doing that which he was restrained from doing by the terms of the injunction: see **Smith v Day** (1882) 21 Ch D 421 per Brett LJ at page 427.'*

*(d) What Apotex was trying to do (and what the order restrained it from doing) was to enter a new market for the sale of generic perindopril. It was denied exploitation of this opportunity. The outcome of such exploitation is attended by many contingencies but **Chaplin v Hicks** [1911] 2 KB 786 establishes (per Vaughan Williams LJ at p 791) that whilst 'the presence of all the contingencies on which the gaining of the prize might depend makes the calculation not only difficult but incapable of being carried out with certainty or precision' damages for the lost opportunity are assessable.*

*(e) The fact that certainty or precision is not possible does not mean that a principled approach cannot be attempted. The profits that Apotex would have made from its exploitation of the opportunity to sell generic perindopril depend in part upon the hypothetical actions of third parties (other potential market participants) and in part upon Servier's response to them. A principled approach in such circumstances requires Apotex first to establish on the balance of probabilities that the chance of making a profit was real and not fanciful: if that threshold is crossed then the second stage of the inquiry is to evaluate that substantial chance (see **Allied Maples v Simmons & Simmons** [1995] 1 WLR 1602). As Lord Diplock explained in **Mallett v McMonagle** [1970] AC 166 at 176E-G '... in assessing damages which depend on its view as to what ...would have happened in the future if something had not happened in the past, the court must make an estimate as to what are the chances that a particular thing ... would have happened and reflect those chances, whether they are more or less than even, in the amount of damages it awards...'*

*(f) The conventional method of undertaking this exercise is to assess damages on a particular hypothesis and then to adjust the award by reference to the percentage chance of the hypothesis occurring. In many cases it is sufficient to postulate one hypothesis and make one discount: but there is no reason in principle why one should not say that either Scenario 1 or Scenario 2 would have occurred and to discount them by different percentages. That is the course which Mr Watson QC urged in the present case: and I note that it has some support in **Earl of Malmesbury v Strutt & Parker** [2007] PNLR 570.”*

- [25] I would adopt this summary of principles in assessing the damages payable by Pfizer, particularly since all the parties in the instant matter have relied on the **Apotex** case, as well as a number of the authorities referred to by Norris J and by extension Kitchin LJ. I will similarly ask myself: what loss did the making of the order (i.e. the injunction granted by N. McIntosh J) and its continuation until discharge cause to Medimpex and Lasco?
- [26] I would also be mindful that the approach is therefore essentially compensatory and not punitive. While I will have regard to the general approach as set out in the obiter observation of Lord Diplock in **F. Hoffmann-La Roche v Secretary of State for Trade**, *'The assessment is made upon the same basis as that upon which damages for breach of contract would be assessed if the undertaking had been a contract between the Plaintiff and the Defendant that the Plaintiff would not prevent the Defendant from doing that which he was restrained from doing by the terms of the injunction: see **Smith v Day** (1882) 21 Ch D 421 per Brett LJ at page 427.'*; I will also have regard to the reasoning of McCombe LJ from **Richard John Hone and others v Abbey Forwarding Ltd. (In Liquidation) and Another**, which was relied on by both counsel for Pfizer and Lasco.
- [27] After reviewing a number of authorities McCombe LJ had this to say:

*“63. In the result, therefore, and perhaps not surprisingly, I reach the conclusion that the law as to the recoverability of loss suffered by reason of a cross-undertaking is as stated by Lord Diplock in his dictum in Hoffmann-La Roche, but with this caveat. **Logical and sensible adjustments may well be required, simply because the court is not awarding damages for breach of contract. It is compensating for loss for which the defendant “should be compensated”** (to apply the words of the undertaking). Labels such as “common law damages” and “equitable compensation” are not, to my mind, useful. **The court is compensating for loss caused by the injunction which was wrongly granted. It will usually do so applying the useful rules as to remoteness derived from the law of contract, but because there is in truth no contract there has to be room for exceptions.***

*64. In my judgment, the law also meets the justice of the matter. A defendant wrongly enjoined should be compensated for losses that he should not have suffered, but a claimant should not be saddled with losses that no reasonable person would have foreseen at the time when the order was made, unless the claimant knew or ought to have known of other circumstances that was likely to give rise to the particular type of loss that occurred in the case at hand. A claimant may, however, find himself liable for losses which would not usually be foreseen in particular cases. One such case may be if a loss, not usually foreseeable, arises before a defendant has had any real opportunity to notify the claimant of the likely loss or sensibly to apply to the court for a variation.*

*65. In mentioning this possible example, the court must be realistic as to the dilemma facing a defendant when served, out of the blue, with a freezing order. Some claimants are far from reasonable in practice – the present case provides a very clear example (see below). Applications for variation are not that simple. They take time to prepare and are not without cost. At the same time, under the terms of the order, the defendant will be limited as to costs and living expenses and will, no doubt, also be under requirements to identify and verify his assets. In addition, he will be seeking quickly to assess, with his lawyers, the*

*claimant's evidence, both with regard to whether to oppose continuation of the order on the return day (or perhaps to apply for variations) and with regard to the ultimate defence of the action. Approaches to claimants to agree variations, or even to provide suitable written indications to banks and other third parties that particular payments are not caught by the order, are often far from straightforward. If, in such circumstances, a defendant is shown to have suffered an unusual loss, then in my judgment the claimant should not be surprised if the court orders him to pay for it.*

*66. In the context of the present case, and before turning to factual issues, I would add that I accept Mr Coppel's submission that, for a loss to be recoverable, the remoteness rules only require that the claimant giving the undertaking should have reasonably foreseen loss of the type that was actually suffered by the defendant and not the particular loss within that type: see (again by analogy) Chitty on Contracts, 21st Edn. Vol. 1 paragraph 26-113, p.1828.*

*67. I do not consider that the judge misstated the principles applicable, as the Appellants contend, when he said (at paragraph 27 of the judgment) that the rules rendered,*

*“...recoverable either loss suffered by the Injunctee that falls within the first or second rule in Hadley v Baxendale and arises from circumstances that were either actually known to the injunctor or deemed to have been known to the injunctor at the time when the injunction is granted...”*

*Nor do I think the judge was in error (in paragraph 29) when he said that,*

*“...the cardinal point remains this: absent express notice of special circumstances [my emphasis] arising after the date when the injunction is granted, the conventional approach is that compensation will not be recoverable for events occurring after the grant of the injunction that could not be foreseen at the time when the injunction was granted...”*

*68. In my judgment, these passages were not indicating that the judge required proof of “actual notice of the actual circumstance” creating the loss before compensation for it was recoverable (c.f. paragraph 66 of the*

*Appellants' skeleton argument). If a claimant has knowledge of special circumstances, giving rise to potential type of loss, or other actual knowledge of a particular loss it will be recoverable, but what amounts to such knowledge will be intensely fact-sensitive. However, as will appear below, I do think that in respect of one of the claims, the judge did wrongly require proof of "actual notice of the actual circumstance" creating the loss. (Emphasis added)*

- [28] I would adopt the reasoning of McCombe J, as stated above, as well as, the following dictum at paragraph [124]: *"In my judgment, I would not adopt an approach of awarding either "modest" damages on the one hand or "generous" damages on the other. **I think that the correct approach should be award [sic] realistic compensation for what has occurred.**"* In so doing, I agree that the court must consider all the circumstances including the presence of certain 'contingencies' when assessing damages as well as make discounts/adjustments by reference to the likelihood of a hypothesis occurring (see: Norris J's principles (d) – (f)).
- [29] Finally, I would accept counsel for Pfizer's submission that the liberal assessment principle does not entitle either of the defendants to damages which cannot be supported by evidence. Counsel for Pfizer submitted that a 'liberal assessment' is a means of assessment which may be utilised by a judge, who when faced with a hypothetical scenario, must estimate a realistic award based on the relevant indications available and admitted into evidence. The principle does not serve as a substitute for the fundamental principles of the law of evidence. Although Lord Wilberforce was speaking in relation to an assessment of damages where a patent had been infringed, in ***General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd*** [1975] 2 All ER 173,179, I find the following statement apt: *'The ultimate process is one of judicial estimation of the available indications.'* It is also clear from the authorities that the court must embark upon a balancing exercise, consequently regard must be had to all the



relevant evidence in order to determine the appropriate weight to be given in arriving at the final judicial estimate.

- [30] I will address the question as to whether or not Medimpex and/or Lasco are to be awarded damages for the post-injunction period later in the decision.

## **THE EVIDENCE**

- [31] For convenience the evidence of each party's witnesses, save for the financial experts, has been set out below. I will return to the financial experts subsequently. I wish to indicate that I found that the witnesses all gave evidence in a forthright manner. However, it is important to determine what aspect of their evidence is reliable or not in the context of the issues to be resolved.

### **Evidence for Pfizer**

- [32] Pfizer called two (2) ordinary witnesses and a medical doctor whose evidence is summarised as follows:

#### **Mr. Ronald Camps**

- [33] Mr. Camps gave evidence in his capacity as the Regional Sales Manager at Pfizer Caribbean. He stated that both Pfizer Caribbean and the claimant are wholly owned subsidiaries of Pfizer Inc, collectively and individually referred to as Pfizer.
- [34] Mr. Camps outlined the trajectory of Norvasc sales in Jamaica showing that when the generics entered the market its sales figures declined significantly and that they recovered during the injunction period. (This evidence shows clearly the benefit of the injunction to Pfizer).
- [35] The point highlighted by Mr. Camps that is more notable where the instant case is concerned, was his evidence on the percentage of the market for hypertension drugs that amlodipine had, the conclusion being that this preparation was a small

per cent of the market for these drugs.<sup>4</sup> (This amounted to four per cent (4%) which from a dollar value standpoint was between two to seven per cent (2-7%).

**[36]** Given that this aspect of Mr. Camp's evidence is supported by documentary evidence, I accept it.

Mr. Sebastian Sas

**[37]** Mr. Sas gave evidence for Pfizer as the Finance Director of the Central America and Caribbean division of Pfizer Inc. He presented sales figures showing that the sales of Norvasc were significantly greater, for the most part,<sup>5</sup> during the injunction period.

**[38]** This aspect of the evidence was not disputed and therefore is accepted by the court.

Dr. Sheldon Tobe

**[39]** Dr. Tobe gave evidence via video-link. He is an experienced Canadian Professor of Medicine. The focus of his practice over the past thirty (30) years has been on improving the lives of people who are at risk of, or who have been diagnosed with kidney disease by focusing on the diagnosis and control of hypertension. He has conducted research in Tanzania, Russia and Saudi Arabia. He was asked to give his expert opinion on whether amlodipine products are regarded internationally, as established by clinical research, as the most appropriate medication for the treatment of hypertension in persons of colour.

**[40]** He directed the court to two (2) studies which proved particularly important in arriving at a conclusion on that question. Firstly, the Major outcomes in High-risk

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<sup>4</sup> See: paragraph 6 of Supplemental Witness Statement filed July 14, 2016

<sup>5</sup> There was a significant decline in sales 2011 when Norvasc was no longer listed with the NHF

hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker versus diuretic: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial conducted by the ALLHAT Collaborative Research Group (2002) (the 'ALLHAT Report'). Secondly, and more recently the data was reassessed in a review conducted in Canada titled Intra-class Differences among Antihypertensive Drugs.

[41] Dr. Tobe opined that there is not sufficient evidence that amlodipine leads to superior blood pressure control or better survival outcomes over diuretics in persons of African descent with hypertension. He also noted that there were lower cost diuretics and other long acting CCBs blockers that were effective. He ended his report by noting, *“while calcium channel blockers like amlodipine are excellent once a day therapy for lowering blood pressure in people of African origin with both evidence for efficacy and improved long term outcomes, thiazide and thiazide diuretics are also once a day therapy and have even stronger evidence for efficacy and improved long term outcomes. This is why the major guidelines organizations like JNC8 and CHEP in Canada recommend both classes of agents for the management of hypertension.”*

[42] Dr. Tobe came across as a straightforward and honest witness and I accept the evidence that he gave.

### **Evidence for Medimpex**

[43] Medimpex called two (2) ordinary witnesses. Their evidence is summarised as follows:

#### Mr. Basil Wright

[44] Mr. Wright, the Regional Marketing Manager of Medimpex Jamaica Limited, gave evidence that Medimpex started importing and distributing a generic form of

amlodipine under the name Normodipine. He reported a steady increase year over year in the sales of Normodipine<sup>6</sup> starting in July 2001 up until the imposition of the injunction in 2005. (The total gross income from sales of Normodipine for the period July 2001 to March 2005 amounted to almost JMD\$120 million). He asserted that when the injunction was imposed and Medimpex was obliged to cease its trade, it had stock to the value of JMD\$5,205,655.00,<sup>7</sup> which could not be returned to the manufacturer and therefore had to be destroyed.

**[45]** This aspect of Mr. Wright's evidence is backed by financial records and is accepted by the court.

**[46]** Mr. Wright said that the sale of Normodipine would have continued to increase even with the presence of Lasco's generic undercutting it in sale price. He suggested that this was tied to patient loyalty and familiarity which often made it unlikely for them to switch to another drug. He notably stated that considerable discounts through government programmes (NHF/JADEP) would contribute to this effect as these significantly reduced the cost burden.

**[47]** Before accepting this portion of Mr. Wright's evidence, a careful evaluation is required especially in light of financial data that was presented (on the actual market shares and sales pre-injunction), as well as, the evidence that came from two (2) of Lasco's witnesses - Ms Hulyn Blackwood and Ms Juliet Kossally-Chang that there was in fact switches from Normodipine to Las Amlodipine. I accept Ms Blackwood and Ms Kossally Chang on this aspect of the evidence and am inclined to the view that in the counterfactual scenario Medimpex's sales and market shares would have declined as a result of Las Amlodipine's prices.

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<sup>6</sup> See: paragraph 11 of Witness Statement filed June 27, 2016. The figures given are gross income from sales.

<sup>7</sup> This figure has been amended as a result of the exchange rate used. See: paragraph [116] to [117] below.

**[48]** It may be noted here that certain portions of paragraph 18 of Mr. Wright's witness statement were struck out on the application of counsel for Pfizer.

Ms Loraine Hussey

**[49]** Ms Hussey gave evidence as a Systems Supervisor at Medimpex Jamaica Limited. She said she is responsible for the company's Information Technology System, the administration and security of data and of ensuring that reports are accurate and complete. Ms Hussey told the court that the computers were in working condition and that she extracted the records for use in this matter from the database.

**[50]** Her evidence is agreed.

**Evidence for Lasco**

**[51]** With the exception of its financial expert Mr. W. St. Elmo Whyte and Professor Rainford Jonathan Wilks, Lasco called seven (7) witnesses: two (2) pharmacists, four (4) employees of the company and a medical doctor. Their evidence is summarised as follows:

Ms Hulyn Blackwood

**[52]** Ms Blackwood is a senior pharmacist at Young's Pharmacy in May Pen, Clarendon. The crux of her evidence is that when generic amlodipine was introduced it was selling at a considerably lower price than Norvasc and started to outsell the Pfizer drug. She asserted that many patients switched to the cheaper generic.

**[53]** When cross-examined by Dr. Barnett she said that Las Amlodipine sold better than Normodipine because of the price. However, under cross-examination by Mr. Williams she indicated that her evidence as to the switching between Norvasc and the generics was limited to what took place at the pharmacy where she worked.

Ms Juliet Kossally-Chang

- [54] Ms Kossally-Chang is a pharmacist who owns and operates Independence City Pharmacy in the parish of St. Catherine. She says that through the computerisation of her records at the pharmacy she has accurate records since about January 2001. She asserted that with the introduction of Las Amlodipine and Normodipine the sales of Norvasc declined drastically. Normodipine initially cut into the sales of Norvasc and thereafter Las Amlodipine cut significantly into the sales of both Norvasc and Normodipine, as it was the cheapest of the three (3) drugs.
- [55] Ms Kossally-Chang agreed under cross-examination by learned counsel for Pfizer Mr Williams, that all the information she gave was in relation to her experience at Independence City Pharmacy and she couldn't speak for any other region. She also said that a good percentage of the prescriptions she received were from persons who were hypertensive. She further stated that about twenty-five per cent (25%) of those patients were on Norvasc, and that the lion's share of the Norvasc users switched to Normodipine and then to Las Amplodipine because of the lower prices.
- [56] I find that both Ms Blackwood and Ms Kossally-Chang are honest and reliable witnesses. I have taken into account the evidence that they gave when cross-examined. I find that it shows that their experiences with the sales of the three pharmaceuticals in question (and any switching from one to the other) were limited to what took place at the respective pharmacies where they worked and was not representative of what occurred in other pharmacies located elsewhere in Jamaica.

Mr. Peter Hylton

- [57] Mr. Hylton, at the time of his evidence, was the Information Technology Manager at Lasco. He noted that his primary duty is the supervision and operation of all the computer hardware and systems assuring the security, accuracy and

completeness of the system. He noted that Lasco backs up the data with a company in the United States and that the computers were operating properly at all material times.

**[58]** Mr. Hylton's evidence is agreed.

Ms Wincella Cummings

**[59]** Ms Cummings, at the time of her evidence had over thirty-seven (37) years of experience and works as a Business Management Consultant. She was previously employed at Lasco as General Manager and Group Financial Officer.

**[60]** Under cross examination Ms Cummings agreed with Dr Barnett that the market offered great potential to Pfizer's competitors. She also agreed that Medimpex made tremendous in-roads in the market with their drug Normodipine.

**[61]** The cross examination of Ms Cummings by Mrs. Kitson QC revealed that she was following the instructions of Mr. W. St Elmo Whyte when she computed the data on which Lasco is relying to justify the award of damages that it is seeking.

**[62]** I thought that Ms Cummings was a forthright witness. However, when one compared the evidence she gave concerning how she arrived at the figures she used to calculate Lasco's losses with that of Mr. Whyte's on this same point, it would be fair to say that a discrepancy has arisen. Mr. Lascelles Chin in his evidence also stated that he asked Ms. Cummings to prepare a projection of the value of the sales that Lasco lost using the percentage increases given by Mr. Whyte<sup>8</sup> which seems to be supportive of Ms Cummings on this point. I am prepared to accept Ms Cummings on this aspect of the evidence. Having done so, this will have a bearing on the view I take of Mr. Whyte's reliability on this area of the evidence.

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<sup>8</sup> See: paragraph [71] below.

Hon. Mr. Lascelles Agustas Chin OJ

- [63] Mr. Chin, at the time of his evidence, was the Chairman and CEO of Lasco. He spoke of his experience with selling a number of products and his ability to successfully capture the majority of the market in Jamaica.
- [64] He claims that over the years he has become familiar with the requirements of Jamaican retailers and the market. This experience with the market conditions, according to Mr. Chin, allows him to give a credible analysis of market trends. His knowledge, he said, spans food distribution, financial, chemical, cosmetic and pharmaceutical products. He gave evidence that when high quality products are priced at affordable levels, they sell well and it allows him (his company) to gain substantial market shares from his competitors. Mr. Chin stated that he has followed this 'philosophy' with regards to his businesses and has continuously experienced great success.
- [65] With regards to Lasco, Mr. Chin states that he operated the distribution business and made decisions as to what products to trade in. Part of Mr. Chin's responsibilities includes meeting with suppliers and pricing goods for resale.
- [66] According to Mr. Chin he became aware that about 40% of the Jamaican population has hypertension and the majority of those afflicted were low income earners. Further, he said that there is supposedly a possibility of a further 20% of the population becoming hypertensive. Due to the demand as well as the high cost of Norvasc, Mr. Chin stated that he sought a supplier to provide a generic medication at a more affordable price. To this end he found CIPLA, a manufacturer based in India.
- [67] It is Mr. Chin's evidence that on the 9<sup>th</sup> of January 2002, a purchase was made from CIPLA to test the market with a view to achieving at least 80% of the market share. He stated that he personally fixed the price for the tablets, the 5mg was one-eighth the price of Norvasc and the 10mg was one-seventh. Although the markup/profit margin was 800%, this still resulted in Las Amlodipine's selling



prices being substantially lower than Norvasc and as such its sales increased dramatically and resulted in the diminution of Norvasc's sales.

- [68] Evidence was given by Mr. Chin that he planned to list Las Amlodipine with the NHF at the price fixed by Lasco for the period of the injunction. Patients would have been able to access Las Amlodipine through the NHF at JMD\$0.73 for the 5mg and JMD\$1.33 for the 10mg tablets. By contrast, Mr. Chin stated that Pfizer's drug, Norvasc, when sold through the NHF cost patients JMD\$38.97 for the 5mg and JMD\$77.94 for the 10mg.
- [69] In cross-examination Mr. Chin gave evidence that he held seminars for medical doctors informing them of the availability of Las Amlodipine and its low price. He gave evidence that he told the doctors at these seminars to educate the poorer people in the society about the dangers of the disease. He deposed that in Jamaica the sales of medication for hypertension depend primarily on the medical profession and the affordability of the drugs. With this aspect of his evidence (i.e. the factors which drive sales of medication) I agree.
- [70] Mr. Chin estimates that had the injunction not been granted, the sale of Las Amlodipine would have continued upwards in 2005 since its sales increased by 451% over the previous year.
- [71] It was also his evidence that he instructed Ms. Cummings to prepare a projection of the value of the sales that Lasco lost using the percentage increases given by Mr. Whyte. These were 200% for the balance of 2005, 250% for 2006 and 2007, 150% for 2008, 90% for 2009, 15% for 2010, 8% for 2011 and 5% for 2012.
- [72] Mr. Chin stated as follows at paragraph 24 of his witness statement (as amended):

*"24. Las Amlodipine was put on the market in 2002 and from the [sic] Exhibit 4 the records of the 3<sup>rd</sup> Defendant shows that in that first year the 3<sup>rd</sup> Defendant sold 100,300 tablets at a sales value of \$746,380.83 with a gross profit of \$450,852.15; in 2003 3<sup>rd</sup> Defendant [sic] sold 552,280*

*tablets at a sales value of \$5,688,874.59 with a gross profit of \$3,949,589.40; in 2004 3<sup>rd</sup> Defendant [sic] sold 1,018,990.00 tablets at a sales value of \$10,991,891.00 with a gross profit of \$7,096,788.16 and for the 4 months to April 2005 when the injunction was granted 3<sup>rd</sup> Defendant [sic] sold 672,510 at a sales value of \$7,012,341.00 with a gross profit of \$5,270,007.84 these being the actual sales made by the company."*

- [73] In cross examination he stated that Las Amlodipine was making a large profit for Lasco and that this one product would have outstripped all the other products in terms of markup value and earnings. Mr. Chin stated that it would have amounted to 65% of Lasco's total revenue.
- [74] Mr. Chin told the court that food and juice was the largest segment of Lasco's business being responsible for about 60% to 70% of its total revenue. Pharmaceuticals realized about 20% and cosmetics about 5%. This evidence, in my judgment, is of great importance in assessing whether in fact the sale of one (1) drug out of the many other products that Lasco sold (bearing in mind that the entire pharmaceutical division is responsible for only 20% of Lasco's entire revenue) would have accounted for 65% of its total revenue 'but for' the injunction. I think this would be quite unlikely for the reasons that are stated in my findings.
- [75] It is Mr. Chin's evidence that after the injunction was granted, Lasco was unable to return the stock which valued JMD\$155,738.90 and as such it had to be destroyed. Lasco is also seeking to recover for this loss.
- [76] During the injunction, Mr. Chin stated that it came to his attention that certain persons had commenced trading in amlodipine products and that he caused Lasco's attorneys-at-law to bring this to Pfizer's attention. Mr. Chin stated that sometime prior to November 2009, Lasco's attorneys informed Pfizer's attorney, Mrs. Kitson QC, by telephone about this. Subsequently, Mr. Chin said he became aware that another company started trading in a similar product. By way of letter dated the 23<sup>rd</sup> of November 2009, Lasco's attorneys-at-law communicated the

activities of the second company, as well as, confirmed that of the first company. A request was made in this letter that steps be taken to bring the existence of the injunction to the attention of the third parties and further steps to bring contempt proceedings if there was a failure to comply.

- [77]** In July 2010, Mr. Chin says that he became aware of three (3) additional parties who began selling amlodipine tablets. It is his view that the entry of these competitors into the same segment of the market resulted in the unfair displacement of Lasco from the market, since Lasco was prevented from trading but the third parties were free to trade. A further letter was written by Lasco's attorneys-at-law to Pfizer's attorneys-at-law bringing the state of affairs to their attention and a further request was made that steps be taken to restrain the third parties. Mr. Chin acknowledged that Lasco's attorneys were copied on letters dated the 30<sup>th</sup> of August 2010 which were sent by Pfizer's attorneys to the five (5) parties he complained about.
- [78]** Mr. Chin recounted that one of the parties responded (through its attorney-at-law) stating that they were not of the view that the injunction applied to them, particularly since they were not named in the proceedings.
- [79]** It is Mr. Chin's view that no effective steps were taken by Pfizer or its attorneys to prevent the third parties from trading. Notwithstanding that another letter dated the 29<sup>th</sup> of September 2011 was sent from Lasco's attorneys to Pfizer's attorneys repeating the request for the third parties to be restrained from trading in their amlodipine products. Save for the letters written by Pfizer's attorneys, Mr. Chin stated that he is not aware of any other steps that were taken by Pfizer in relation to this matter.
- [80]** It was emphasized by Mr. Chin that the entry into the marketplace of third parties has done and continues to do substantial harm to Lasco as the other generics are being sold at a price designed to compete with and capture the market segment which Lasco had entered. The result, according to him, is that Lasco

has experienced difficulty in regaining its position in the market and has suffered irreparable damage. Mr. Chin stated that based on his knowledge of sales in the Jamaican market, Lasco may never be able to regain the ground lost.

- [81]** Mr. Chin has calculated the rate of recovery in the market place using the same rate of start up at the commencement of trading but has discounted same by 50% to account for the incursion of the third parties who traded in similar products at lower prices. In all, he regards USD\$311,026,767.00 (in reliance on Exhibit 4) as the reasonable loss. He also wishes to recover the JMD\$155,738.90 for the product that had to be destroyed. Further he is asking the court to award interest on the total amount up to the date of payment and for the cost of the proceedings.

Ms Joy Ivy Mitchell-Grant

- [82]** Ms Mitchell-Grant, at the time of her evidence, was the Sales Manager at Lasco and is responsible for the management of medical representatives engaged with the department known as Las Med. She has worked in the pharmaceutical industry for the past eighteen (18) years.
- [83]** She gave evidence that she has actively worked at promoting anti-hypertensive medications to physicians and pharmacies in Jamaica and that she is aware that there is a substantial market for anti-hypertensive medications.
- [84]** In her view, Norvasc is regarded as the most appropriate medication for persons of colour and as such is most appropriate for the Jamaican market. According to Ms Mitchell-Grant, Las Amlodipine is an exact copy of Norvasc and has the same properties and effect.
- [85]** In response to Mr. Camp's evidence, Ms Mitchell-Grant agreed that the NHF awarded other blood pressure medication in far greater quantities and at a greater dollar value than for amlodipine. She however stated that this was the very market that Lasco wished to take advantage of and penetrate but was

prevented from doing so by the injunction. She also referred to the drugs mentioned by Mr. Camps namely Enalapril, Hydrochlorothiazide, Nifedipine and Diltiazem and disagreed that these were competing anti-hypertension drugs since these drugs are used to treat other cardiovascular conditions and are often used in combination with amlodipine to treat hypertension.

[86] With reference to the NHF subsidy, she stated that if Las Amlodipine were listed as a specified drug then it would have been available to the public for JMD\$1.33. Ms Mitchell-Grant gave evidence that had Lasco not been restrained and its product been listed, its selling price would have been substantially lower than the prices listed for other anti-hypertensive drugs save for Hydrochlorothiazide.

[87] I found that Ms Mitchell-Grant was a forthright witness. However, I did not accept that certain drugs that were put to her in cross-examination by counsel for Pfizer were not competing anti-hypertension drugs with amlodipine because in my view they were.

Dr. Lorenzo Gordon

[88] It should be noted that Dr. Gordon was never appointed an expert witness pursuant to Part 32 of the **CPR**. This point was only taken by counsel for Pfizer, in closing submissions. However counsel for Pfizer contends that, “the medical evidence, when viewed as a whole, does not warrant the searching scrutiny that the financial expert evidence warrants.”

[89] However, the court notes that since Dr. Gordon was not appointed as an expert, his evidence ought to be treated as that given by an ordinary witness. However, during the enquiry he was asked by counsel for all the parties to give his opinion on certain issues and he did so. Counsel for Pfizer, has now taken the point that he is not an expert, and the upshot of this would mean that as an ordinary witness he would not be allowed to render opinions. However, having scrutinized his evidence carefully, I have observed that the salient aspects of it concerned alleged facts concerning his prescribing habits and his own experiences with his

patients as it relates to their treatment for hypertension which he is allowed to speak to. In my own judgment, the opinions he expressed about the efficacy of amlodipine as an effective treatment for hypertension in persons of colour, is not disputed. Pfizer's Dr. Tobe, as well as, Lasco's Professor Wilks said so. To some extent, what has been challenged is whether it is the preferred first line of treatment as Dr. Gordon opined.

- [90]** Dr. Gordon is a medical practitioner in the field of internal medicine and diabetology. At the time of his evidence he had been a qualified doctor for 16 years. His practice serves a wide cross-section of Jamaicans of varied socio-economic statuses. He sees about 150 patients each week. However, he practises medicine exclusively in the Corporate Area (Kingston and St. Andrew). Dr. Gordon stated that at least 65% of his practice is concerned with the treatment of hypertension.
- [91]** Dr. Gordon gave evidence that when Las Amlodipine came onto the market in 2001, it became the most highly requested prescription from his patients by virtue of its affordability. In his estimation 60% to 70% of his patients would request Las Amlodipine, 20% would ask for Normodipine and about 10% would ask for Norvasc.
- [92]** Dr. Gordon said that the effectiveness of the generics was said to be the same as that of Norvasc. He said that he noticed no difference in them nor did he receive any complaints about any of them.
- [93]** Dr. Gordon observed that in 2005 when the injunction took effect and neither Las Amlodipine nor Normodipine was available, the majority of his patients could not afford Norvasc. The result was that their blood pressure became uncontrolled. He recounted that the substitute drugs he prescribed in had to be given more frequently in terms of dosage. By contrast, Las Amlodipine would only have to be administered once daily. In his view the substitutes/alternative drugs were not as suitable because they had to be combined and administered more frequently.

This resulted in greater costs and more patients not achieving the desired blood pressure control which could lead to a number of complications.

- [94]** It was Dr. Gordon's evidence that had Las Amlodipine remained on the market it would have been more convenient to prescribe in terms of dosage and affordability and that he would have continued to prescribe it more often than Norvasc or Normodipine. He mentioned that his main concern when prescribing was whether the patient would comply with the taking of the medication and that the convenience of taking Las Amlodipine once daily without the need to urinate frequently was a major factor in his preference for it.
- [95]** With regards to the need to urinate frequently, Dr. Gordon gave evidence that amlodipine does not cause this when compared to diuretics. He stated that because Jamaica does not have toilet facilities as readily available as other more developed countries, this causes some patients who were prescribed diuretics to refrain from taking their medication especially when they had to be away from their homes. This often led to elevated blood pressure levels. However, he agreed that diuretics were the cheapest medication on the market for the treatment of hypertension.
- [96]** Dr. Gordon referred to supporting journals and publications to support his view that amlodipine was a preferred medication for treatment in persons of African descent.
- [97]** I found Dr. Gordon to be a reliable and honest witness. However, on the totality of the evidence and perusing the publications and journals he referred to I gleaned that diuretics, as well as, CCBs (of which amlodipine is but one of a number of such drugs), or a combination of both is the preferred treatment for persons of colour.

## **THE EXPERT EVIDENCE**

### **The Cohen Hamilton Steger Report for Pfizer**

**[98]** Mr. Prem Lobo, in his expert report (hereinafter referred to as the 'CHS Report'), presented two likely scenarios of what would have taken place 'but for' the injunction. He also critiqued the ACTMAN and Sierra Reports. In making his assessment Mr. Lobo used the methodology outlined below<sup>9</sup>:

*"In order to quantify Lasco and Medimpex's financial losses, we undertook the following steps:*

*We estimated Lasco and Medimpex's annual 5mg and 10mg tablet sales volumes that would have occurred from March 29, 2005 to May 31, 2012 "but for" the Injunction pursuant to Scenarios 1 and 2, as described below*

*Multiplied "but for" tablet sales volumes by the estimated price per tablet to arrive at estimated but for sales revenue for each year;*

*Subtracted cost of sales as a percentage of sales revenue to arrive at lost gross profit; and,*

*Subtracted incremental operating expenses as a percentage of sales revenue to arrive at lost profits."*

**[99]** The CHS Report in its estimation of the amlodipine market in Jamaica noted that there was an inability to obtain independently prepared assessments, forecasts and analyses of the total market for amlodipine in Jamaica prior to, during and subsequent to the injunction period. Mr. Lobo indicated that this was one of the limitations of the report. (I note too that Mrs. Moss also gave evidence of the difficulty she encountered when trying to get data for the pharmaceutical market in Jamaica). The report relied instead on the data of actual tablet sales. It did not use the data for 2002 as it noted that Lasco had just entered the market at that point and was beginning to ramp up sales. The CHS report also did not use data from 2010 onwards noting that in or around 2011, Norvasc was effectively removed as a drug offered on a subsidised basis under the NHF, resulting in a

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<sup>9</sup> CHS Report at page 73



decline in Pfizer's institutional (not retail) sales and a decline in Pfizer's total sales from 2011 onwards. In its assessment the CHS report, using actual tablet sales, determined that between 2003 to 2005 (pre-injunction) there was an average of 2.934 million tablets sold per annum, while between 2006 and 2010 (during the injunction) an average of 2.908 million tablets were sold per annum.

**[100]** As noted above the CHS report presented two (2) likely scenarios. The first scenario is that Pfizer's tablet sales during the injunction represented *"the total size of the Jamaican Amlodipine market, and, "but for" the Injunction, these volumes would have been shared as between Pfizer, Lasco and Medimpex."* It was assumed that Pfizer's sales from the 29<sup>th</sup> of March 2005 to the 31<sup>st</sup> of December 2010 represented the market for amlodipine. It was also assumed that the market for 2011 and 2012 was equal to the 2010 tablet volume as in those former years Norvasc sales declined as it had been removed from the NHF. The pre-injunction market share of Lasco and Medimpex was then multiplied by the total market (Pfizer's tablet sales) to determine their respective 'but for' tablet sales. It was assumed that their pre-injunction market share would be their market share during the injunction.

**[101]** The CHS Report also presented a hypothetical Scenario 2. In this scenario it was assumed that, during the injunction period, Pfizer, Lasco and Medimpex would have maintained their 2005 pre-injunction market shares of 22%-38%-40% respectively for the 5mg tablets, and 16%-36%-48% for the 10mg tablets. The report was then able to estimate the sales of Lasco and Medimpex using those percentage market shares and the actual Pfizer tablet sales. The CHS Report noted as an example, in 2006, Pfizer's actual 5mg tablet sales volume was 1,312,000 tablets. It was assumed that this represented 22% of the market for 5mg tablets, such that Lasco's 38% of the market would have represented 2,266,182 tablets, and Medimpex's 40% of the market would have represented 2,385,454 tablets. In this scenario, the following assumptions were made, firstly for the period from the 29<sup>th</sup> of March 2005 to the 31<sup>st</sup> of December 2010, Pfizer's tablet sales volumes would have represented 22% and 16% of the total size of

the Jamaican amlodipine market for 5mg and 10mg tablets respectively, and secondly that for the period from the 1<sup>st</sup> of January 2011 to the 31<sup>st</sup> of May 2012 Pfizer's tablet volume for 5mg and 10mg tablets would have been equal to what Pfizer sold in 2010 (given that Norvasc was removed from the NHF, resulting in a decline in Pfizer's total sales from 2011 onwards), and this represented 22% and 16% of the total Jamaican market for 5mg and 10mg tablets respectively. For this scenario an extrapolation was done, in essence if Pfizer's actual tablet sales were to represent 22% and 16% of the 5mg and 10mg tablets respectively, then one could determine the tablet sales of Lasco and Medimpex as the 2006 example above.

**[102]** Where the cost of sales and incremental operating expenses are concerned, "*in the absence of specific documentation and to facilitate compatibility*" the CHS report adopts the figures used by Lasco's ACTMAN Report. These are figures of 33% and 15.64% for Lasco's cost of sales and incremental operating expenses respectively. Where Medimpex is concerned the CHS Report used "*the prices that Medimpex purchased Normodipine from MWI during the years 2002 to 2005*", resulting in an average cost of sale percentage of 88% for 5 mg and 92% for 10mg in the 'but for' period. For the same reasons explained, namely the absence of specific documentation and to facilitate compatibility a 7% incremental operating expense figure was adopted from the Sierra report.

**[103]** In Scenario 1 Lasco's total lost tablets during the injunction period was assumed to be 7.522M while that of Medimpex was 9M. Lasco's lost profits were estimated at JMD\$40,146,000.00 or USD\$518,000.00. Medimpex's loss profits were estimated at JMD\$5,245,000 or USD\$68,000.00. In Scenario 2 Lasco's lost tablets during the counterfactual scenario was put at 40,759,000 and that of Medimpex at 49,662,000. Lasco's loss profit, according to Mr. Lobo, was estimated at JMD\$227,872,000.00 or USD\$2,939,000.00 while Medimpex's was JMD\$26,326,000.00 or USD\$342,000.00.

Table 22a

Total Actual and Estimated "But For" Tablet Sales Volumes (5mg and 10mg Total) - Scenario 1  
Rounded

I: Actual Tablet Sales Volumes

Calendar Years	2002	2003	2004	Jan-Mar 29, 2005	Market Share - Jan-Mar 29, 2005
Pfizer	416,000	533,000	647,000	341,000	18.9%
Lasco	90,000	550,000	1,015,000	670,000	37.1%
Medimpex	768,000	1,268,000	1,961,000	795,000	44.0%
Total	1,274,000	2,351,000	3,623,000	1,806,000	100.0%

II: Estimated "But For" Tablet Sales Volumes - Scenario 1

Calendar Years	Market Share	Injunction Period							Jan-May 31, 2012
		Mar 30-Dec 31, 2005	2006	2007	2008	2009	2010	2011	
Pfizer	18.9%	199,000	491,000	593,000	584,000	449,000	629,000	629,000	262,000
Lasco	37.1%	380,000	955,000	1,140,000	1,153,000	879,000	1,248,000	1,248,000	520,000
Medimpex	44.0%	444,000	1,133,000	1,340,000	1,387,000	1,050,000	1,509,000	1,509,000	629,000
Total	100.0%	1,023,000	2,579,000	3,073,000	3,124,000	2,378,000	3,386,000	3,386,000	1,411,000

Table 22b

Total Actual and Estimated "But For" Tablet Sales Volumes (5mg and 10mg Total) - Scenario 2									
Rounded									
I: Actual Tablet Sales Volumes									
Calendar Years	2002	2003	2004	Jan-Mar 29, 2005	Market Share Jan-Mar 29, 2005				
Pfizer	416,000	533,000	647,000	341,000	18.9%				
Lasco	90,000	550,000	1,015,000	670,000	37.1%				
Medimpex	768,000	1,268,000	1,961,000	795,000	44.0%				
Total	1,274,000	2,351,000	3,623,000	1,806,000	100.0%				
II: Estimated "But For" Tablet Sales Volumes - Scenario 2									
Injunction Period									
Calendar Years	Market Share	Mar 30-Dec 31, 2005	2006	2007	2008	2009	2010	2011	Jan-May 31, 2012
Pfizer	18.9%	1,023,000	2,579,000	3,073,000	3,124,000	2,378,000	3,386,000	3,386,000	1,411,000
Lasco	37.1%	1,995,000	5,117,000	6,031,000	6,292,000	4,751,000	6,858,000	6,858,000	2,858,000
Medimpex	44.0%	2,376,000	6,186,000	7,221,000	7,705,000	5,778,000	8,439,000	8,439,000	3,516,000
Total	100.0%	5,394,000	13,882,000	16,325,000	17,121,000	12,907,000	18,683,000	18,683,000	7,785,000

The Wilks Report relied on by Medimpex and Lasco

[104] The Wilks Report authored by Professor Rainford Wilks was relied on by the Sierra and the ACTMAN Reports. It asserts that the global burden of blood pressure related diseases accounts for 7.6 million premature deaths, 92 million disability adjusted life years, 54% of strokes and 47% of ischemic heart diseases annually. It highlights that, *"adverse effects associated with increased blood pressure occur even at levels not classified as hypertension. It was estimated that only half of this burden is borne by persons with defined hypertension and that 80% of the disease burden attributable to blood pressure is borne by persons in low and middle income countries like Jamaica and the Caribbean."*

*Hypertension occurs most frequently in persons aged 45-69 years and more predominantly in blacks compared to other ethnic groups.”*

- [105] The Wilks Report notes that at present there is consensus that hypertension is defined as sustained blood pressure greater than or equal to 140/90 mmHg. It further notes that, *“all guidelines agree that except for very special circumstances, pharmacological intervention will be reserved for blood pressure equal to or greater than 140/90.”* For the purposes of the report hypertension requiring pharmacological intervention is defined as blood pressure equal to or greater than 140/90 mmHg.
- [106] Where treatment and control are concerned, the report asserts that many studies have demonstrated a “Rule of Halves.” This means 50% of those with hypertension are aware, of that number 50% are being treated and of the number being treated 50% would have their condition described as being under control. The report notes that, *“The Jamaica Health and Lifestyle Survey (JHLS) II reported that among females with hypertension a higher than 50% are aware (70%) but treatment levels of 58% and control of 45% are close to other population estimates and results in approximately 11% of hypertension patients being controlled. Among males the awareness, treatment and control proportions of 31%, 21% and 31% are much worse than expected with approximately 2% of male hypertension patients under control.”* The report highlights that, *“there are excellent clinical outcome trial data proving that lowering blood pressure with several classes of drugs, including angiotensin converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta-blockers (BBs), calcium channel blockers (CCBs), and thiazide-type diuretics, will all reduce the complications of hypertension.”*
- [107] The report obtained estimates of the prevalence of hypertension in five (5) year age bands for ages 15-74 using data from the Jamaica Health and Lifestyle Surveys I and II carried out in 2000-2001 and 2007-2008 respectively; round 2 of Spanish Town arm of the International Collaborative Study of Hypertension in

Blacks (ICSHIB) carried out in 1999-2000; and, for persons 60 years and older, from the 2012 study of the elderly as well as the 1999-2000 Study of Determinants of Health and Well-being among the Elderly in Latin America and the Caribbean (SABE). Demographic data on the population distribution were also obtained from the Statistical Institute of Jamaica.

- [108]** In terms of the analytical approaches, the data set used to obtain yearly estimates of the prevalence of hypertension comprised year of measurement, prevalence estimates for each age category within sex, and socioeconomic status (SES). SES is defined by a composite of education and source of water as one measure, and a composite of monthly household income and toilet facilities as another measure. The report also used census data and data provided by the Statistical Institute of Jamaica to obtain the number of persons within the population within the relevant age, sex and SES categories. Where SES categories were unavailable, particularly for some of the older age groups, the multiple imputation technique was used to obtain plausible values for these categories.
- [109]** The Wilks Report highlights certain limitations, notably that the estimates for the prevalence of hypertension for 2013 and 2014 used data that did not go beyond 2012 in any group and not beyond 2008 for some age and SES groups, estimates were extrapolated assuming a linear relationship. It is acknowledged that while prevalence estimates for these years may be somewhat unstable, the estimates are plausible values for the occurrence of hypertension in the population.
- [110]** There was some inconsistency with the evidence of Professor Wilks relating to the total number of persons suffering from hypertension in Jamaica. The figures ranged from a high of over 850,000 to a low of 460,000 persons during the relevant periods. However, it is agreed and I accept that for the purpose of the exercise that the court is engaged in that the total number of persons in Jamaica who are suffering from hypertension is approximately 800,000. Therefore

applying the “Rule of Halves”, a principle which I accept, then of that number 400,000 persons are aware that they have hypertension; of that number only 200,000 are being treated and only 100,000 are under control.

#### The Sierra Report for Medimpex

[111] The Sierra Report was prepared and presented by Mrs. Kathleen Moss who noted that overall market demand for any drug is not available in Jamaica. She asserted however that demand for a drug is a function of many factors, primarily price, other factors include availability of health care both public and private and recommendations from doctors. The report notes that the following factors were taken into account in estimating the demand for the drug: the prevalence of the hypertensive population in Jamaica, information on demand data for amlodipine in Hungary (Gedeon Richter’s home market), data on Hungary and Jamaica based on World Health Organisation (WHO) statistics and information on the historical supply provided by Pfizer and Lasco.

[112] The report notes that the demand for Normodipine has been assessed with reference to the Wilks Report using treated hypertensives as the minimum size of the potential market and the total hypertensives as the maximum size of the total market. It acknowledges that while Medimpex estimates that amlodipine accounts for 95% of the market for CCBs, it is unable to verify this percentage and has instead used a range of 20% to 50% of the market that would be prescribed amlodipine. Based on the above estimates, the report presented the demand for Normodipine in Jamaica as follows:

Summary of Range of Demand for Normodipine with 40% market share	Low	High
<b>All Hypertensives - Maximum Demand Pool</b>		
By Income	41,980	176,154
By age	35,219	88,048
<b>Treated Hypertensives - Minimum Demand Pool</b>		
By Income	14,474	60,822
By age	15,794	39,486

- [113] The Report in its assessment also considered the demand for Normodipine in Hungary. The drug peaked at 60% and now commands about 20% of the market while Norvasc holds about 10%. It is highlighted that there are differences between the Jamaican and Hungarian markets. There is a higher demand for lower priced medication in Jamaica due to income differences. However, there is less competition in the generic market in Jamaica.
- [114] In ascertaining the projected demand for Normodipine, the report showed that between 2002 and 2003 growth was 63.8% for the 5mg and 66.3% for the 10mg tablet. In 2003 to 2004, after Lasco's entrance increases were 39.4% for the 5mg and 69.6% for the 10mg. These figures declined to just under 32% for both the 5mg and 10mg tablets, the report noted that this was prior to any price adjustment on the part of Medimpex (downwards) and Lasco (upwards).
- [115] This Report projects that demand would peak in 2014 and taper off in 2015. It notes that the time period is based on factors including the global success of amlodipine, the Hungarian market experience and Medimpex's own experience with another hypertensive drug it has on the market (Ednyt/Enalapril). The report suggests the peak for Normodipine to be about 35,200 patients, noting that this falls comfortably in the range between the minimum (treated hypertensives) and maximum (all hypertensives as set out in the Wilks report) and on the assumption of a 40% market share for Normodipine. The report noted that the ACEI, Enalapril, peaked at 11,597 patients in 2008 contending that ACEIs are purported to be less effective than CCBs.
- [116] The scenario advanced by Mrs. Moss on behalf of Medimpex indicates that their total lost tablets during the injunction period was assumed to be 61,683,000 and 88,958,000 post-injunction. The estimated loss of profits during the injunction is USD\$5,525,050.00 and post-injunction is USD\$5,998,897.00. Medimpex also claims USD\$830,835.00 for simple interest on lost profits and USD\$77,075.00 for disposal of stock in February 2007. The total claim is for USD\$12,431,858.00



[117] Mrs. Moss puts the exchange rate in February 2007 as being USD\$1 to JMD\$67.54. I note, however, that Messrs Whyte and Lobo used the average rate from the Bank of Jamaica (BOJ) for the year 2007 which was USD\$1.00 to JMD\$69.06. The court will use the latter figure in its calculations of the Jamaican dollar equivalent for the disposal of stock.

[118] I agree with Mrs. Moss on the factors she listed which influenced the demand for a drug. However, I did not find her comparison of the Hungarian and Jamaican amlodipine markets particularly helpful or persuasive given the vast differences between both countries such as size, demographics, socio-economic, cultural and other factors. The comparison between Endyt was more appropriate and relevant. It was duly considered.

[119] I will address the scenario she presented shortly.

#### The ACTMAN Report for Lasco

[120] Mr. W. St. Elmo Whyte was the author and presenter of the ACTMAN Report. The report indicates that Lasco was aiming for total market expansion and domination and would have likely achieved this aim. In numerical terms the belief was that Lasco could have reached up to 90% of the total potential market at the end of 2012 (that is, the total number of persons suffering from hypertension which is agreed at 800,000). The report noted that this, *“belief and conclusion resulted from extensive discussions with Lasco’s senior management. They regarded this product as their flagship product for the whole company.”* The report further noted that *“Lasco’s business approach was to sell the products at significantly lower prices than Pfizer for the first three years so as to get a firm foothold in the market. Thereafter, Lasco intended to use a price which, on average, would be in the range of 10% to 20% of the price of Pfizer.”*

[121] The ACTMAN Report relies on the Wilks report to determine the potential market for the CCB, amlodipine. It notes that approximately 40% of Jamaicans, 15 years and older, have hypertension as defined by internationally agreed guidelines; this

translates to between 700,000 and 900,000 Jamaicans, the numbers increasing consistently between 2005 and 2014. The Report further highlights that the majority of Jamaicans are in low socio-economic classes which constitute the largest proportion of persons with hypertension and that less than 40% of the persons with hypertension in this category are being treated.

[122] In arriving at its results the ACTMAN Report estimates the tablet sales Lasco would have generated 'but for' the injunction and for a period thereafter (May 1, 2005 to December 31, 2022). Lasco's actual tablet sales in 2004 are used and then there is an extrapolation where the 'but for' sales are grown by assumed percentages.

Year	Lasco Increase in Sales (# of Tablets)
2002	
2003	451%
2004	85%
2005	200%
2006	250%
2007	250%
2008	150%
2009	90%
2010	15%
2011	8%
2012	5%

[123] Mr. Whyte presented a scenario on behalf of Lasco which assumed that the lost tablet volumes during the time that the injunction was in place at 979,482,000 with estimated loss of profits of USD\$132,019,000.00. For the post-injunction period (2012 to 2022) it was put forward that the lost tablet volume was

2,319,700,000 with estimated loss profits of USD\$179,008,000.00. Total loss profits being claimed amounts to USD\$311,027,000.00.

[124] This scenario will be evaluated and addressed later in the judgment.

### **THE NHF DATA FOR CCBs**

[125] The Heath Corporation's (now NHF Pharmaceutical Division) Summary of Products/Schedule of Pharmaceutical Awards was contained in the agreed documents (Exhibit1). Save for 2007 to 2009, data was provided for the following five (5) periods between 2003 to 2017: 2003 to 2005, 2005 to 2006, 2009 to 2011, 2012 to 2014 and 2015 to 2017.

[126] Counsel for Pfizer provided the following statistics in her oral submissions which is accepted by the court after a careful perusal of the data:

- (1) 2005 to 2006 – CCBs accounted for 4.24% of hypertensive drugs (no amlodipine was purchased by the NHF);
- (2) 2007 to 2009 – no data was presented;
- (3) 2009 to 2011 – CCBs represented 28.07% of the total hypertensive drugs and amlodipine made up 7.1% of the CCBs purchased;
- (4) 2012 to 2014 – CCBs represented 10.6% (no figure was given for amlodipine). What the data in the table represents is that the NHF made allowances for 18,000 5mg and 30,000 10mg dosages of Amlodipine, but no award was made;
- (5) 2015 to 2017 – no figure given in relation to total CCBs but amlodipine represented 1.8% of all drugs purchased.

## **Analysis of the NHF data**

- [127]** It is to be noted that there were at least eight (8) different types of hypertensivemedication that were purchased by the NHF during the periods alluded to above. These included ACEIs, ARBs, BBs, CCBs, vasodilators, alpha blockers (ABs) and diuretics.
- [128]** There were at least three (3) types of CCBs which were purchased by the NHF. These were amlodipine, nifedipine and verapamil. No CCBs were purchased in the period 2003 to 2005. In 2005 to 2006 no amlodipine was purchased but nifedipine and verapamil were, although there is no information as to the suppliers.
- [129]** There is no data for the 2007 to 2009 period and no award for amlodipine is recorded for the 2012 to 2014 period.
- [130]** Of the three (3) CCBs, nifedipine has been by far the most supplied in terms of quantity and dosage type for all the periods where CCBs were supplied and data provided.<sup>10</sup>
- [131]** Both Medimpex and Lasco were given awards for nifedipine. In 2009 to 2011 Lasco supplied 1,800 units of 30mg SR tablets. In 2012 to 2014 Medimpex supplied 4,050 units of the same 30 SR tablets. In 2015 to 2017 Lasco supplied 7,000 units of the 30mg and 4,000 units of the 60mg tablets. Medimpex supplied 33,333 units of the 20mg.
- [132]** Based on the Schedules of Pharmaceutical Awards for 2009 to 2011 and 2015 to 2017, the awarded supplier for amlodipine was Indies Pharma. In the period 2009 to 2011 (the injunction was still in place against Lasco and Medimpex at this time, but Jones J on the 30<sup>th</sup> of April 2009 had ruled that Pfizer's patent was

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<sup>10</sup> That is for the periods 2005 to 2006, 2009 to 2011, 2012 to 2014 and 2015 to 2017.

invalid),<sup>11</sup> Indies Pharma supplied the NHF with 8,000 units of 5 mg and 14,400 units of 10mg amlodipine tablets. In 2012 to 2014 there was no award but the NHF made allowances for 18,000 units and 30,000 units of the 5mg and 10 mg dosages but no awards were eventually made.

**[133]** For the period 2015 to 2017 the NHF award went again to Indies Pharmacy which supplied a total of 11,571 and 14,286 units of the 5 mg and 10 mg dosages respectively. (See the table below for comparative purposes)

**TABLE SHOWING MARKET FOR CCBs BASED ON THE NHF DATA**

		2003/2005 (units)	2005/2006 (units)	2007/2009 (units)	2009/2011 (units)	2012/2014 (units)	2015/2017 (units)
<b>Amlodipine</b>	<b>5MG</b>	NO AWARD	NO AWARD	NO DATA	8,000	18,000  (NO AWARD)	11,571
	<b>10MG</b>	NO AWARD	NO AWARD	NO DATA	14,400	30,000  (NO AWARD)	14,286
<b>Nifedipine</b>	<b>10MG</b>	NO AWARD	500	NO DATA	NO AWARD	NO AWARD	NO AWARD

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<sup>11</sup> See paragraph [5] above

<b>Nifedipine SR</b>	<b>10MG</b>	NO AWARD	1,000	NO DATA	72,000	82,500  (NO AWARD)	70,000
	<b>20MG</b>	NO AWARD	5,400  12,600	NO DATA	144,000	139,500	80,000  33,333* (Medimpex)
	<b>30MG</b>	NO AWARD	NO AWARD	NO DATA	1,800*  (Lasco)	4,050*  (Medimpex)	7,000*  (Lasco)
	<b>60MG</b>	NO AWARD	NO AWARD	NO DATA	NO AWARD	NO AWARD	4,000*  (Lasco)
<b>Verapamil</b>	<b>80MG</b>	NO AWARD	900	NO DATA	648	600	540
	<b>2.5MG/L</b>	NO AWARD	100	NO DATA	216	625  (NO AWARD)	900

[134] I have found this information to be instructive because it relates to the market for amlodipine. I find that this is independent evidence that is representative of what took place during the relevant periods, as it concerns the purchase of amlodipine by the NHF. The rest of the data presented (which is not reflected in the table above) shows all the purchases made by the NHF for hypertensive drugs. The significance of this data is amplified when one considers that approximately 150,000 persons in Jamaica subscribe

to the NHF and JADEP regimes. This figure, in my judgment, is representative of a significant percentage of the treated hypertensive population. This evidence (and the entire NHF data on a whole), in my view, would tend to show the prescribing habits of doctors not only for amlodipine, but for the other hypertensive drugs as well, and the demand for these drugs. It would be fair to say, as far as the NHF is concerned, that amlodipine represents a very small percentage of its total awards (about 4% to 7%).

**[135]** However, I am not unmindful that it is more probable than not that at least from 2002 to 2009 (as the data shows) the NHF would quite likely not have made an award to any other supplier but Pfizer since they were the patent holder for amlodipine and had taken steps to prevent any infringements. I have also considered (which is set out in more detail later in the decision) that the monopoly that Pfizer enjoyed for most of the period of the injunction and the prices at which Norvasc was sold could have been a barrier to the potential growth of the amlodipine market. I will bear this mind when I am reconstructing the counterfactual scenario.

### **PFIZER'S SUBMISSIONS**

**[136]** The essence of the submissions on behalf of Pfizer is that the defendants' claims for compensation are highly inflated and legally unsupported. Pfizer's view is that if the court is minded to award damages then it should firstly be awarded in Jamaican currency. Secondly, the appropriate award advanced by Pfizer (which was stated in United States currency) is USD\$518,000.00 for Lasco and USD\$68,000.00 for Medimpex as provided in their Scenario 1. Alternatively, it was submitted that if the court is not satisfied as to the cogency of the evidence with regards to the maturity of the amlodipine market then and only then should

regard be had to Scenario 2 which estimates Lasco's and Medimpex's lost profits to be USD\$2,939,000.00 and USD\$342,000.00 respectively.<sup>12</sup>

**[137]** Both scenarios represent the financial losses quantified over the injunction period between the 2<sup>9th</sup> of March 2005 and the 3<sup>1st</sup> of May 2012 and do not contemplate any potential losses post-injunction when the parties were permitted to re-enter the market.

**[138]** Learned counsel for Pfizer Mrs. Kitson QC has commended to the court the evidence and assessment made by its expert Mr. Prem Lobo, encapsulated in the CHS Report. She has also made detailed submissions as to why the experts relied on by the defendants ought not to be accepted on by the court. These will be discussed subsequently.

**[139]** She asked the court to accept Mr. Lobo's evidence that the treated hypertensive market in 2005 (i.e. when all the parties were in the market) was approximately 278,000 patients (now rounded down to 200,000) and this did not change materially for the next ten (10) years. Further, in 2012 after the injunction was lifted the market was approximately 280,000 patients. She stated that this is the market for amlodipine and not the "potential market" of 800,000 or more persons as put forward by Medimpex and Lasco. I agree with her that the evidence discloses that the treated hypertensive market was relatively stable from 2005 to 2012.

**[140]** Mrs. Kitson submitted that the court should accept Mr. Lobo's findings that the market for amlodipine was approximately 3M tablets per annum and that the market did not change despite the reallocations of market share. She pointed the court to Mr. Lobo's analysis of the actual sales data for the period 2003 to 2010 (as summarised in Table 21) where he concluded that:

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<sup>12</sup> See: paragraph [103] and Table 22a and 22b above.



- a. the overall market tablet volume was reasonably stable between 2003 and 2005, and averaged approximately 2.934 million tablets per year during this period (pre-injunction); and
- b. the overall market tablet volume was also reasonably stable between 2006 and 2010 and averaged approximately 2.908 million tablets per year during this period (injunction period).

In essence, Mr. Lobo is saying that after Lasco and Medimpex were removed from the market in 2005, the market size remained the same and Pfizer merely captured their market shares. Lasco's market share was 37.1%, Medimpex's was 44% and Pfizer's 18.9%.

**[141]** Mrs. Kitson also emphatically submitted that the evidence establishes that the size of the hypertensive market is far larger than the amlodipine market. Put another way, the amlodipine market is merely a subset of the hypertensive market which represents 4% of the total market. This according to Mrs. Kitson is much smaller than the defendants contend. Based on the actual data presented I am inclined to agree with this position. However, Lasco and Medimpex are saying that if they had not been enjoined the amlodipine market would have 'exploded' (to use their words).

**[142]** Having carefully considered the evidence and submissions on this point, I have concluded that the assumptions made by Mr. Lobo in Scenario 1 as to tablet sales/volumes and market shares are somewhat flawed. His evidence was confined to the information that he was able to garner about the amlodipine market, before, during and after the injunction from the parties. He admitted (as did Mrs. Moss) the difficulty in obtaining data as it relates to the sales of amlodipine and other drugs in Jamaica from other pharmaceutical entities.

**[143]** Mr. Lobo concluded that the amlodipine market was basically static; (to use the words of Mr. Camps, *'the amlodipine market had matured'*) that is, it was comprised of about 3 to 3.6 million tablets.

- [144] It was also his opinion that the market shares of the drugs would have remained fixed among the parties during the period that the injunction was in place. These market shares were indicative of the position that each party had in the pre-injunction period (2004).
- [145] His analysis, in my view, fails to take into account, the fact that Lasco was effectively making serious inroads into the market shares enjoyed by both Pfizer and Medimpex, as was clearly demonstrated by the evidence. It also ignores that the growth of the amlodipine market could have been static during the injunction period based on the much higher prices at which Norvasc was being sold even when subsidized by the NHF (when compared to the unsubsidized prices of the generics). The evidence given by Lasco's witnesses and Mrs. Moss that one of the factors which drives demand (and by extension everything else) is price and this is accepted by the court. To my mind, the high prices of the branded product Norvasc would have impacted adversely on the growth and size of the amlodipine market during the period that the injunction was in place.
- [146] I am unable to unequivocally accept that the actual sales of amlodipine amounted to 3 to 3.6 million tablets. I say so for the following reasons. Firstly, there is no data as to the actual sales of amlodipine from one of the initial defendants in this matter (namely NMF) who was selling generic amlodipine from about 2002 to 2004.<sup>13</sup> Secondly, the undisputed evidence is that other players entered the market in 2009 selling generic amlodipine during the period that the injunction was in place. Additionally, there is no evidence that they left the market after the injunction was lifted in 2012 when Lasco relaunched. In fact, it was Mr. Chin's evidence, which was not challenged, that in 2009 there were two (2)

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<sup>13</sup> See: paragraph 4 of Mr. Basil Wright's witness statement filed on June 27, 2016. This information was also made available to the court when the claim commenced.

players in the market, this increased to five (5) in 2010 and by 2012 there were about twelve (12). (He went on to say that in 2014 there were about fourteen to twenty (14 - 20). No data was available as to the number of amlodipine tablets these additional entrants sold during the relevant periods and the percentage of the market that they captured. This has propelled me to say, based on the evidence presented, that the amlodipine market, certainly up to 2004 and after 2009 could have been different from the figure presented as it relates to the number of tablets sold and the market shares held.

**[147]** There was also no allowance made in the CHS Report and Mr. Lobo's calculations/scenarios for the possibility that, but for the injunction, both Lasco's and Medimpex's generics could have been prescribed to patients who were on other hypertensive medication thereby increasing both their tablet sales and market share not only in the "amlodipine market" but also in the wider "treated hypertensive market."

**[148]** This was likely in light of the unchallenged evidence, and the court's own familiarity with the culture of the Jamaican people, that price is a significant factor which drives the demand for a drug.

**[149]** However, notwithstanding the trend in total tablet sales volumes (which to a large degree influenced his Scenario 1), the court notes that Mr. Lobo has provided an alternative scenario with respect to the size of the market during the injunction period.<sup>14</sup> In Scenario 2, Mrs. Kitson submitted (and Mr. Lobo testified) that Lasco's and Medimpex's 'but for' tablet sales are greater than and not supported by, their actual sales experience. She has asked me to bear this in mind when I come to my assessment of it. I have done so.

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<sup>14</sup> See: Table 21 of Mr. Lobo's report

## The Experts

- [150] It should be noted that Mrs. Kitson took issue with the qualifications of Lasco's expert, Mr. Whyte who is an actuary with no experience in the calculation or assessment of damages. It was submitted that Mr. Whyte's evidence cannot be relied on as the exercise being undertaken by this court is not one of actuarial science and as such it is outside Mr. Whyte's qualifications/area of expertise as well as his experience.
- [151] In respect of Medimpex's expert, Mrs. Moss, no issue was taken with her qualifications as she holds professional qualification as a Chartered Business Valuator (CBV) similar to Pfizer's expert, Mr. Lobo. Instead, Mrs. Kitson submitted that Mr. Lobo's evidence ought to be preferred over Mrs. Moss' since he has undertaken approximately 400 exercises in relation to calculation of damages, whereas there was no evidence that Mrs. Moss had ever undertaken such an exercise. Further, it was submitted that the foundation for large sections of Mrs. Moss' evidence and the content of her expert report was either missing or could not be explained.
- [152] Mrs. Kitson contended that the three (3) expert witnesses are so far apart on their analyses, presentations to the court and their ultimate conclusions, that the court must of necessity discard the evidence of two (2) in favour of one (1). The court was referred to the case of ***Price Waterhouse (A Firm) v Caribbean Steel Company Limited*** [2011] JMCA Civ 29, in particular paragraphs [41] – [45] of the judgment of Panton P was commended to the court. It is useful however to have regard to Panton P's admonition in paragraph [40] wherein his Lordship opined, "...*there are situations in which there is no dispute as to the facts, and it is a question of the opinions of several experts. In such cases, the qualification, experience and expertise of the expert in the particular field are of great importance.*"

[153] In the **Price Waterhouse** case, the trial judge had the benefit of three (3) persons, two (2) of them with the expertise in the area of share valuation and one definitely without. The Court of Appeal remarked that the trial judge's preference of the evidence of the one without was surprising and noted that no reasons were given for the rejection of one of the qualified expert's evidence. At paragraph [43] Panton P said, "*Given Mr Holland's qualifications and vast experience as well as his chairmanship of the disciplinary committee of the ICAJ<sup>15</sup>, it is difficult to understand how the learned trial judge could have rejected his evidence virtually out of hand...*" Ultimately, the Court of Appeal concluded that the learned trial judge fell into error by virtue of placing so little value on the need for expertise (in share valuation) and his elevation and acceptance of the unqualified expert above professionals in the specific field.

[154] By contrast, Mrs. Kitson submitted that the medical evidence, when viewed as a whole, does not warrant the searching scrutiny that the evidence of the financial experts requires. It was noted that Dr Lorenzo Gordon was never appointed an expert witness pursuant to Part 32 of the **CPR**. However, as stated before, Professor Wilks and Dr Tobe have agreed with Dr Gordon that amlodipine is an effective treatment of hypertension in people of African descent. All three (3) were in agreement that there were other effective medications, apart from CCBs for the treatment of hypertension. There was some disagreement among the three (3) as to which medication is to be administered as a first line treatment in hypertensive patients of African descent. Mrs. Kitson submitted that the evidence, both oral and documentary, seems to firmly support the prevalence of the use of thiazide diuretic as the first line treatment.

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<sup>15</sup> Institute of Chartered Accountants of Jamaica

## **The Wilks Report**

**[155]** Mrs. Kitson advanced (based on Mr. Lobo's evidence) that neither Mr. Whyte nor Mrs. Moss used the data from the Wilks Report in their calculations, instead the data was used to estimate the total potential market for amlodipine as a whole, and by extension for Las Amlodipine and Normodipine. Additionally, while the report sets out the statistics with respect to the total hypertensive population of Jamaica, the report does not specifically address the total market for amlodipine in Jamaica (nor does it address the market for Norvasc, Las Amlodipine or Normodipine).

**[156]** According to counsel for Pfizer the Wilks Report was considered to be of limited relevance with respect to estimating (1) the total market for amlodipine and (2) the projected sales for Norvasc, Las Amlodipine and Normodipine 'but for' the injunction. Despite mentioning that there are several classes of drugs for treating hypertension, it was criticised for not containing any statistical data with respect to the types and quantities of drugs prescribed; failing to present any insights with respect to expected future trend and to mention any initiatives which may impact on the prevalence of hypertension in Jamaica. The court was also directed to some internal inconsistencies in the data as well as incorrect subtotals.

**[157]** In summary, Mrs. Kitson QC has launched a three-fold attack on the opinions proffered by the defendants' experts. She asserts that the expert reports of Mrs. Kathleen Moss (relied on by Medimpex) and Mr. W. St. Elmo Whyte (relied on by Lasco) are based on three (3) major faulty premises, which when reviewed in their entirety show that the reports are unreliable and should be disregarded by the court. These are:

1. The reliance on Professor Wilks' Report and/or research to construct the size of and/or potential size of the amlodipine market;

2. The introduction of an assessment period lasting beyond the injunction; and
3. The assumption that the amlodipine market was larger than 3 – 3.5M tablets in any given year before, during and/or after the injunction.

### **SUBMISSIONS ON BEHALF OF MEDIMPEX**

**[158]** Counsel for Medimpex, Dr. Barnett, submitted that the court should adopt the assessment by its expert, Mrs. Kathleen Moss given in her report (the Sierra Report) and award the sum of USD\$12,431,858.00 to Medimpex. In relation to interest, Dr. Barnett adopted the submissions made by counsel for Lasco, which will be set out subsequently.

**[159]** It should be noted at the outset that it was agreed that Medimpex's claim cannot properly include the losses suffered by Medimpex West Indies and as a result a recalculation was undertaken and provided by Mrs. Moss.

**[160]** Dr. Barnett has asked the court to consider that when Medimpex entered the amlodipine market, Pfizer was the only player. As such, Medimpex was able to gain immediate traction, particularly since its selling price was half of Pfizer's Norvasc. According to Dr. Barnett, it was incontestable that Medimpex achieved record and increasing sales of its drug, Normodipine. He commended to the court the following sales figures:

2001	Part Year	(JMD) \$3.41M
2002	Full Year	(JMD) \$16.44M

2003	Full Year	(JMD) \$29.35M
2004	Full Year	(JMD) \$49.87M
2005	Part Year (3 months only)	(JMD) \$20.67M

[161] Dr. Barnett contends that if the figure for 2005 was annualised it would be approximately JMD\$82.68M and this does not factor in the multiplying increase trend. Naturally, it was submitted that these escalating sales and the resultant expanding profits were halted by the injunction which prevented Medimpex from selling its drug for over seven (7) years, but by then the situation had changed by the entry of new suppliers in the market. It was contended that this entry by other generic providers which gained a foothold in the market during the injunction period, by offering lower prices means that one can reasonably infer that Medimpex would not be able to regain a viable position seven (7) years later because of its prices being higher than the new entrants.

[162] Dr. Barnett submitted that counsel for Pfizer has '*placed their case on four articulate and clearly erroneous premises.*' These were as follows:

- 1) The first is that recovery of damages, pursuant to an undertaking, is confined in the period of the injunction, and although damages are suffered as a result of the injunction, post the injunctive period, those damages are not recoverable.
- 2) The second is that the estimates of damages have to be calculated on the basis of "independent evidence".



- 3) The third is that the amlodipine market is confined to the sales recorded by Pfizer, Medimpex and Lasco in a short period and that market had no potentiality for expansion.
- 4) The fourth of these postulates is that whether the factors used in the basic calculations are conservative and discounted or not, there must be an automatic discount of the results of such calculation.

**[163]** Further, Dr. Barnett criticized Mr. Lobo as having no experience in marketing or understanding of the market variables and dynamics. As such, he has ignored them completely. It is Dr. Barnett's contention that the ability to penetrate the market at different levels and to control a share therefore depends on several factors, such as (1) the demographics, (2) the efficacy of particular drugs, (3) their acceptability in the medical profession, (4) their availability in the pharmacies, clinics and hospitals, (5) the competitive prices and (6) their compatibility with the needs and preferences of potential users.

**[164]** Submissions were made in relation to the six (6) factors identified above.

### **Demographics**

**[165]** Dr. Barnett contends that the only expert evidence as to the demographics was given by Professor Wilks. While there have been some criticisms of the Wilks Report, no one who has conducted any relevant study or work or who has experience in the relevant field has given any evidence to contradict the basic facts stated in his Report.

**[166]** According to Dr. Barnett, some important relevant facts stated by Professor Wilks are:

- (1) *Hypertension occurs most frequently in persons aged 45-69 years and more predominantly in persons of African descent compared to other ethnic groups;*

(2) *Current control rates (SBP<140 mmHg and DBP <90 mmHg), though improved, are still far below international targets such as Healthy People 2020.*

*Many studies have shown that in the case of hypertension, population surveys have demonstrated the “rules of halves”, i.e. 50% are aware, of which 50% are on treatment and a further 50% are under control. This would mean that only approximately 13% of persons with hypertension would have adequately controlled blood pressure. The Jamaica Health and Lifestyle Survey (JHLS) II reported that among females with hypertension a higher than 50% are aware (70%) but treatment levels of 58% and control of 45% are close to other population estimates and results in approximately 11% of hypertension patients being controlled. Among males the awareness, treatment and control proportions of 31%, 21% and 31% are much worse than expected with approximately 2% of male hypertension patients are under control.*

(3) *The prevalence of hypertension increases with age from approximately 7% in the 15 -24 year old age group to almost 70% in those 65 years and older (see: Table 4a). For all age groups the prevalence was approximately 5% greater among females. Over the 10 year period under review the prevalence of hypertension increased annually with a net increase of approximately 2% in the 15-34 year age group and 4-5% in the older age groups peaking at the 65 years and older age group (see: Table 4a). Table 4b shows that hypertension is less frequent among the lower SES category of the Jamaican population and not different between the middle and high SES groups. It is also noticeable that the differences across all three groups are small.*

(4) *The proportion of persons with hypertension who are not being treated varies slightly by SES with higher proportions in lower SES by both income and education. However, the numbers are largest in the lower SES categories (see: Table 6c). Overall approximately 600,000 persons with hypertension are not being treated in 2014.*

[167] Dr. Barnett also asked the court to have regard to the following evidence from Mr. Ronald Camps, Pfizer’s Regional Sales Manager, under cross-examination by counsel for Lasco, Mr. Chen:

*“Okay, I would say about six hundred thousand have hypertension; about three hundred thousand know that they have hypertension...” (see: V.N., Nov. 25, 2016, p. 26.)*

[168] From this it is submitted that Mr. Camps has admitted that up to 600,000 people have hypertension. With generic low priced drugs, a sizable proportion of this population can be treated. In the ‘but for’ scenario, Medimpex has projected that

there would have been a plateau in its pricing between 2005 and 2009 , at which time the prices would fall by 10% and a further plateau until 2013 when a further 10% reduction in prices would occur. Dr. Barnett contends that Medimpex could project this level of price stability given Lasco's stated intention and pricing strategy of pricing their products at very low prices for a few years, in order to capture the market, and then subsequently increasing their prices.

### **Efficacy of Particular Drugs**

[169] Dr. Barnett submitted that the expert evidence in respect of the efficacy of the CCBs in the treatment of hypertension and the growth in its use is overwhelming. He referred to Professor Wilks' evidence with respect to 'Guidelines for Treatment (medication class recommendations)' which states, '*There are excellent clinical outcome trial data proving that lowering BP with several classes of drugs, including angiotensin converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta-blockers (BBs), calcium channel blockers (CCBs), and thiazide-type diuretics, will all reduce the implications of hypertension.*'<sup>16</sup>

[170] Further, reliance was placed on the evidence of Dr. Lorenzo Gordon, who has had wide experience in the Jamaican society with reference to Norvasc, Las - and Normodipine. Dr. Gordon said:

*"The effectiveness of the drugs were [sic] the same and I noticed no difference in them. I received no complaints about any of the three drugs." Para. 5 of Witness Statement dated June 27, 2016; IBS 72.*

*"The alternative drugs which we had to rely on were not suitable as they had to be combined and administered more frequently which resulted in a high cost and greater cost resulting in more persons not achieving the desired blood pressure control. Because of these complications it may result in heart attack kidney failure stroke and death." para. 8, **ibid.**'*

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<sup>16</sup> See: The Wilks Report at page 3 Tab C of the Bundle of Experts' Reports

[171] Dr. Barnett contends that Pfizer's expert witness, who has not practised medicine in Jamaica, confirmed rather than contradicted the opinion of the Jamaican experts. He submitted that Dr. Sheldon Tobe placed his conclusion no higher than:

*"There is not sufficient evidence that in black persons with hypertension that amlodipine leads to superior blood pressure control or better cardiovascular and survival outcomes over diuretics for blood pressure control or for preventing heart disease."*

*While calcium channel blockers like amlodipine are excellent once a day therapy for lowering blood pressure in people of African origin with both evidence for efficacy and improved long term outcomes, thiazide and thiazide diuretics are also once a day therapy and have even stronger evidence of efficacy and improved long term outcomes."*

[172] It was submitted that the literature exhibited does not support this qualification. In particular, The ALLHAT Report (Appendix 2) states:

*However, the optimal choice for initial pharmacotherapy of hypertension is uncertain... Over the past decade, major placebo-controlled trials have documented that ACE inhibitors and CCBs reduce cardiovascular events in individuals with hypertension."*

[173] Further reference was made to the publication exhibited by Dr. Tobe titled 'Intraclass Differences Among Antihypertensive Drugs', which states at page 146 (Appendix 4):

*"Calcium channel blockers have demonstrated efficacy in reducing cardiovascular disease in hypertension equal to the other recommended agents, including thiazide diuretics, ACE inhibitors, ARBs, and B-blockers, but appear to have added efficacy for stroke prevention. Calcium channel blockers, when combined in low doses with these recommended agents, lower BP more than is observed when any of these agents are used in isolation at a doubled dose."*

[174] The court was also referred to page 301 of Exhibit 3D entitled 'Amlodipine Versus Nifedipine in the Treatment of Mild-to-Moderate Hypertension in Black Africans', which according to Dr. Barnett is of some importance in view of the Afro centric nature of the Jamaican population, it states:

*“The calcium antagonists have rapidly become established as effective antihypertensive agents in the last decade, surpassing other more conventional drugs. The acceptance of these agents by physicians could be attributed to the unique features of the dihydropyridine derivatives which also have several indications (e.g., hypertension, ischemic heart disease, and hypertrophic cardiomyopathy). The antihypertensive activity of amlodipine and nifedipine, both dihydropyridines, is a result of vasodilation of the peripheral vasculature. The first-generation prototype, nifedipine, showed some limitation in clinical use and produced some adverse effects; the problems have been addressed in newer generation derivatives, including amlodipine.*

*Amlodipine has unique pharmacokinetic and pharmacodynamic properties and may offer some advantages over nifedipine. It has a long half-life of 35 to 60 hours, and a gradual absorption, with time to peak plasma levels of 6 to 12 hours; these factors allow the once-daily dosing. Furthermore, amlodipine is more vasoselective, and its slow association and dissociation at the receptor site contribute to a favourable safety profile and a lower incidence of vasodilatory side effects than nifedipine. Remarkable efficacy has been observed with amlodipine and nifedipine in African blacks.”* (Emphasis added)

### **Acceptability in the Medical Profession**

[175] Dr. Barnett submitted that the referenced literature confirms the acceptability of the CCBs by the medical profession, particularly for the treatment of persons of African descent. Specifically in relation to Jamaica, the two (2) Jamaican medical practitioners Professor Wilks and Dr. Gordon, indicated decisively the extent of the acceptance of CCBs for the treatment of hypertension by the Jamaican medical profession.<sup>17</sup>

[176] Dr. Barnett contends that the pharmacists are on the front line of the distribution of drugs. As such they not only fill the prescriptions ordered by the doctors but they observe the Government of Jamaica's mandate to offer generics where appropriate. Where necessary, they communicate with doctors to obtain the

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<sup>17</sup> See: Dr. Lorenzo Gordon's Supplemental Witness Statement filed on September 24, 2016.

authority to dispense the substitution. Two (2) pharmacists, Ms Huly-Blackwood and Ms Juliet Kossally-Chang testified as to the considerable switch from the more expensive Norvasc to Las Amlodipine and Normodipine and the willingness of doctors to approve the change.

### **Availability in the pharmacies, clinics and hospitals**

[177] It was submitted that as a first generic, Normodipine was available in the distribution centres and had gained from its advantage of being the first mover in the amlodipine generic market.

### **Competitive/Comparative Prices**

[178] It was submitted the pricing differentials between Pfizer for Norvasc, Medimpex for Normodipine and Lasco for Las Amlodipine are summarised by Mrs. Moss at page 17 of her First Report and illustrated by the Tables. She stated the conclusion as follows:

*“Comparing Medimpex’s and Lasco’s prices to those of Pfizer in 2009, both average and highest shows that the prices range between 35% and 57% of Pfizer’s.”*

[179] In her second report dated the 29<sup>th</sup> of September 2016, Mrs. Moss further adds, that using estimated distributor’s margin of 27% falling to 25%, that Medimpex’s projected prices to the retail trade during and after the period of the injunction range between 24% and 48% for the 5mg and 27% and 41% for the 10mg of Pfizer’s prices to the retail trade.

[180] Further, Dr. Gordon and the two (2) pharmacists called by Lasco confirmed that preference for the lower priced generics by patients and customers respectively.

[181] Counsel for Medimpex submitted that Mrs. Moss correctly and appropriately took into account the demographic, statistical, pricing and pharmaceutical data in computing her assessment of the losses suffered by Medimpex.

### **Compatibility with the needs and preferences of potential users**

[182] Dr. Barnett submitted that the medical evidence indicates that CCBs are attractive to patients for a number of reasons. They are once a day medication thus facilitating compliance with the directions for use. Unlike diuretics they do not produce an impulse to urinate. They can, where necessary, be prescribed to be taken along with diuretics.

### **Penetration of the Market**

[183] Dr. Barnett submitted that there was a trend towards the increased penetration of generic forms of amlodipine in the market for hypertension medication and that there is no empirical evidence to the contrary nor is there any evidence that a plateau was in sight.

[184] Dr. Barnett contends that it is common ground that there is actual data in respect of the sales of Norvasc, Las Amlodipine and Normodipine for the period from 2002 to 2015.<sup>18</sup> This shows that in its first year of marketing the generic drug Medimpex made 60% of the total tablet sales for the three (3) parties and with the entry of Lasco with a similar generic at a lower price, this share declined to 44%. However, according to counsel for Medimpex it is very significant that for Pfizer its sales decreased from 33% to 19% for the same period, while Lasco increased from 7% to 37%. Further, during the injunction period Pfizer, despite its high price, recorded tablet sales of 2,378,000 to 3,386,000. Before the year in which the injunction was imposed total sales by these three (3) distributors were 1,274,000 (2002); 2,351,000 (2003) and 3,623,000 (2004).<sup>19</sup>

[185] The court was referred to the available statistical data and the developing prescribing patterns for the treatment of hypertension. Dr. Barnett referred to the

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<sup>18</sup> Partly reflected in Table 2a of Mr. Lobo's Report at page 16

<sup>19</sup> These figures are consistent with the figures presented in Mr. Lobo's Table 2a, on page 16 of the Lobo Report.

abstract of a paper titled 'A Review On Prescribing Patterns of Antihypertensive Drugs (2016)',<sup>20</sup> which states:

*"Hypertension continues to be an important public health concern because of its associated morbidity, mortality and economic impact on the society. It is a significant risk factor for cardiovascular, cerebrovascular and renal complications. It has been estimated that by 2025, 1.56 billion individuals will have hypertension. The increasing prevalence of hypertension and the continually increasing expense of its treatment influence the prescribing patterns among physicians and compliance to the treatment by the patients. A number of national and international guidelines for the management of hypertension have been published. Since many years ago, diuretics were considered as the first-line drugs for treatment of hypertension therapy; however, the recent guidelines by the Joint National Commission (JNC8 guidelines) recommend both calcium channel blockers as well as angiotensin-converting enzyme inhibitors as first-line drugs, in addition to diuretics. Antihypertensive drug combinations are generally used for effective long-term management and to treat comorbid conditions."*

[186] Dr. Barnett submitted that there is overwhelming evidence of a successful penetration by amlodipine products in the hypertension market. Prior to Medimpex and Lasco entering the market with its generic form of amlodipine, Pfizer's sale of Norvasc expanded rapidly despite its high price. Reference was made to the evidence of Mr. Camps<sup>21</sup> wherein he said:

*"The Claimant's sales data for Norvasc in Jamaica discloses that since the Defendants commenced selling the cheaper generic drugs containing Amlodipine Besylate, the Claimant's revenue from the sale of Norvasc in Jamaica fell substantially. Revenues from the sale of Norvasc rose from US\$6,000.00 for the year 1994 to US\$1,225,000.00 for the year 2001. In 2002 after the introduction of the infringing products in the Jamaican market, the Claimant's revenues from the sale of Norvasc in Jamaica fell to US\$481,000.00. In 2003, sales of Norvasc totalled US\$517,000.00 and in 2004 ended the year at US\$614,000.00, a slight increase over the*

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<sup>20</sup> Exhibit 6A

<sup>21</sup> See: paragraph 5 of Mr. Ronald Camp's witness statement dated the 16<sup>th</sup> of April 2006



*amount which had obtained in November 2004 when I swore an Affidavit in the proceedings for an interlocutory injunction.”*

Further, it was shown that when Medimpex entered the market in 2001, Pfizer’s revenue from sales of Norvasc rose from USD\$6,000.00 in 1994 to USD\$1,225,000.00.

**[187]** Reference was also made to the evidence of Mr. Sebastian Sas, the Finance Director of the Central American and Caribbean division of Pfizer. He stated that the revenue from 2002 to 2015 were as follows:

(USD\$ ‘000s)

2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
\$481	\$517	\$618	\$1,106	\$2,461	\$2,555	\$2,228	\$2,582	\$1,894	\$522	\$768	\$592	\$601	\$498

### **Medimpex’s Treatment of the Expert Evidence**

**[188]** Dr. Barnett addresses both of Mr. Lobo’s scenarios, in his view Scenario 1 represents the situation in which the total sales of tablets by Pfizer during the injunction is taken as equivalent to 100% of the market and that the market share is fixed at the pre-injunction levels. Whereas Scenario 2 represents Pfizer’s sales post-injunction and represents only Pfizer’s market share.<sup>22</sup>

**[189]** In Scenario 1 only approximately 9,200 persons are being treated with amlodipine while in Scenario 2 the number of persons making up the market peaked at 51,186 persons. The calculations for Scenario 1 are based on market estimates with the injunction in place, that is. there is no assessment of a ‘but for’ calculation. For Scenario 2 there has been no recognition of the rapid market penetration that Medimpex and Lasco would have continued to make ‘but for’ the injunction. There is no empirical evidence on which the selection of either

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<sup>22</sup> See Mr. Lobo’s Report, paragraphs. 260 and 261 and Tables 22A and 22B

scenario can be justified. Accordingly, the assessment of the market potential has to be based on reasonable assumptions.

**[190]** On the point of assumptions, Dr. Barnett acknowledges that Mr. Lobo agreed that in measuring probable or prospective losses where there are no specific figures it is appropriate to make reasonable assumptions.<sup>23</sup> It was submitted that the making of reasonable assumptions does not mean that any assumption which is unfavourable to the defendants should be accepted and any assumption which is favourable to the claimant should be accepted.

**[191]** Mr. Lobo concedes that as much as 85% of Jamaicans suffering from hypertension are not being treated and that this amounts to several hundred thousand persons.<sup>24</sup> Dr. Barnett submitted that it follows from this that there is an untapped market of considerable potential for CCBs which is a preferred anti-hypertension drug.

**[192]** Further, in view of the medical profession's favourable disposition to the prescription of CCBs, a reasonable assumption can be made that an increasing number of Jamaicans will be prescribed such drugs for the treatment of their hypertension. On the other hand, there is no independent or empirical source provided by Mr. Lobo for an inference that less than 20% of the Jamaican hypertensive population would be prescribed amlodipine. He admitted that he did not make any assessment of the willingness of Jamaican doctors to prescribe CCBs for the treatment of hypertension.

**[193]** Dr. Barnett took issue with Mr. Lobo's approach. He submitted that the fallacy of Mr. Lobo's approach is that it treats the market for amlodipine as the total of sales of Norvasc, Normodipine and Las Amlodipine made by Pfizer, Medimpex and Lasco respectively. All persons who are suffering from hypertension are

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<sup>23</sup> Verbatim notes of evidence dated January 11, 2017 at pages 81 and 99.

<sup>24</sup> Verbatim notes of evidence dated January 24, 2017, pages. 84, 85 and 99.

potential amlodipine customers, since this will be determined by physician and patient and be influenced by affordability and marketing strategies. The evidence shows an increase in the Jamaican population, an increase in the prevalence of hypertension between 2001 and 2008 and a continuation of these trends.

[194] Dr. Barnett then turned to his own Expert's Report. Mrs. Moss stated<sup>25</sup> that:

*"Although the tables differ in the total amount of persons with Hypertension, the percentages range as follows:*

*Hypertensives as % of population 31% to 47%*

*Treated hypertensives as % of total hypertensives 31% to 37%*

*Treated hypertensives as % of total population 12% to 15%."*

[195] This is confirmed by her reference to World Health Organisation (WHO) data which states that, *"for Jamaica, 32% of males and 28% of females over 25 have raised blood pressure."*<sup>26</sup> Mrs. Moss, Dr. Barnett said, expressed the opinion which is rational and uncontradicted that the treated hypertensive market is likely to grow. She opined:

*"The demand for Normodipine has been assessed with reference to the Wilks Report using **treated hypertensives** as the **minimum** size of the potential market and the **total hypertensives** as the **maximum** size of the total market. With the availability of low cost generic medication, the size of the treated hypertensive market is likely to grow."*<sup>27</sup>

[196] Dr. Barnett submitted that although Mrs. Moss assessed the Normodipine market share at 40%, this is a very conservative figure as it omits the total low income segment of the hypertension population. The second related assumption

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<sup>25</sup> Bundle of Experts' Reports Tab B page 7

<sup>26</sup> Bundle of Experts' Report page 8 and note 9.

<sup>27</sup> *Ibid*, p. 8

is that 20% to 50% of the hypertensives who are being treated, are prescribed amlodipine. Bearing in mind that the range is 20% to 50%, the selection of the lowest end of the range is a very conservative approach. Mr. Lobo acknowledged that there is no empirical evidence that requires the selection of the lowest point in the range.

### **Response to Pfizer's Expert**

**[197]** In her second Report dated the 29th of September 2016, Mrs. Moss responded to Mr. Lobo's (CHS) criticism of her Report. In respect of the use of USD\$ to calculate revenues and costs, Mrs. Moss explained that "the exchange rate is the major determinant of the pricing in the retail trade". According to Dr. Barnett this is a factor which a Jamaican would readily appreciate where the exchange rate has moved from JMD\$48.08 to USD\$1.00 in 2001 to JMD\$122.00 to USD\$1.00 in 2015.

**[198]** It was submitted that Mrs. Moss' Sierra Report which appreciates the dynamics of the market and the untapped marketing potential nevertheless took a conservative approach in estimating demand for amlodipine generally and Normodipine in particular. As pointed out above, she used only the figures for upper and middle income segments of the hypertensive population. She further omitted any possibility of NHF support for amlodipine type drugs. In the absence of statistical data on the percentage of the hypertensive population that would be prescribed amlodipine, she employed a reasonable assumption, which Mr. Lobo concedes is the appropriate methodology in those circumstances. Similarly, Mr. Lobo's criticism of her, using a 40% share of the market is erroneous as it was made in the absence of statistical data where reasonable assumptions, as Mr. Lobo concedes, are appropriate. Indeed, Mr. Lobo, Dr. Barnett emphasised, has made similar assumptions where he did not find the data. The position is similar in respect of Mrs. Moss' estimates of "but for" tablet sales volumes and the estimated Medimpex price adjustments.

**[199]** It is Dr. Barnett's view that Mr. Lobo's CHS Report and oral evidence characterised him as an advocate for advancing Pfizer's case rather than an expert aiming at assisting the court. It was submitted that he ignores a number of factors, namely the important statistics which Mr. Camps admits that about 600,000 Jamaicans are suffering from hypertension, and about the 300,000 persons who are aware of it. It was submitted that Mr. Lobo in his report:

- i) ignores the fact that of the potential market, based on the tablet sales, only 9,200 persons were purchasing amlodipine tablets from Pfizer, Lasco and Medimpex; .
- ii) ignores the acceptability and/or preference for amlodipine-type medication for hypertensives;
- iii) Ignores the importance of competitive pricing;
- iv) treated the amlodipine market as static and comprised of only sales by Pfizer, Medimpex and Lasco, although there is evidence that during and after the injunction period other persons were selling amlodipine generics in the Jamaican market; and
- v) ignores the fact that for seven (7) years, between 2002 and 2009 Pfizer's USD\$ revenues increased by over 437%.

**[200]** Dr. Barnett submitted that there was no rational basis for Mr. Lobo's conclusion (based on his approach) that the total size of the amlodipine market is a maximum of three million which would equate to only 8,200 persons out of the 300,000 persons who knowingly suffer from hypertension.<sup>28</sup>

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<sup>28</sup> Verbatim notes of evidence dated January 24, 2017 pages 12 and 13

**[201]** Further Mr. Lobo assumed that after the injunction period Lasco, Medimpex and Pfizer would have the same percentage market share<sup>29</sup> although the empirical evidence showed that where all three (3) parties were in the market Lasco's and Medimpex's market shares continued to increase and Pfizer's continued to decline. Dr. Barnett submitted that taking into consideration that Lasco's pricing strategy was to increase its prices after an initial very low price, this would have had the effect of slowing down its growth in market share, relative to Medimpex's. Therefore, Mrs. Moss' projection that Medimpex would have maintained a 40% market share of the total amlodipine market was not only conservative but also reasonable.

**[202]** It was further submitted that Mr. Lobo did not make any reasonable assumptions as would be appropriate for the sales by the other players in the market although he indicated that he would have liked to have had access to this information.<sup>30</sup> Mr. Lobo, Dr. Barnett continued, admitted that he had no empirical evidence from which to draw the inference that less than 20% of the Jamaican hypertensive population would be prescribed amlodipine and offered no basis on which to challenge a reasonable assumption in this regard.<sup>31</sup>

**[203]** It was submitted that Mr. Lobo's proposition was that in the growth of sales, the tendency was for an initial increase to decline which may be reversed but conceded that there is also a general proposition that in the early stages it may be more difficult to penetrate the existing market. However, Dr. Barnett said Mr. Lobo made no allowance for this factor.

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<sup>29</sup> Verbatim notes of evidence dated January 24, 2017 page 58

<sup>30</sup> Verbatim notes of evidence January 24, 2017 pages 80 and 81

<sup>31</sup> Verbatim notes of evidence dated January 24, 2017 pages 84 and 85

[204] It was further submitted that there can be very little doubt that the price of drugs is a significant factor in the market but he ignored that factor on the basis that he is not a marketing expert<sup>32</sup> and then stated that the data as to sales speaks for itself. However, it is obvious that pricing is an important factor in growth in the market and the maintenance of market share. In the circumstances, Mr. Lobo's general approach is unrealistic and amounts to an assumption that if you need the drug you will acquire it, which according to Dr. Barnett reflects an insensitivity to and a complete misunderstanding of socio-economic conditions in Jamaica.<sup>33</sup>

[205] Dr. Barnett has argued that the court should accept the scenario that was put forward by Mrs. Moss in the Sierra Report.

### **The Sierra Report**

[206] The following was commended to the court by Dr. Barnett. Namely, the result of Mrs. Moss' approach:

*"In summary, based on the assumption that amlodipine would be prescribed and used by 20% to 50% of hypertensives in Jamaica, the range for Normodipine demand by different classification categories, would be as follows:*

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<sup>32</sup> Verbatim notes of evidence dated January 25, 2017 pages 13 to 15

<sup>33</sup> Verbatim notes of evidence dated January 25, 2017 pages 19, 20 and 43

<b>Summary of Range of Demand for Normodipine with 40% market share</b>	<b>Low</b>	<b>High</b>
<b>All Hypertensives – Maximum Demand Pool</b>		
By Income	41,980	176,154
By age	35,219	88,048
<b>Treated Hypertensives – Minimum Demand Pool</b>		
By Income	14,474	60,822
By age	15,794	39,486

**[207]** In further support of her approach, Mrs. Moss used the Hungarian data to obtain a sense of the size and duration of the amlodipine market. It is submitted that this is a reasonable approach, bearing in mind that she identified and took into account the relevant differences in the two (2) jurisdictions. There is no evidence to contradict her conclusion that, *“The projected peak patient demand for Normodipine of 35,185 patients is 3 times that of Ednyt and is justifiable given the superior efficacy of CCB drugs over ACE inhibitors.”*

**[208]** Mrs. Moss pointed out that with respect to Mr. Lobo’s summary, Medimpex’s sales for 2001 were omitted although presented to him. As such, Mr. Lobo’s Table of Summary of Sales excludes relevant available data which shows that Medimpex had sales of 67,000 tablets in 2001.



**[209]** In calculating Medimpex's losses, Mrs. Moss used prices ranging between 24% and 48% for the 5mg tablets and 27% to 41% for the 10mg tablets of Pfizer's prices which are consistent with the pre-injunction ranges. Further, she assumed that the National Health Fund (NHF) would not be ordering amlodipine, used data for persons aged over forty-five (45) only and excluded the low income segment of the hypertensive market. In these circumstances, the Sierra (Moss) assessment of the market is conservative and as such Medimpex's losses are reasonably computed, Dr. Barnett opined.

**[210]** The actual sales data for Normodipine as demonstrated by Mr. Lobo's Table 2a and Mrs. Moss' Table "Normodipine Product Sales 2001-2005" show a growth rate of 63.8% for the 5mg tablet and 66.3% for the 10mg tablet. The annual increase decreased on Lasco's entry in the market but was still considerable. Bearing in mind that Lasco entered the market at a deliberately very low price as explained by Mr. Chin to be followed by a price increase as stated in the ACTMAN projections from JMD\$7.20 to JMD\$19.13 for the 5mg tablet and JMD\$13.74 to JMD\$23.42 for the 10mg tablet and the possibility of downward price adjustment by Medimpex, the projections for Normodipine sales in the 'but for' scenario made by Mrs. Moss are reasonable. Mr. Lobo, Dr. Barnett said, has given no evidential or statistical basis for its rejection.

**[211]** In dealing with the projected volumes of sales Mrs. Moss made further reasonable adjustments. As explained in page 20 of her first report:

*The Claim is based on the projected volumes of sales of Normodipine by strength multiplied by selling prices and gross margins as at April 2005. The prices and margins are adjusted downward by 10% and 5 basis points in 2009 and 2013 to reflect the typical adjustments that occur in the generic market and to ensure that the J\$ price to the retail trade remains reasonable."*

**[30]** Mrs. Moss further adjusted the gross margins downwards for an allocation of variable overheads from Medimpex's Jamaican operations.

[212] In concluding, Dr. Barnett sought to address firstly Medimpex's failure to re-enter the market post-injunction and secondly whether the court ought to apply a discount to the award. I will endeavour to summarise these briefly.

#### **Failure to re-enter the market**

[213] It was averred that the decision taken by Medimpex not to re-enter the market on the lifting of the injunction was made on the basis of marketing factors. Reliance was placed on the evidence of Mr. Basil Wright who has experience in the marketing of drugs and training in business administration. Mr. Wright was of the view that during the injunction period other players had entered the market and undermined Medimpex's potential and, "*effectively destroyed its prospects for re-entry after the lifting of the injunction*".<sup>34</sup>

[214] It was further submitted that Pfizer increased the probability that Medimpex would be unable to re-enter the market by failing to take any steps to obtain similar interlocutory injunctions against other dealers who had entered the market, although this was brought to their attention. This also resulted in Medimpex losing the advantage of being the first significant distributor of a generic amlodipine and was no longer in the position of first mover.

[215] Dr. Barnett submitted that the legal principles are quite clear. A party is only required to take steps to mitigate his damages where they can reasonably be expected to have that result. Accordingly, Medimpex should not be burdened with an obligation to take what they considered a business risks. Reliance was placed on ***Lesters Lecker and Skin Co. v. Home and Overseas Brokers*** (1948) 64 TLR 569 (C.A.). According, it was averred that the burden of proving that Medimpex should have re-entered the market to mitigate its losses is on Pfizer and that Pfizer has not discharged that burden. On this point, reliance was

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<sup>34</sup> See: paragraph 19 of Mr. Basil Wright's witness statement filed on June 27, 2016.

placed on two (2) authorities, namely ***Roper v. Johnson*** (1873) L.R.8C.P.167; ***Garnac Grain Co. v. Faure and Fairclough*** [1968] A.C. 1130.

[216] Further, in her addendum to the Sierra Report dated the 18<sup>th</sup> of November 2013, Mrs. Moss justified the decision of Medimpex not to re-enter the market and asserts that Medimpex could not have re-entered the market on the removal of the injunction as the pricing of the product in the market at that time would have resulted in losses for Medimpex.

### **Discount of the award**

[217] On this point, Dr. Barnett submitted that while he agreed that the final award should take into account the time value of money and discount projected lost profits post the award date, he did not agree with Mr. Lobo's calculation of the Weighted Average Cost of Capital (WACC) as shown in his Schedule A13-ii. The calculation shows low and high WACC's and assigns a high Company specific risk premium based on Mr Lobo's own assessment of the business. As such, Dr. Barnett contended that this is not representative of an understanding of the Jamaican market conditions, (for example, the risk factor assigned to Medimpex for the Company specific premium is 12% to 17% and belies the fact that Medimpex has been in business since the 1970's and is a stable and profitable operation and has led the way in bringing generic products to the Jamaican market).

[218] It was submitted that if the court is minded to discount the calculation of the award, a liberal approach should be taken, namely:

- i) the discount should be applied to lost profits from the date of the award to the end of the claim period i.e. from 2017 to 2021, given the five (5) years that have elapsed between the lifting of the injunction in 2012 and the determination of the damages;
- ii) and the discount rate applied should be low and not exceed 10%.

## **COUNSEL FOR LASCO'S SUBMISSIONS**

[219] Counsel for Lasco is asking this court to award the sum of USD\$311,026,767.00 or alternatively to fix an appropriate discount and recalculate the loss based upon that discount. Further, counsel for Lasco submitted that interest should be allowed at the rate of 8.23% per annum to be calculated as set out in Mr. Whyte's report and discounted for future loss in accordance with the said report.

[220] Reliance was placed on ***Algonquin Mercantile Corporation v. Dart Industries Canada Limited*** (supra), a decision of the Federal Court of Canada<sup>35</sup>, wherein the court considered, *inter alia*, whether damages can be awarded for lost sales resulting from the injunction but actually occurring during the post-injunction period. This court was asked to have regard to paragraph [37] of the judgment, wherein Addy J opined:

*"[37] The usual undertaking given to the Court by parties requesting an interlocutory injunction in the context of today's society in Canada involves, in my view, **an undertaking to pay all damages which flow from the granting of the interlocutory injunction and is not in any way restricted to those which occurred during the period of the existence of the injunction itself, nor does the common law impose any artificial cut-off date.** The assessment for the period following the injunction remains subject to the usual limitations as to remoteness, that is, as to whether in the particular circumstances of the case, after a certain period of time has passed and other circumstances have intervened, losses, if any, can still on a balance of probabilities, be*

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<sup>35</sup> The Federal Court of Appeal of Canada dismissed the plaintiff's appeal, see: ***Algonquin Mercantile Corporation v. Dart Industries Canada Limited*** (unreported), Court of Appeal, Canada, [Federal Court of Canada] [Trial Division] Court File No. A692-86, judgment delivered 17 June 1987

*attributed to the injunction with any reasonable degree of certainty.”*  
(Emphasis added)

[221] Counsel for Lasco, Mr. Chen, has commended to the court the reports of its experts as fair and reasonable estimates of what would have happened, on balance, had the injunction not been in place. Conversely, Mr. Chen contends that the report of the Pfizer’s expert is wrong and should not be accepted. I will endeavour to summarise Mr. Chen’s strident submissions, which as indicated previously, counsel for Medimpex, Dr. Barnett has adopted for the most part.

[222] Mr. Chen prefaced his submissions by stating what he considered to be undisputed or rather unchallenged evidence, namely: (1) Lasco sells the highest quality products for the lowest price and this business model is what Mr. Chin attributes his success to; (2) On the introduction of Las Amlodipine into the market it outsold both Norvasc and Normodipine; (3) The NHF subsidy on Las Amlodipine would have been 95% of the retail selling price and the selling price to NHF cardholders only 5%; (4) In 2016 the retail selling price of Norvasc was JMD\$185.00 for 5mg and JMD\$260.00 for 10mg; and (5) Pfizer was informed of the intrusion of third parties into the amlodipine market but decided not to take any steps to stop them.

### **The Market**

[223] By way of background, Mr. Chen helpfully described the three (3) tier market for pharmaceuticals such as amlodipine in Jamaica. First the private market which sells at normal retail prices; secondly a combination of the private and government market through the NHF subsidy system; and thirdly, the government or institutional market.

### **Tier One**

**[224]** The private market is operated through pharmacies and other private outlets. It is the retail market and these entities which purchase their supplies directly from the distributors. The distributors deal with the manufacturers who are mainly outside of the island and all purchases are made in foreign currency, mainly United States dollars. The goods are delivered directly to the retailers through the distributors. The government does not handle the drugs in this market. It should be noted that the court was not presented with any data from these entities about their sales for hypertension medications in general and amlodipine specifically.

### **Tier Two**

**[225]** The second tier is a combination of the private market and the government or institutional market and is operated through the NHF card system. In this market the private retailer buys and takes delivery of the drug in the normal way. If a holder of an NHF card is purchasing the drug which is within the list of drugs subsidised by the government, the buyer pays a small portion of the price to the seller who then collects from the government the balance of the selling price. The balance represents the subsidy provided by the government.

### **Tier Three**

**[226]** The third tier is direct sales by either the distributor or the manufacturer directly to the government and is at a lower price than in the private market or the subsidised market. The drugs are supplied directly to the government or the institutions such as the public hospitals and certain pharmacies which then dispense the drugs free of charge to the patients. Included in this system is the JADEP<sup>36</sup> which provides drugs free of charge (or at minimal costs) to

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<sup>36</sup> Jamaica Drug For the Elderly Programme

beneficiaries over 65 years suffering from selected chronic illnesses such as hypertension.

**[227]** The court was asked to consider that manufacturers and distributors sell directly to the Government at such low prices mainly for marketing and promotional reasons. First, large earnings in United States Dollars are generated; secondly, the product is introduced to patients in Jamaica to gain familiarity and trust in them so they will buy in the private market at the normal retail prices; and thirdly, patient and doctor exposure and acceptance. Further, in the private pharmacies there is a mandatory requirement that where generic versions of the branded drugs are available the pharmacist dispensing the drug must bring this to the attention of the patient who then has the right to elect which drug to buy.

#### **The position of the parties**

**[228]** Mr. Chen contended that Pfizer participated in the second tier, namely the NHF subsidy system during the life of the injunction, but prior to and after the injunction it did not. There is no evidence that it sold directly to the government for free dispensation under the third tier system described above.

**[229]** Medimpex did not participate in any of the government or institutional sales nor in the NHF card system described above as the second tier system. It relied on private sales only through the private pharmacies. Indeed, in its claim it specifically eschews what Mrs. Moss describes as the lower end of the market and uses Professor Wilks' computation for the higher and second higher income categories.

**[230]** On the other hand, Lasco has always and intended to continue to participate in all three (3) tiers of the systems of marketing mentioned above. It sold through the private pharmacies at its full distributor's price, it listed its drugs with the NHF for subsidy and it participated in the direct sales to the Government through its manufacturers.

**[231]** It was submitted that Lasco would have combined the three tiers of the market in the counterfactual scenario. It was selling at a relatively high price to make a substantial profit at the normal retail price, but at the same time it would have listed on the NHF system to sell at a very low price to participants in this system and its manufacturer (CIPLA) would have continued to sell directly to the Government at a very low price to facilitate the distribution of this product at no cost to the patient. According to Mr. Chen, this would have enabled Lasco to achieve what it intended. The free distribution would introduce the patients to a very desirable and effective medication, the NHF subsidy would enable those same patients and others to access the same drug at a low price and Lasco would make a substantial profit to enable it to fund its aggressive and effective marketing programmes to educate more patients and potential patients to treat their condition with Las Amlodipine.

**[232]** Mr. Chen avers that this would have gone a long way to address the lamentation of Professor Wilks when he said that the Kingston Public Hospital (KPH) is overflowing with patients and there are no beds because patients are not aware of the seriousness of their condition until strokes and heart attack result. It was argued that no effective programme of education is in place in Jamaica to address this and that Lasco wanted to do this but the injunction denied it the opportunity to do so and that opportunity is now lost forever as the chance to establish itself in the market during the period from 2005 to about 2009 was destroyed by the free entry into the market of dealers in competing generics without this same sensitivity. It cannot now generate the profits required to sustain such a programme. Lasco did not present any evidence of their marketing preparations prior to the injunction to undertake this effective education programme and marketing strategy that would lead to the total number of persons with hypertension (800,000) being diagnosed and treated. I found this area of the evidence to be overstated.

**[233]** It was contended that Lasco is in a unique position in the market as it has and had at the time it started to trade in amlodipine, an existing market which



comprised persons in the lower socio-economic sector of the population. What it was doing was to satisfy this existing market that it had by finding yet another good product that was high in quality and low in price. It was supplying an existing need which its own customers had; it was not identifying a desirable product and then going out to market it. It was the other way around and is an important factor for the court to bear in mind when assessing the likelihood of the rate of penetration that Mr. St. Elmo Whyte has assumed in his projections. However, no evidence was provided as to the number of persons who comprised this market and how many of Lasco's existing customers were hypertensive.

**[234]** The court was asked to consider that Lasco helped the government to distribute HIV drugs to the population in a very effective and economic manner with great success. Mr. Chen submitted that its success is mainly because the customer base is made up of the cadre of persons within the population requiring low cost medication and goods.

#### **Lasco's Treatment of the Expert Evidence**

**[235]** With regard to Lasco, there were three (3) scenarios put forward by the rival experts, one (1) by Mr. St. Elmo Whyte and two (2) by Mr. Prem Lobo. These were supported by opinions and empirical information and findings and conclusions put forward by Professor Wilks for Lasco and Dr. Tobe for Pfizer. Mr. Chen stated that he would not deal with the experts for Medimpex in his submissions except where necessary to make a point in regard to the Lasco's case.

**[236]** Mr. Chen commended to the court the Wilks Report which considered the demographics of Jamaica. Professor Wilks established the population of the island, those who were suffering from hypertension, those who knew that they were suffering from hypertension, those who were treated for hypertension and those who had been stabilised. He based his findings and conclusions on information from the Statistical Institute of Jamaica (STATIN) and other published

works which he identified. He also segmented his report to give the court information as to the incidents of hypertension in Jamaica based upon age, sex and socio-economic status. He set out his conclusions and findings which were used by Lasco's expert, Mr. Whyte, in his projections.

**[237]** Mr. Chen submitted that apart from the criticism of the ratios that were found by Professor Wilks in the various sectors of the society and the misreading by Mr. Lobo of the calculation of the distribution of the incidence of hypertension in the population to give a total for those suffering from hypertension which could not have been intended by Professor Wilks, there is no challenge to the report that he filed. Further, it was submitted that there is no contrary expert report from Pfizer save for the views expressed by Mr. Lobo. Additionally, the conclusion by Professor Wilks that those suffering from hypertension was about 800,000 was not far from the acceptance by Pfizer's witness Mr. Camps of about 600,000 and eventually his concession that it could be between 600,000 to 800,000 supports Professor Wilk's conclusion.

**[238]** It was further submitted that the court should consider the portion of the Wilks Report which dealt with the preference for amlodipine and the use of CCBs in the Jamaican population which was largely African in origin. Dr. Tobe was called as an expert to contradict this position but in the end, after reviewing the publications relied on by both experts and especially the ALLHAT report, it became apparent that there was not any significant difference between these two (2) experts on this aspect of the matter. Significantly, Dr. Tobe who does not practice in Jamaica, agrees that convenience, efficacy and price are factors that determine the demand for a drug. Dr. Tobe did not challenge Professor Wilks' opinion that in Jamaica these matters are of great importance in deciding whether amlodipine should be prescribed. Mr. Chen submitted that Professor Wilks' opinion should be accepted and relied upon by this court as it was not successfully challenged.

## Treatment of the Scenarios

- [239] With regards to Mr. Lobo's scenarios, Mr. Chen submitted that his scenarios are based on a misguided view of what he needs to do to help the court. The guidelines suggested by Lord Diplock in **Mallett v McMonagle** [1970] AC 166 requires him to disregard what actually happened after the injunction. It was submitted that Mr. Lobo should have assumed that the injunction was not granted and considered what, on a balance of probabilities, might have happened. Mr. Chen submitted that he did the opposite. He took what actually occurred. This according to Mr. Chen is completely wrong and renders his scenarios completely wrong and useless. Reference was made to Tables 2a to 2c at pages 16 to 19, Mr. Chen submitted that in all of these tables he has no sales for Lasco and Medimpex during the injunction period because as he says in his evidence: *"this is the actual data, I am looking at the actual data before as I said, before the injunction and during the injunction. And I am using this to estimate the, but for scenario."* Mr. Lobo's position is that the market for amlodipine is finite and the injunction did not change it.
- [240] Mr. Chen disagreed with this approach and submitted that because of this error Mr. Lobo has not made provision for the obvious: there was a potential market for amlodipine at the prices that Lasco was charging.
- [241] Further, it was submitted that the tables have ignored the trend that had developed prior to the injunction, that Lasco and Medimpex were increasing their sales and market size when compared to Pfizer. According to Mr. Chen this confirms that in Mr. Lobo's mind neither Lasco nor Medimpex would have continued the very trend that he identified existed prior to the injunction in the 'but for' scenario.
- [242] Mr. Chen submitted that Mr. Lobo focussed on the actual in the counterfactual scenario and failed to make the reasonable and appropriate assumptions that he ought to have done. It was further submitted that Mr. Lobo's criticism of Mr.

Whyte's report at paragraph 90 of the CHS Report for not providing an independent empirical source for the annual growth rates that he uses to estimate 'but for' tablet sales volumes, illustrates this point. Mr. Chen contends that Mr. Lobo has lost sight of the fact that Mr. Whyte is making these assumptions in the counterfactual and not the factual.

[243] It was submitted that Mr. Lobo's report is incorrect and should not be relied upon. It was contended that Mr. Lobo uses the actual sales in his charts at 2a to 2c to calculate what he says is the 'but for' scenarios. As a result, both of his scenarios are based on the actual sales of tablets and this error has caused the gross understatement of the sales and loss.

[244] By contrast, Mr. Chen submitted that Mr. Whyte's report has taken the actual sales up to the time of the injunction and made assumptions as to what would probably have happened if the injunction was not made. He has followed the guidelines set out by Lord Diplock in **Mallett**. He has created a single scenario. He looked at the known facts and made the assumptions based upon them and the evidence available to him.

[245] Mr. Chen pointed out that Mr. Whyte has provided the court with a calculation of the loss suffered by Lasco in three (3) segments. Firstly, the actual sales and profits being made before the injunction, secondly a projection of the loss between the imposition of the injunction and its lifting and thirdly a projection of the loss that would have been incurred during the recovery of Lasco's market share that it would have had at the time of the lifting of the injunction. Mr. Chen submitted that this is in conformity with the applicable legal principles and leaves the door open for the court to apply the law in accordance with the guidelines suggested by Lord Diplock as expanded in the recent cases.

[246] It was further submitted that Mr. Whyte's report should be accepted by the court because it takes into account the potential market of persons with hypertension

as stated by Professor Wilks and presents a reasonable estimation of what would have occurred in the counterfactual scenario.

### **Lasco's proposed approach**

**[247]** Counsel for Lasco has commended the following two (2) stage approach to the court. Firstly, a probable scenario should be selected and secondly the assumptions should be considered with a view to determining the likelihood of the assumptions occurring. To the extent that the court finds that a particular assumption is likely or not, an appropriate discount should be applied.

**[248]** It was submitted that in the instant case it is common ground that Lasco was trading successfully, making a profit, gaining market share and increasing the number of persons buying its product. Reliance was placed on the **Astrazeneca AB** case which is summarized below.

**[249]** In **Astrazeneca** the defendants were restrained from introducing a generic form of esomeprazole which was a drug marketed by AstraZeneca in the United Kingdom under the brand name Nexium for which it had a monopoly by virtue of a European patent. Krka a large manufacturer of generic drugs in Slovenia and Consilient a small sales and marketing company sought to introduce into the UK market a generic form of esomeprazole under the name of Emoxul in September, 2010. Before 2010 Consilient had never made a profit. An injunction was issued to stop Consilient from selling Emoxul in the UK before it began to sell. The injunction was lifted by AstraZeneca in July, 2011. Notwithstanding that Consilient had not sold a single capsule of Emoxul in the UK, the court awarded it damages in excess of 27 million British Pounds based on the evidence of the preparations of Consilient to introduce Emoxul in a vigorous marketing campaign which was never executed because of the injunction and the possibility of marketing managers switching to Emoxul. The court made the assessment based upon evidence of the opportunity that Krka and Consilient had lost.

[250] Mr. Chen submitted that in **Astrazeneca** there was no existing track record of sales by Consilient of Emoxul in the UK but notwithstanding that the court made a substantial award for the opportunity lost during a period of less than one year. By contrast, in the case at bar there is a track record of success by Lasco with the sales and penetration of the market by Las Amlodipine and the making of a profit by Lasco was an established fact. Mr. Chen submitted that the first threshold mentioned in **Apotex** has been crossed as such the court should embark on the second stage of the inquiry which is to evaluate the 'substantial chance of continuing to make a profit'.

[251] It was further submitted that the loss should be assessed based on the scenario advanced by Mr. Whyte and adjusted by reference to the percentage chance of the scenario occurring. In carrying out the assessment, Mr. Chen contends that the court ought not to consider the factual position after the injunction, namely the sales prices, tablet numbers, and actual profits made. Such an approach would, according to counsel for Lasco, be contrary to Lord Diplock's guidelines and compound the wrong as it would translate the wrong caused by the injunction into the computation of the loss caused by the injunction.

[252] It was submitted that the relevant assumptions made by Mr. Whyte in postulating the counterfactual scenario are as follows: (1) The rate of penetration that would have occurred; (2) the time when such penetration would have plateaued; (3) the price which Las Amlodipine would have commanded; (4) the size of the potential market for Las Amlodipine; (5) the ultimate share of the market that Las Amlodipine would have attained; and (6) the time it would have taken for Lasco to regain the market share that it would have had at the time of the lifting of the injunction in the counterfactual scenario.

### **The rate of penetration**

[253] It was submitted that Lasco had an existing cadre of customers which constituted its base. It was catering to this group when it started to deal in Las Amlodipine. It would therefore have had an easy task as it had an existing market with which it was dealing in other products of high quality at reasonable prices.

[254] Mr. Chen submitted that in the first year 200% represents only 6,533 people. Reliance was placed on the evidence of Mr. Lascelles Chin. According to Lasco, the total number of persons to be added would, after eight (8) years up to 2012, would have been 635,539 out of a potential market of about 800,000. It is contended that this is not an unreasonable number.

[255] It was further submitted that during the period of the most rapid percentage growth between 2005 and 2009 the evidence is that there were no other players in the generic market as third parties started to enter the market in about 2009. As such it is Lasco's view that had it not been prevented by the injunction from continuing it would have had an unfettered opportunity to dominate the marketplace during this period. Based on the projections of Mr. Whyte the percent of the market that Lasco would have gained is 74% against the normal percentage that Mr. Chin usually attains in these circumstances which is about 90%.

[256] In essence, Mr. Chen contends that the assumptions as to the rate of penetration of the market are fair and reasonable and if discounted should only be by a small amount.

### **The time when such penetration would have plateaued**

[257] The evidence suggests that during the life of the injunction third parties started to trade in competing amlodipine products (i.e. in about 2009). Pfizer was notified about this.

- [258] The evidence is also that at that time only Norvasc was available on the market and it was sold at a high price. Mr. Chen submitted that this court is entitled to infer from this evidence that there was a substantial demand for amlodipine products at prices below Pfizer's which could not be resisted by third parties who were willing to take the risk of offending the court's injunction by entering the market. (I take this to mean taking the risk to offend Pfizer's patent since those third parties were not enjoined).
- [259] Further, if Lasco had not been prevented from continuing its penetration of the market a lacuna would not have been created to enable third parties or indeed to make it necessary for them to enter the market since the marketing and sales machinery of Lasco would have addressed the needs of the marketplace during this period. Therefore it was submitted that the plateau in the market would have occurred in about 2010 but at that time Lasco would have attained its market share and would have established its prices. As such, it is Lasco's position that there should be no discount for any plateau period.
- [260] I disagree. There was another generic being sold by NMF prior to the injunction (2002 to 2004). The claim by Pfizer was commenced in 2002. This, in my judgment, would have prevented other potential players from entering the market (this was the 'at risk' period since Pfizer was in possession of its patent). Within four (4) years of the injunction being in place at least six (6) other entrants came into the market. Mr. Chin's evidence is that by 2014 there were 14 to 20. In **Apotex** Norris J stated that the move from monopoly to open market would take about three to four years. In the instant case, the monopoly was broken in 2001 when Medimpex entered the market. They were followed by Lasco and NMF. I am convinced therefore that in the counterfactual scenario there would be other entrants in the market and this would have happened, in my estimation, long before 2009/2010. I find that a fairer assumption of when this would have occurred in the counterfactual scenario would have been no later than 2006. Therefore the plateau in the market would have occurred before 2010 (I estimate



in about 2008 to 2009) and as a result there should and will be a discount for this.

**The price which Las Amlodipine would have commanded**

[261] Mr. Whyte has used a price of JMD\$19.13 for the 5mg and JMD\$23.42 for the 10mg during the period. He has applied these prices from the date of the injunction to 2022 when he projects that full recovery would have taken place. According to Mr. Chen, these prices represent an increase over the prices prevailing immediately before the injunction but are less than 18% of the Pfizer prices. The evidence is that by 2016 the retail selling price of Pfizer's Norvasc was JMD\$185.00 for the 5mg and JMD \$260.00 for the 10mg. The conclusion that counsel is asking this court to draw is that the increases in Pfizer's retail prices would have caused the percentage to become even lower.

[262] It was further submitted that Lasco intended to list Las Amlodipine with the NHF and applying the subsidy the selling price to the users of the NHF card would have been JMD\$0.73 for the 5mg and JMD\$1.33 for the 10mg since the subsidy would have been 95% of the selling price. It is Lasco's view that this would have made Las Amlodipine competitive with or even less expensive than most of the other antihypertensive drugs, such as Enalapril available under the NHF card system.

[263] Mr. Chen submitted that Las Amlodipine would have been sold primarily to people who were already customers of Lasco with whom there was an existing acceptance and trust in the goods Lasco sold. Additionally, Lasco was known for its aggressive and forceful sales and marketing force. Lasco was unique in the market for these reasons and would have held its prices whilst expanding into its customer base.

**[264]** Without reference to any authority, it was further submitted that pharmacies were required to bring to the attention of patients prescribed with a branded product that a generic version was available. From April 2005 to about mid 2009 the least expensive generic containing amlodipine would have been Las Amlodipine the other being Normodipine. Mr. Chen submitted that Lasco would have maintained its price during this period and it is likely other generics would not have successfully competed in price. According to him it is also likely that the scenario would have played out as Mr. Whyte projected the prices and as such this court should not make a discount on account of this. Alternatively, it was submitted that if a discount is found to be appropriate then it should be a very small discount not to exceed 5%.

#### **The size of the potential market for Las Amlodipine**

**[265]** The meaning of 'amlodipine market' varied between the claimant and defendants. The claimant means by this, the total sales of amlodipine products by Pfizer, Medimpex and Lasco before during and after the injunction. Whereas the defendants mean all those persons suffering from hypertension in Jamaica. Mr. Chen acknowledged that this is a vast difference since by virtue of their respective definitions the market for the claimant is about 9,000 people and for the defendants about 800,000.

**[266]** The claimant asserts that the market for amlodipine in Jamaica is fixed at about 9,000 and has never varied. Mr. Chen contended that this assertion is mistaken as it is referring to the sales of the product and does not take into consideration the effect of the fall in price consequent upon the entry of Normodipine and Las Amlodipine into the marketplace. It is therefore the satisfied market.

**[267]** The court was asked to have regard to the evidence that the claimant held a monopoly for its Norvasc from its introduction to the date Normodipine entered the market place and again from April of 2005 until the lifting of the injunction in 2012. The evidence is that Norvasc was introduced in Jamaica in 1999 so it was

traded for about 13 years. Normodipine was introduced in the year 2001 and the injunction imposed in April, 2005. Of these 13 years Norvasc had a monopoly for about 10 years. It was submitted that the way that Pfizer has viewed the amlodipine market is really a reference to the Norvasc sales at high prices or largely the market of the monopoly.

**[268]** Since this monopoly was being broken by the defendants, Mr. Chen submitted that had they not been stopped they would have enlarged the amlodipine market in the sense used by the claimant. It is to be noted that in Mr. Lobo's tables at 2a to 2c the total number of persons using amlodipine was steadily increasing. Further the evidence of Professor Tobe for the claimant confirmed that once the monopoly was broken in the United States and Canada, by the entry of the generics, the market exploded and sales increased rapidly.

**[269]** The amlodipine market as viewed by the defendants means all persons suffering from hypertension. It is the unsatisfied market. It was submitted that the market would have grown exponentially had the defendants not been restrained, particularly Lasco. It had deliberately entered the market at a low price, since it was catering to its own base and was about to engage in its normal aggressive marketing campaign to educate the people through the medical profession of the availability of amlodipine at very low prices. It was submitted that this would have had the same effect as the entry of the generics in the market in the USA and Canada.

**[270]** It was submitted that the size of the market for amlodipine in Jamaica is directly related to the price at which it is available. It is also affected by the programme of education of those suffering from the condition and not knowing, or those who know and are not seeking treatment, as well as, those who are being treated with other less effective medications. The assumption by Mr. Whyte in this regard is based on the findings and data supplied by Professor Wilks. It is admitted that the numbers are an educated guess. Mr. Chen submitted that if the court is of the

view that a discount should be applied it should not be much to factor in the uncertainty of the guesstimate.

**The ultimate share of the market that Las Amlodipine might have attained**

**[271]** It is Mr. Chin's evidence that he would normally obtain up to 90% share of the market when he trades in goods that are good in quality and reasonable in price as he usually prices his goods at a low price and then increases it. Mr. Whyte was more conservative and used 74% as the maximum share Las Amlodipine would have achieved. The remaining 26% would be taken by other traders in anti-hypertensive preparations and home remedies. This would be about 200,000 people given the estimated size of the market.

**[272]** It was submitted that the attainment of a 74% share is consistent with the past history and performance of Lasco. It is consistent with the trend emerging from Mr. Lobo's tables 2a to 2c and is likely to have occurred as it had commenced.

**[273]** It is Pfizer's view that the amlodipine market cannot exceed 9,000 patients. Mr. Chen submitted that Mr. Lobo goes to great lengths to calculate a 'but for' market using the 'because of' base to keep the size of the market he calculates at approximately this level. So too did Mr. Camps, in his cross-examination, insist that the amlodipine market was mature and could not much exceed 9,000 patients but along comes Pfizer's expert, Dr. Tobe, who gives clear evidence that the market exploded when the generics started to enter the USA and Canadian markets after the patent had expired.

**[274]** It is Lasco's view that the same would have occurred in Jamaica if the injunction had not been put in place. Based on the evidence, the court is being asked to draw the inference that this did occur since there was an explosion of new entrants in defiance of the injunction in the form of the third parties complained about. The pressure for generic amlodipine had become so great that dealers were willing to risk offending the injunction.

- [275] It was submitted that had Lasco not been prohibited from trading prior to the time that the third parties entered the market, it would have attained at least 74% of the persons suffering from hypertension which is the real market for amlodipine in Jamaica. Therefore the court should not apply a discount for this.
- [276] Further, the sales figures for Las Amlodipine from the lifting of the injunction to 2015 shows the strength of Lasco's reputation in the market place and demonstrates that had it not been kept out of the market it would have attained its objective. After being kept out of the market for seven (7) years, it returned in 2012 and immediately garnered a substantial share of sales. The difficulty was that by then too many other generic dealers had established themselves in the market and Lasco had lost the first entry advantage that it had in 2005.

**The time it would have taken Lasco to recover its market share**

- [277] It was submitted that at the time that the injunction was made, it would have been in the reasonable contemplation of Pfizer that if Lasco was kept out of the market, there would be required a certain time for it to regain its lost market share once the injunction was lifted. Pfizer is a major participant in the ethical drugs market and as an experienced participant in this trade, Pfizer must be taken to understand the ordinary practices and exigencies of the trade or business of which Lasco is another, but far less important, participant.
- [278] Further, it was submitted that it was reasonably foreseeable by Pfizer that if the injunction was wrongly imposed then at its lifting Lasco would have had to take steps to restart its trading and it would take some time for it to recover its share of the market that it would have attained at the date of the lifting but for the injunction. As a major participant in the ethical drugs trade, Mr. Chen submitted that Pfizer would be aware that it would have been likely that during the life of the injunction third parties would attempt to trade in the restricted drug. On the facts, this did occur after about four (4) years and the attempts were brought to the attention of Pfizer. The evidence is that once this was brought to the attention of

Pfizer, the local manager at the time wanted steps taken to stop the intrusion by the third parties, but the lawyers and managers of Pfizer headquartered in New York, USA made a conscious decision not to intervene and to allow the third parties free reign to trade. They in effect overruled the local manager.

**[279]** Mr. Chen submitted that this decision had the effect of destroying the opportunity of Lasco and Medimpex as first entrants in the generic market at the two different levels that they had. The result of the decision is the destruction of the opportunity and was a deliberate and conscious decision in circumstances where Pfizer could have taken steps to enforce the injunction as against the third parties, or else, to apply to the court to revoke the injunction to permit the defendants to resume trading and to compete against the third parties.

**[280]** According to counsel, the circumstances existing at the making of the injunction, and at the time the third parties entered the market, were brought to the attention of Pfizer and are relevant to the issue of remoteness. Especially so in relation to the conscious and deliberate decision of Pfizer not to stop the third parties. Pfizer, as a principal in the drug trade must have known what would have resulted if it allowed the injunction to keep Medimpex and Lasco out of the market place whilst allowing third parties to enter. It was submitted that the court is entitled to take these matters into consideration when deciding if the loss incurred during the recovery period from 2012 to 2022 should be borne by Pfizer by virtue of the present state of the law.

**[281]** Further it was submitted that the loss arising after the lifting of the injunction is not remote and should be allowed on the basis that this Claimant, Pfizer, being an experienced and major participant in the trade ought to have known of other circumstances, such as the intervention of third parties into the market, that was likely to give rise to the particular type of loss that occurred in this case.

**[282]** Mr. Chen concedes that he has not found any English cases directly on point which deals with the period beyond the lifting of the injunction where there has

been a prohibition of trading in a particular commodity. However, he posits that this is because interim injunctions in jurisdictions like the UK do not last for seven (7) years, as in the instant case. The injunctions are either discharged or a trial occurs within a reasonable time. Mr. Chen observed from his review of the cases cited that the period is typically within one (1) year and in the **Astrazeneca AB** case it was only ten (10) months.

[283] The court was referred to the **Algonquin Mercantile Corporation** case. This was a case before the Trial Division of the Federal Court of Canada. One of the issues identified at paragraph [27] of the judgment was whether damages can be awarded for loss sales resulting from the injunction but actually occurring during the post-injunction period. After reviewing the law, at paragraph [37] of the judgment the learned Judge concluded:

*“The usual undertaking given to the Court by parties requesting an interlocutory injunction in the context of today's society in Canada involves, in my view, an undertaking to pay all damages which flow from the granting of the interlocutory injunction and is not in any way restricted to those which occurred during the period of the existence of the injunction itself, nor does the common law impose any artificial cut-off date. The assessment for the period following the injunction remains subject to the usual limitations as to remoteness, that is, as to whether in the particular circumstances of the case, after a certain period of time has passed and other circumstances have intervened, losses, if any, can still on a balance of probabilities, be attributed to the injunction with any reasonable degree of certainty.”*

[284] Mr. Chen submits that this reasoning clearly supports Lasco's contention that in the context of the modern law, the flexibility that this court ought to bring to bear in its application of the law and the circumstances of this case and should give rise to the assessment of damages for the loss occurring during the post injunction period from 2012-2022.

[285] Lasco contends that the decision by Pfizer not to take steps against the third parties is an event giving rise to the need for Lasco to have at least ten (10) years to attempt to regain the market share it would have had at the lifting of the injunction. This was estimated by Mr. Whyte to be about 635,539 people or in terms of tablet sales about 231,969,972 tablets and this should be taken into account by the court in assessing the damages.

[286] Further Mr. Whyte made the assumption that because of the injunction and the refusal of Pfizer to do something about the intrusion of the third parties into the market, Lasco's market had in effect been destroyed and it would take at least ten (10) years to recover, if at all. In the circumstances it is submitted that the assumption is reasonable and should not be discounted but the court is minded to apply a discount it should be modest, considering the wilful and deliberate action or inaction of Pfizer.

## Interest

[287] It was submitted that this evaluation of loss relates to a prohibition against the carrying on of trade. Since it is a commercial transaction it should be treated as such. Reference was made to the Court of Appeal decision of **British Caribbean Insurance Company Ltd. v Delbert Perrier** (1996) 33 JLR 119, which has set out the position relating to interest. Carey J.A. opined at page 127 as follows:

*"In summary, the position stands thus:*

*Awards should include an order for the defendant to pay interest.*

*the rate should be that on which the plaintiff would have had to borrow money in place of the money wrongfully withheld by the defendant; and*

*the plaintiff is entitled to adduce evidence as to the rate at which money could be borrowed.*

*Having regard to the evidence led before the learned judge viz, the contents of the statistical digest published by the Bank of Jamaica, he was entitled to fix the rate at which he did. His approach was consonant with my understanding of the law."*



[288] Further the method of calculation was discussed by Morrison JA (as he then was) in **Goblin Hill Hotels Limited v. John Thompson et al** (unreported) Court of Appeal, Jamaica [Supreme Court] Civil Appeal 57/2007, judgment delivered which was delivered on 5 June 2009 at paragraph [22] of the judgment:

*“As to the rate of interest, Dr. Barnett invited us to apply the rate of 15% per annum to the United States dollar equivalent of the arrears, on the basis that Sykes J had upheld the validity of the loan in that currency and at that rate which on the appellant’s case it had been obliged to obtain to meet the expense of the property. In the alternative, Dr. Barnett submitted that interest should be assessed on a commercial basis and at commercial rates as expressly sanctioned by this court in **British Caribbean Insurance Company Ltd. v Delbert Perrier**. While Dr. Barnett’s instructing attorneys-at-law very helpfully provided calculations based on both alternatives, I prefer the simplicity of a modified version of the second (the first involves the further complication of having to take into account the rate of devaluation of the Jamaican to the United States dollar over the period between forfeiture of the shares under date of judgement), that is, to take advantage of the commercial banks’ weighted loan rates over the period 23 December 2001 to 6 November 2006. Applying the interest rate data supplied by the appellant (which were not challenged by the respondents), I make the average interest rate per annum on this basis for the period to be 14.68%.”*

[289] It was submitted that in the case at bar, the defendants are the recipients of the funds and stand in the shoes of the defendant in **British Caribbean Insurance Co. Ltd**. It was submitted that this court is entitled to look at the information contained in the agreed copy of extract from the publication of the statistical digest published by the Bank of Jamaica.

[290] Based on the foregoing, it was submitted that the appropriate rate should be the average between the highest and lowest rates prevailing at the time of the injunction which is 8.23 % per annum, as agreed by the parties.

### **ANALYSIS & FINDINGS**

[291] I wish to make the following observations before embarking on the details of my analysis and findings:

- a. it is my responsibility to assess the damages that are payable under the cross-undertaking. While precision and certainty are impossible, a principled approach is not;
- b. the defendants must show that the injunction caused them loss and that their chances of making a profit from the sale of generic amlodipine was real and not fanciful. They must establish their loss by adducing relevant evidence;
- c. once this threshold has been passed, the court must then evaluate that chance and reflect it in the amount of damages it awards;
- d. I find that it was certain that both Lasco and Medimpex would have continued to supply the market with generic amlodipine and that they would have made a profit from doing so during the period that the injunction was in place. Happily, this is one of the few areas that is agreed. All that is left is the quantification of the loss and on this matter, to frame it delicately, the parties are poles apart;
- e. the approach to the quantification shall be compensatory and not punitive;
- f. I will make the assessment based on the same principles as those applicable to breach of contract because I find this approach will

enable me to determine all those issues that have arisen. However, I will bear in mind that since realistically there was no breach of contract, the damages can be assessed liberally but with logical and sensible adjustments;

- g. I will adopt the words and approach of McCombe J<sup>37</sup> that, *“In my judgment, I would not adopt an approach of awarding either “modest” damages on the one hand or “generous” damages on the other. I think that the correct approach should be to award realistic compensation for what has occurred”*;
- h. in making the assessment as to what would have occurred in the counterfactual scenario, I have, like Sales J in **Astrazeneca AB**<sup>38</sup> and Norris J in **Apotex**<sup>39</sup>, compared the extent to which Lasco and Medimpex were successful with their generic products in penetrating the market prior to the injunction and in Lasco’s case, after the injunction with the relevant counterfactual position. However, I recognise that the task is to reconstruct the hypothetical market ‘but for’ the injunction;
- i. mirroring the method adopted in two authorities cited in (h.) above I will employ the conventional method of assessing the damages on a particular hypothesis and then to adjust the award by reference to the percentage chance of the hypothesis happening;
- j. In carrying out the exercise I am engaged in, I am guided by the dicta of Sales J in **Astrazeneca AB** that, *“The function of the Court at trial is to assess the evidence it hears for itself, bringing to bear its own understanding of the surrounding circumstances and making its own*

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<sup>37</sup> See: paragraph [25] above.

<sup>38</sup> See: paragraphs [15] and [16] of the judgment.

<sup>39</sup> See: paragraphs [26], [29] and [33] of the judgment.

*evaluation of the sincerity, reliability and credibility of the evidence given, in the context of an overall assessment of probabilities and of possible prejudices or incentives to embroider or distort. This is not a matter for expert evidence.”*

- k. I have also taken into account and adopted the approach of Norris J in **Apotex** (who relied on Stuart Smith LJ in **Allied Maples Group Ltd**<sup>40</sup> (supra) who “warned against placing reliance on the evidence of a claimant as to what he would have done in hypothetical circumstances, and I consider that similar caution must be exercised in relation to the evidence of the defendant...One must measure what a witness now says he honestly believes he would have done against such objective benchmarks as are available...”<sup>41</sup> The court therefore recognises that evidence presented by the parties in this matter may be innocently self-serving and must be subject to careful scrutiny. Reasonable inferences are therefore to be drawn from actual transactions which took place and are in line with commercial realism. In my assessment of the counterfactual position, I have guarded against what may seem to be generous estimates of market shares, the number of tablets sold, the prices at which they were sold (which are some of the factors used to calculate the lost profits), as well as, estimations that may be modest;
- l. finally, there was a dearth of evidence as it relates to how the pharmaceutical market operates in Jamaica and evidence as to sales made by other distributors and pharmacies of the drug in issue was simply not available/forthcoming. The experts in this matter all testified as to the challenges they faced in obtaining this information. This is a

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<sup>40</sup> For citation see paragraph 24 above

<sup>41</sup> See: paragraph 41 of the judgment

factor that would, in my view, as well as theirs, have been of tremendous importance to inform their respective reports. This shortfall, no doubt, will have implications for the assessment of the true market for amlodipine in Jamaica. Nonetheless, the court must arrive at its findings in the context of all the circumstances of the instant case.

[292] It is clear that the defendants are entitled to recover for the cost of their respective stock which had to be destroyed as it could not be sold or returned to the manufacturers. I accept the evidence of both defendants in this regard and would therefore award the sum of JMD\$5,322,799.50 to Medimpex and JMD\$155,738.90 to Lasco.

[293] Notwithstanding the strident submissions of counsel and the extensive reports by the financial experts, I am unable to accept any of the scenarios *in toto*. While I am satisfied that all three (3) experts are qualified to assist the court in resolving the instant matter, the court has reservations with aspects of each of the reports. These will become apparent subsequently.

## **THE SCENARIOS**

[294] I begin now with the consideration of the scenarios. There are four (4) competing scenarios, two (2) that were presented by Pfizer and one each by Lasco and Medimpex. The details of these scenarios have been discussed earlier in the decision.<sup>42</sup> I will refer to certain aspects of them as are necessary.

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<sup>42</sup> See: paragraphs [98] to [103] for Pfizer's; paragraphs [111] to [119] for Medimpex's and paragraphs [120] to [124] for Lasco's. The scenarios have also been discussed extensively in the submissions of learned counsel for the parties. See: paragraphs [136] to [157] for Pfizer's submissions, paragraphs [158] to [218] for Medimpex's and paragraphs [219] to [290] for Lasco's.

## **THE MARKET**

- [295]** The starting point, in my view, is to determine what the market for amlodipine would be (i.e. its size). This issue is not agreed. Lasco and Medimpex say that (to use their words) the potential market is comprised of approximately 800,000 persons. Pfizer's position is that approximately 200,000 people represent the total treated market of which amlodipine is a mere subset.
- [296]** Mr. Chin in his evidence quite stridently said that during the counterfactual scenario Lasco would have undertaken a massive education and marketing strategy resulting in its generic being prescribed and taken by 90% of those persons who are hypertensive. Taking the figure of 800,000 as representing the total number of persons suffering from hypertension in Jamaica (which Lasco says is the market) this would have amounted to 720,000 persons in Jamaica who would have been treated with Las Amlodipine. Lasco's expert Mr. Whyte projected the more conservative figure of 74% which amounts to about 592,000 persons.
- [297]** Applying Professor Wilk's principle of the "Rule of Halves" which has been accepted by the court, this seems to me that Lasco's position is that they would have had 100% of the persons who knew they had hypertension and who did not seek treatment, as well as, almost 50% of those who were not even aware that they had the disease taking their generic.
- [298]** While Medimpex's figures, I agree, at first blush may appear to be more conservative, they also took into account at its lowest a percentage of the treated hypertensives and at its highest those who knew they had hypertension and were not being treated, as well as, persons who did not know they had the disease. Between both Medimpex and Lasco combined, they say, at the highest, they would have captured approximately all of this potential market (and even more if the figures are added) and at its lowest more than 90% of the market. It is my

view that the chance of this occurring during the counterfactual situation would have been highly improbable for a number of reasons.

[299] Firstly, there is absolutely no evidence before me that by the time Pfizer obtained the injunction (bearing in mind that those proceedings commenced in 2002 shortly after Pfizer obtained its patent and the defendants had been in the market for sometime before the injunction was granted) that Lasco had commenced or prepared any plan for this purported highly intensive and effective marketing strategy that would help them to realize or achieve their ambition of penetrating and dominating (as they said) the “potential market” of approximately 800,000 persons to the degree claimed.

[300] There is no evidence from Lasco or Medimpex as to the details or what steps they would have taken to advance their campaign to capture and dominate the potential market (such as detailed marketing plans and strategies which I observed were presented to the courts in both the **Apotex** and **Astrazeneca AB** cases). I do not regard mere ‘say so’ as proof that this is a reasonable assumption. I am of the belief that it required and certainly it would have been helpful to the court if more detailed and cogent evidence had been made available. The inadequacy of the evidence in this area, therefore, did not persuade me.

[301] Evidence was led by Lasco of their previous successes in dominating the market for adhesives, black pepper, food and drink and even HIV medication (no evidence of a similar vein came from Medimpex). While I have no doubt about Lasco’s marketing strategies and their ability to dominate the market for the products named above, in my view, those are completely different markets which are affected by different considerations given our cultural norms and reality. In terms of the market for hypertension, as an example, Professor Wilks pointed out one such nuance – one of the side effects that treatment may cause in men – erectile dysfunction. It is therefore, to my mind, not surprising to find that the evidence illustrates that the figures for men, when compared to those for women,

who are being treated and under control, are significantly lower. I draw the reasonable inference from this evidence that there will be men in Jamaica who as a result of this side effect who will refuse treatment, bearing in mind our cultural reality. I believe that this inference is well supported by the evidence that even among those persons who know that they are suffering from hypertension they have not sought treatment in the form of any ethical drugs.

**[302]** It was also my opinion that this aspect of the evidence (as to the penetration of and dominance by the parties of the potential market) ignores certain factors. Firstly, there are other medications and generics on the market for the treatment of hypertension, some of which, like diuretics, are even cheaper than generic amlodipine. There is also the evidence (including the literature exhibited) that diuretics are considered as the appropriate medication to be prescribed as a first line treatment for persons of colour diagnosed with hypertension, whether by itself or in combination with other medications of which amlodipine is but one. Therefore, it is not a reasonable assumption to make, that every single person who suffers from hypertension or the majority of those who do, would have been prescribed and treated with generic amlodipine. This to me seems quite far-fetched.

**[303]** Secondly, implicit in the “Rule of Halves” principle is that there will be persons, for one reason or another, who will not take any medication for the disease even if they have been diagnosed, as the evidence discloses. Some persons may as Professor Wilks and Dr. Gordon said embark upon lifestyle changes (such as diet and exercise) while others may resort to home remedies (or ‘bush medicine’ as it is commonly called in Jamaica). Others may never be diagnosed, much less treated, during their lifetime (as the evidence tends to show) and the discovery of the disease may take place post-mortem. (It is no wonder hypertension goes by the alias “The Silent Killer”.)

**[304]** It was submitted that Lasco had an existing customer base and that it was their intention to sell Las Amlodipine to them. Again I noticed the paucity of evidence



on this subject. What is Lasco's customer base? And in particular what is the number of those persons who had hypertension or was being treated for it? There was no evidence presented to the court to enable it to assess what bearing this could have firstly, on the market size and secondly, on the market share that Lasco says it would have attained 'but for' the injunction. I did not find this argument convincing.

**[305]** I also found wanting the evidence that attempted to address the issue of switching, whether from Norvasc to the generics or from other hypertensive medications to generic amlodipine. I believe that this evidence was intended to show one of the means by which the defendants (since both pharmacists spoke of the switch initially from Norvasc to Normodipine and then from Normodipine to Las Amlodipine) would have expanded the market for amlodipine and gained more market shares in the counterfactual scenario.

**[306]** The evidence put forward by Lasco on this point came mainly from Dr. Gordon and two pharmacists – Ms Blackwood and Ms Kossally-Chang. Dr. Gordon practises medicine in two (2) out of 14 parishes. Ms Blackwood's pharmacy is located in May Pen, Clarendon and that of Ms Kossally-Chang in Independence City, St. Catherine.

**[307]** Dr. Gordon testified as to his prescribing habits – that he began to switch his patients to the generics and in particular to Las Amlodipine when it became available because of its price and efficacy. Both pharmacists spoke of the switches that were taking place between Norvasc, Normodipine and Las Amlodipine. They also gave evidence that they would advise patients of the availability of generic versions of Norvasc (this evidence relates specifically to inter-brand switching in my view).

**[308]** I have two (2) comments. This was the only evidence presented that addressed the issue of switching (which in my view would be very important if Lasco and Medimpex wished to gain the market shares they said they would). There is no

evidence from Dr. Gordon as to how many patients were being switched. There was also no evidence from the pharmacists of the number of persons to whom they had dispensed generic amlodipine.

**[309]** The more glaring deficit, in my view, would be that the evidence adduced came from just one (1) doctor whose practice is based in the Corporate Area and two (2) pharmacists representing two (2) pharmacies in two (2) parishes in the entire Jamaica. I can safely conclude that there are many more doctors and pharmacies located in and around the Island. At the very least I expected that evidence of this nature would have come from doctors and pharmacists from a wider cross section of the country. I am therefore not satisfied, on a balance of probabilities, that this evidence provided a good representative example from which the court could gain more insight as to the operation of the market in general and the switching from other medications for hypertension to generic amlodipine specifically.

**[310]** However, it is likely, given my understanding of the evidence as to how the pharmaceutical industry operates in Jamaica and the marketing strategies that are utilised, that doctors and pharmacists through the medical representatives of the defendants would have been informed of the efficacy, prices and availability of the generics and this, in my view, would have facilitated some amount of switching.

### **Market size**

**[311]** To my mind, there is absolutely no doubt that there is a significantly larger potential market for amlodipine than the number of tablets being sold over the years would suggest. In this regard, I do agree to a certain extent with Dr. Barnett and Mr. Chen that the market is not limited to Pfizer's tablet sales

(approximately 3,000,000 tablets or 9,000 persons)<sup>43</sup> during the injunction period, as contemplated by Mr. Lobo's scenario one. However, in the same vein, I do not accept that the market for amlodipine is the same as the entire population afflicted with hypertension, which was estimated by the Wilks Report to be in the region of about 800,000 persons (who if treated with amlodipine would translate to approximately 292,000,000 tablets per annum). The market is somewhere in this vast middle.

[312] Having regard to the "Rule of Halves" as presented by Professor Wilks, the number of persons being treated for hypertension is accepted as being no higher than 200,000. In essence this would be the market for all drugs used in the treatment of hypertension, including amlodipine. The evidence reveals that the number of persons who are treated for hypertension has remained relatively constant from 2005 to 2014. Taken at its highest the market, in my judgment (after considering the approach taken in authorities cited and relied upon by the parties especially the **Apotex** and **Astrazeneca AB** cases) would not likely exceed 200,000 persons during the counterfactual scenario. These are the persons who not only knew that they have hypertension but who have also made the choice to be treated. They are the ones who would be purchasing drugs for the disease. To say otherwise would be descending into the realm of speculation, a journey that will be strenuously resisted and avoided by this court.

[313] Therefore, the question is whether the defendants have provided sufficient evidence to the court to suggest that, on balance, they would have been able to take advantage of this market of 200,000 persons (which would translate to approximately seventy-three million (73,000,000) tablets per annum) and increase tablet sales significantly as opposed to the sort of marginal year over year increase actually seen by the evidence and data presented.

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<sup>43</sup> See: paragraph [99] herein

**[314]** It must be borne squarely in mind that there are several competing drugs used in the treatment of hypertension, of which amlodipine is but one. While it was suggested that amlodipine could be used as a first line treatment in hypertensive patients of African descent, which constitutes the majority of the Jamaican population; it was also opined that other types of drugs could be just as effectively used as well. As such, it seems that even if amlodipine became the most prescribed drug, it would still share the market with other drugs. In essence, the court could not readily accept that amlodipine, one of a number of generic CCBs (nifedipine and verapamil as examples of two others purchased by the NHF and available to patients in Jamaica)<sup>44</sup>, as well as only one of a number of medications used for hypertension in Jamaica, would become the only drug used in the treatment of hypertension. I find this to be somewhat far-fetched.

**[315]** It is to be noted that Mrs. Moss, in her Sierra Report opined that the demand (particularly as it related to Normodipine) was assessed by reference to the Wilks Report which used the treated hypertensives (200,000 persons) as the minimum size of the potential market and the total hypertensives (800,000 persons) as the maximum size of the total market. To my mind the court must be careful not to conflate the market for CCBs with the market for all drugs used to treat hypertension. In this regard I agree with Mrs. Kitson QC that the former must be a subset of the latter.

### **Unit prices**

**[316]** I will next consider unit prices. This aspect of the evidence is also disputed. I have accepted Mr. Lobo's evidence as to the prices that Medimpex projected that they would sell their generics in the counterfactual scenario. There were JMD\$19.62 and JMD\$28.35 for the 5mg and 10mg dosages of Normodipine respectively. In March 2005 just before the injunction was granted Medimpex

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<sup>44</sup> See: the discussion under the heading the NHF Data for CCBs at paragraphs [125] et seq above.

sold their 5mg for JMD\$20.94 and their 10mg for JMD\$29.99. These projected prices therefore represent a marginal decrease, which I have viewed as reasonable.

**[317]** Lasco on the other hand just prior to the injunction sold their 5mg dosage of Las Amlodipine for JMD\$7.23 and 10 mg for JMD\$13.67. However, during the counterfactual scenario the projected prices would be JMD\$19.13 and JMD\$23.42 for their 5mg and 10 mg dosages respectively. The price for the 5mg was more than doubled while that of the 10mg was almost doubled. I found this to be quite curious for two reasons.

**[318]** Firstly, I thought those prices were too high and for the increases to be imposed in April of 2005 just at the very moment when the injunction was imposed seemed a little too convenient for me. I ask myself the question, if there had been no injunction, would this have in fact taken place? I do not accept that there would have been that sort of rapid upward price movement if the injunction was not in place. Therefore, this aspect of the evidence is rejected.

**[319]** Secondly, I have also considered the prices of Las Amlodipine when Lasco re-entered the market in 2012 (which were JMD\$7.59 and JMD\$11.30 for their 5mg and 10 mg dosages respectively). These prices decreased in 2013 (the 5mg was sold for JMD\$3.51 and the 10mg for JMD\$6.01) and to some extent in 2014 (the 5 mg was sold for JMD\$3.48 and the 10mg for JMD\$7.57). There was somewhat of a rebound in 2015 when the 5mg was sold for JMD\$6.20 and the 10 mg for JMD\$12.36.

**[320]** I observe that when Lasco re-entered the market in 2012 it had changed considerably because of the number of generic entrants (about six (6) at that time). The downward adjustment of Las Amlodipine prices after Lasco relaunched would, in my view, illustrate what would have occurred in the open market during the counterfactual scenario.

**[321]** I make the reasonable assumption that both Lasco and Medimpex would have responded to other entrants in the generic amlodipine market in a similar manner. This, to my mind, would be in keeping with sound economic sense and commercial realism (and in fact this was alluded to in Mrs. Moss' report and Dr. Barnett's submission that Medimpex would possibly have reduced its prices in response to Lasco's presence in the market. I assume that this would also apply to other entrants).

**[322]** Accordingly, it is assumed that during the counterfactual scenario when other players entered the market that there would be periods of price adjustment as the market transitioned before any price plateaus. I also draw the inference, on the evidence given by Mr. Chin of the number of players that were in the market when Lasco relaunched in 2012, and that this was the reason for the reduction of prices for Las Amlodipine. This was Lasco's response to the presence of other entrants in the market who were trading their generics at competitive prices. Medimpex, I have assumed, would respond in a similar fashion. However, given their higher cost of sales (when compared to Lasco) it is not expected that the reduction in the prices of Normodipine would be significant or drastic during the counterfactual situation.

**[323]** It was submitted that both Medimpex and Lasco would have dominated the market to such extent that the market would be satisfied and there would be no need for other players to enter the generic amlodipine market (or that this was unlikely). Based on my earlier discussion<sup>45</sup>, I will just simply say that there is no basis in the evidence for accepting this submission. Therefore, I make the assumption that other players would have entered the market in the counterfactual situation and that any scenario presented ought to have taken this fact into account in the calculations of unit prices, as well as, market shares.

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<sup>45</sup> See: paragraph [260] above.

**[324]** In light of the above, I do not accept the evidence of the experts for Medimpex and Lasco as to the prices that their generics would have traded at during the counterfactual scenario. I regard as a fairer assumption the alternative calculations presented by Mr. Lobo (although based on constant unit prices) of JMD\$7.17 and JMD\$13.46 for Lasco's 5mg and 10mg respectively, as well as, JMD\$19.62 and JMD\$28.35 for Medimpex's 5mg and 10 mg.

### **Market shares**

**[325]** Market shares depend on a number of contingencies which include price of the commodity, other entrants in the market and how the parties would have responded to them. In the ordinary course of things the cheaper the price, the higher the demand and the greater the market shares achieved. The converse is also true. The evidence discloses that the market for amlodipine was reacting in accordance with this standard rule of Economics.<sup>46</sup>

**[326]** As discussed earlier<sup>47</sup> I do not agree with Mr. Lobo that the market shares would have been fixed at the pre-injunction level and would have remained constant. As will be seen, I certainly was not persuaded by the evidence of Mr. Whyte and Mrs. Moss on this matter as well.

**[327]** I am of the view that the estimates that all the experts presented in all their scenarios on the issue of market shares require adjustments based on the trends in the market which took place prior to the injunction. The fairer assessment during the counterfactual situation, it is opined, would be that both Pfizer's and Medimpex's market shares would have declined and Lasco's would have increased. I also find that some allowance ought to be made for the other players who would have entered the market. For the same reason, I also do not agree

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<sup>46</sup> See: Table 2a of Mr. Lobo's report at page 16 of the bundle containing the Expert Report

<sup>47</sup> See: paragraphs [142] to [149] above

that the market shares during the counterfactual scenario would have remained constant.

**[328]** However, while I find that Lasco's market shares would have increased I do not agree with neither Mr. Chin nor Mr. Whyte that this would have reached a high of 90% and 74% respectively. This would amount to 180,000 and 148,000 persons respectively (given my determination of what the market size is). These figures, I find are overstated.

**[329]** Mrs. Moss in her report stated that Medimpex estimates that amlodipine accounts for 95% of the market for CCBs, which is certainly not supported by the NHF data. This estimation, as depicted by the evidence, is vastly overstated.<sup>48</sup> Mrs. Moss, quite sensibly, in my view, adjusted and used a range of 20% to 50% of the market that would be prescribed amlodipine. This estimate, based on the findings I have made of what the market size is would be about 40,000 to 100,000 persons. However, having considered the evidence as a whole (and my earlier observations and discussions)<sup>49</sup> I have also found that it is unlikely that Medimpex would have attained this market share during the counterfactual scenario.

**[330]** What then is the court's assessment of the market shares that the parties, and in particular Medimpex and Lasco, would have achieved during the counterfactual scenario? The table below shows what my assumptions are and makes allowances for the market shares of other entrants who would have been in the market as borne out by the evidence. I have already stated my assumptions concerning the market in the 'but for' period and identified when the various

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<sup>48</sup> See: the discussion on the NHF data at paragraph [125] et seq.

<sup>49</sup> See: the discussion at paragraphs [295] to [315] above as well as the discussion on the NHF data at paragraph [125] et seq.



events (at risk period, open market, transitional phases and plateau periods) would in my assessment have taken place.<sup>50</sup>

	<b>Lasco</b>	<b>Medimpex</b>	<b>Pfizer</b>	<b>Others</b>
<b>2005</b>	<b>37.1%</b>	<b>44%</b>	<b>18.9%</b>	
<b>2006</b>	<b>44%</b>	<b>37%</b>	<b>15%</b>	<b>3%</b>
<b>2007</b>	<b>55%</b>	<b>30%</b>	<b>10%</b>	<b>5%</b>
<b>2008</b>	<b>60%</b>	<b>25%</b>	<b>10%</b>	<b>5%</b>
<b>2009</b>	<b>60%</b>	<b>25%</b>	<b>10%</b>	<b>5%</b>
<b>2010</b>	<b>60%</b>	<b>25%</b>	<b>10%</b>	<b>5%</b>
<b>2011</b>	<b>60%</b>	<b>25%</b>	<b>10%</b>	<b>5%</b>
<b>2012</b>	<b>60%</b>	<b>25%</b>	<b>10%</b>	<b>5%</b>

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<sup>50</sup> See: paragraph [260] above.

## Volume of Sales

[331] The next issue to be decided, before addressing whether an award is to be made for the post-injunction period, is the volume of sales. This involves, as Norris J said in **Apotex**, “consideration of market share and total market size.”<sup>51</sup>

[332] The total market size has already been decided at 200,000 persons, as well as the assumed market shares. What is left to be settled is the percentage of the total market amlodipine would have gained during the period that the injunction was in place.

[333] I do not agree with Mr. Lobo’s assessment of volume of sales in his Scenario 1. The estimates provided by both Mr. Whyte and Mrs. Moss appear to me to be too generous (in view of my findings).

[334] In my assessment of the counterfactual scenario:

- i)* It is very likely that the market for amlodipine would have, at the very least, doubled. It is reasonable to me that the number of persons who would have taken amlodipine would have been in the vicinity of about 10% to 11% of the total treated hypertensive market (about 20,000 to 22,000 persons) moving from about 9000 persons. In terms of the number of tablets, this would be in the vicinity of 7.3M to 8.03M per annum. I believe that this would be in line with a 35% discount of Mr. Lobo’s Scenario 2. This to my mind would have occurred because of the availability of the cheaper generics and in light of the fact that price is the dominant factor that drives demand. This would have occurred, in my judgment, because

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<sup>51</sup> See: paragraph [48] of the judgment

of the efficacy of the generics and their availability. I conclude that this is a fair and reasonable assumption on the totality of the evidence;<sup>52</sup>

*ii)* It is likely that this increase in the amlodipine market would also have been attained because I have assumed that the NHF would have made awards to various distributors of the generic drugs on account of their low prices. The final prices to patients would have been very affordable due to the NHF subsidy (another tenet that would influence expansion of the market). Price is also a vital factor, to my mind, that determines the NHF awards since all its transactions are funded from the public purse;

*iii)* It is likely that this expansion would also have been achieved because there would have been a number of doctors (like Dr. Gordon) who would make the relevant switch to prescribe generic amlodipine to their patients on account of their cheaper prices and efficacy. Similarly, there would be pharmacists who would advise patients of the availability of generics in circumstances where the branded product is prescribed and it is more than likely that some of those persons would switch as well;

*iv)* I have also taken into account that post-injunction Lasco returned to the market and sold more tablets than it did prior to the injunction. This was taken into account in determining its market share and volume of sales during the counterfactual situation.<sup>53</sup>

**[335]** I acknowledge that it would have been quite useful to test the reasonableness of the assumptions that I made against the sales of all the actual players who were in the market before, during and after the injunction, but unfortunately, this evidence was not available.

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<sup>52</sup> Evidence as it concerns the presence of other hypertensive drugs on the market, the NHF data, the absence of data from the other players and the market trend prior to the injunction (to identify some of the main areas of the evidence on this point).

<sup>53</sup> See: Tables 2a, 2b and 2c of Mr. Lobo's report

- [336]** Based on my assumptions I believe that of the four scenarios that were presented to the court Mr. Lobo's Scenario 2, with the necessary adjustments and discount, makes the fairest assessment of what would have occurred in the counterfactual scenario. I note that he testified that it was not based on the actual data but made available to the court in the event that it was found that the market for amlodipine had not matured at 3M to 3.6M tablets. And I have so found.
- [337]** In the counterfactual there would in fact be no data, and while the court is required to look at what took place prior to, during and after the injunction to inform what might have occurred in the 'but for' period, it is the law that reasonable assumptions must be made in the absence of certainty (and in this case where there is a lack of vital evidence as to the total sales of generic amlodipine from all the players in the market).
- [338]** I have accepted Mr. Lobo's evidence and the methodology he has used to arrive at his calculations. While I found all the experts to be honest and straightforward, one of the vital issues for me in this case (more so as it concerns the experts) is that of reliability. As far as this is concerned, I found Mr. Lobo to be more reliable and his responses in cross examination more cogent. I have also taken into account, and I mean no disrespect by this, but am merely stating a fact, that unlike the other two experts who were undertaking this exercise for the first time, and who spoke quite candidly (and the court thanks them for their honesty) of some of the difficulties of the exercise, Mr. Lobo has done calculations of this kind on numerous occasions. I was impressed with his demeanour and approach to the task at hand. Nevertheless, I have taken into account all the factors that limited the scope of his report. I thank him too for his forthrightness.
- [339]** However, there is an aspect of his calculations that I believe ought to be adjusted (this is in addition to the market size). These are the costs of sale for Medimpex's 5mg and 10mg doses. Mr. Lobo puts the costs of sale for the 5mg at 88% while that of the 10mg at 92%. I regard these as too high and prefer an average of the

costs of sale for both dosages that were presented by Mrs. Moss. These would be 67% and 70% for the 5mg and 10 mg respectively.

**[340]** In the circumstances, I conclude that Mr. Lobo's Scenario 2 has a probability of about 65%. A 10% discount for all the possible "vicissitudes, contingencies and uncertainties" is appropriate.

**[341]** Before addressing the post-injunction period I wish to address two issues that were raised by Medimpex and Lasco about the players who entered the market during the period that the injunction was still in place against them.

**[342]** Firstly, on April 30, 2009 Jones J found that Pfizer's patent was invalid. It was during this period (after he extended the injunction pending appeal and the decision of the Court of Appeal and discharge of the injunction was on May 31, 2012) that they entered the market. Pfizer's attorneys were notified of this by Lasco's counsel. Letters were written to the alleged "offending" parties but no other steps were taken by Pfizer against them. The evidence revealed that this decision was taken by Pfizer's top executives. Lasco and Medimpex allege that this further destroyed the market and their likelihood to regain the market shares they had enjoyed prior to the injunction. The thrust of their arguments is that the damages awarded ought to take this fact into account.

**[343]** I wish to state that I have done so. The assessment that I have conducted, in my own view, is quite liberal in all the circumstances and this issue is adequately and fairly covered by the damages that I have awarded.

**[344]** Medimpex (and I believe Lasco) alluded that they were first movers in generic market and that the advantages that they would have derived from this position were destroyed by the injunction. This, they say is another circumstance that is to be accounted for in the award. I do not agree. The authorities cited by the parties do not support this submission.

[345] Medimpex was the first mover. It entered the market in 2001. At that time no other generic was in the market. In 2002 Lasco and NMF entered. Any first mover advantage that Medimpex enjoyed would have been destroyed, not by the injunction in 2005, but by Lasco and NMF in 2002. This principle is not applicable at all, in my view, to Lasco. When it entered the market there would have been one or two other players (Medimpex and/or NMF) already in the market. The market at that time (in 2002) was gearing up to become an open one.

### **POST- INJUNCTION PERIOD**

[346] Lasco and Medimpex submitted that they are to be awarded damages post-injunction for 10 and nine (9) years respectively. Their detailed submissions are set out above.<sup>54</sup> Understandably, Pfizer has been strenuous in its opposition to any such award being made. A number of authorities have been cited<sup>55</sup> but one in particular has been referred to by both Medimpex and Lasco. I have set out below the relevant portion of the case that has been relied on.

[347] In ***Algonquin Mercantile Corporation*** (supra), Addy J stated:

*[37] The usual undertaking given to the Court by parties requesting an interlocutory injunction in the context of today's society in Canada involves, in my view, **an undertaking to pay all damages which flow from the granting of the interlocutory injunction and is not in any way restricted to those which occurred during the period of the existence of the injunction itself, nor does the common law impose any artificial cut-off date.** The assessment for the period following the injunction remains subject to the usual limitations as to remoteness, that is, as to whether in the particular circumstances of the case, after a certain period of time has passed and other circumstances have intervened, losses, if any, can still on a balance of probabilities, be*

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<sup>54</sup> See: paragraphs [13] to [20]

<sup>55</sup> *Ibid*

*attributed to the injunction with any reasonable degree of certainty.*  
(Emphasis added)

**[348]** In principle, I agree with Abby J. In my opinion it is only fair and just that if it can be proven that as a result of an interlocutory injunction a party suffers loss that extends beyond the injunction period, I see no reason why that party should not be compensated for it. The question is whether or not in the circumstances of this case, taking into consideration the factors that Abby J stated are to guide the court, the application of the principle is merited.

**[349]** Regrettably, I think not. I am of the view that the losses that Medimpex and Lasco have ascribed to the injunction in the post-injunction period, have not been proven on a balance of probabilities “with any degree of certainty.”

**[350]** I say so because I found that their cases were premised on certain errors of principles and facts (most, if not all of which were over-stated) such as:

*i)* the size of the market;

*ii)* the market shares they would have attained;

*iii)* the market for amlodipine;

*iv)* the unit prices at which they would have sold their generics which seems to me to ignore the dynamics of a truly open market, which would have occurred during the counterfactual (such as transitional periods, periods of price adjustments and period of plateaus);

*v)* their volume of sales;

*vi)* very little, if any, allowances being made for the entrance of other players in the market during the period that the injunction was in place and a paucity of evidence as to how they would have responded to this; and

*vii*)the time that they say the market would have plateaued.

**[351]** I have noted also that Lasco unlike Medimpex (which made a decision not to return to market because it was felt that their generic could no longer compete with the other) returned to the market after the injunction was lifted and sold greater volumes of its product than it did prior to the injunction. This in essence was mitigatory. However, in arriving at its calculations for the period Lasco did not use the actual prices that Las Amlodipine was traded at post-injunction. Instead, the assumed prices during the counterfactual were used. (I note that Ms. Cummings agreed with Mrs. Kitson QC that with calculations of this nature, in those circumstances, the use of actual prices would have been best). It is my view that if an award was made on this basis, in all the circumstances, it would not be “realistic compensation for what has occurred.”<sup>56</sup> .

**[352]** For the avoidance of any doubt, in light of my findings, as well as, my understanding of the authorities, the losses that are being claimed post-injunction by the defendants have not been substantiated by the required evidence.

**[353]** Accordingly no award will be made for the post-injunction period.

### **DISPOSAL**

**[354]** These findings will resolve the disputes between the parties, it is my belief. I am of the view that the awards that have been made are neither too modest nor over-generous but realistic based on the evidence that was presented to the court. What remains is for a recalculation of the final damages that are to be awarded based on my decision. The recalculation of the final figures is to be done in Jamaican currency and is to be agreed by the counsel for the parties and their respective experts. A draft order of the award is to be presented to the court on or before the 24<sup>th</sup> November, 2017. Counsel for the parties and the experts

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<sup>56</sup> See: the discussion under Analysis and Findings at paragraphs [291] to [345]



may make further representation to the court if they require clarification on any aspect of the findings before the final order is made.

**[355]** Medimpex is awarded USD\$77,075 for disposal of stock at a rate of exchange of USD\$69.06 to JMD\$1.00<sup>57</sup> which amounts to JMD\$5,322,799.50.

**[356]** Lasco is awarded JMD\$155,738.90 for disposal of stock.

**[357]** Interest on the final figures for the awards at 8.23% per annum, as agreed, from March 29, 2005 to November 03, 2017.

**[358]** Costs to the 1<sup>st</sup> and 3<sup>rd</sup> Defendants to be agreed or taxed.

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<sup>57</sup> See: paragraph [117] above