JURISDICTION	**:**	SUPREME COURT OF WESTERN AUSTRALIA IN CIVIL
CITATION	**:**	GINZA PTE LTD -v- VISTA CORPORATION PTY LTD [2003] WASC 11
CORAM	**:**	BARKER J
HEARD	**:**	26-30 AUGUST, 2-3 SEPTEMBER 2002
DELIVERED	**:**	17 JANUARY 2003
FILE NO/S	**:**	CIV 1647 of 1998 Consolidated by order 12/5/2000
BETWEEN	**:**	GINZA PTE LTD Plaintiff AND VISTA CORPORATION PTY LTD (ACN 009 446 217) Defendant
FILE NO/S	**:**	CIV 1423 of 2000
BETWEEN	**:**	KONTACK PTY LTD (ACN 062 472 780) Plaintiff AND GINZA PTE LTD Defendant

Catchwords:

Contract - Sale of goods - Claim for cost of goods supplied - Counterclaim and claim for damages for breach of express and implied terms of contract of sale of goods and in negligence - Turns on own facts

Legislation:

Sale of Goods Act 1895, s 52
Sale of Goods (Vienna Convention) Act 1986, Article 50, Article 51(1)
Supreme Court Act 1935 (WA), s 32
Therapeutic Goods Act 1989 (Cth)
Therapeutic Goods Regulations 1990 , reg 11

Result:

In CIV 1647 of 1998: Plaintiff's claim dismissed; judgment for defendant on counterclaim and claim for set-off.
In CIV 1423 of 2000: Judgment for plaintiff on claim; defendant's counterclaim and claim for set-off dismissed.

Category: B

Representation:

CIV 1647 of 1998

Consolidated by order 12/5/2000

Counsel:

Plaintiff	:	Mr M H Zilko SC & Mr M D Cuerden
Defendant	:	Mr P G McGowan

Solicitors:

Plaintiff	:	Doray Solicitors
Defendant	:	Clayton Utz

CIV 1423 of 2000

Counsel:

Plaintiff	:	Mr P G McGowan
Defendant	:	Mr M H Zilko SC & Mr M D Cuerden

Solicitors:

Plaintiff	:	Clayton Utz
Defendant	:	Doray Solicitors

Case(s) referred to in judgment(s):

Casella v Costin Pty Ltd, unreported; SCt of WA; Library No 5416; 22 June 1984
Marimpex Mineralol Handelsgesellschaft MBH v Louis Dreyfus et Cie Mineralol GmbH [1995] 1 Lloyd's Rep 167
Spence v Demasi (1998) 48 SASR 538

Case(s) also cited:

Morgan v 45 Flers Avenue Pty Ltd (1987) 5 ACLC 222

1 **BARKER J**: The plaintiff (Ginza) in action CIV 1647 of 1998 (the Ginza action) is a company incorporated in Singapore. At material times, Ginza manufactured contact lens solution in Singapore and its place of business was in Singapore.

2 The defendant in the Ginza action (Vista) is a company incorporated in Australia. At material times, Vista carried on business in Australia as a wholesaler of Ginza's contact lens solution and its place of business was in Australia.

3 The plaintiff (Kontack) in action CIV 1434 of 2000 (the Kontack action) is a company incorporated in Australia. At material times, Kontack carried on a like business to Vista in Australia and its place of business was in Australia.

4 The defendant in the Kontack action is Ginza.

5 At material times, the persons who directed and managed the business of Vista and Kontack and were entitled to beneficial ownership of the shares in Vista and Kontack were common.

The nature of the claims and counterclaims

6 In the Ginza action, Ginza sues for the invoiced costs of contact lens solution (goods) supplied by it to Vista.

7 Vista says that such goods were supplied, but only some were supplied to Vista. It says Kontack dealt with Ginza for the supply of the majority of the goods in question.

8 Both Vista and Kontack allege, in any event, that the goods so supplied by Ginza were not manufactured in accordance with agreed requirements and were contaminated, in breach of express and implied terms of the respective contracts between them and in breach of tortious duties of care owed to each of them.

9 As a result of the breaches, Vista and Kontack say they were obliged to recall these and like goods from retail sale in Australia. They say they should not be obliged to pay the invoiced costs of the goods and, further, that they are entitled to be paid damages for the losses they have suffered.

10 Ginza denies any agreement with Kontack, denies the alleged breaches and, in any event, denies that either Vista or Kontack suffered losses to the extent claimed.

11 Vista also claims against Ginza a separate sum pursuant to a commission agreement.

The pleaded causes of action

12 In both the Ginza action and the Kontack action, Vista and Kontack respectively plead causes of action in contract and tort.

13 In each action, Vista and Kontack respectively plead that it was an express term of the agreement that:

(1) goods supplied would be manufactured according to the requirements of the Australian Therapeutic Goods Administration (TGA); and

(2) the goods would be sterile.

They also plead implied terms as to merchantable quality and fitness for the purpose of the goods supplied and to this end rely upon the provisions of either the *Sale of Goods Act 1895* (WA) or the United Nations Convention on Contracts for the International Sale of Goods (Vienna Sales Convention) which has been given effect in Western Australia by the *Sale of Goods (Vienna Convention) Act 1986* (WA).

14 Ginza admits there was an agreement with Vista substantially in these express terms. However, Ginza denies that there was ever an agreement concluded between itself and Kontack as alleged or at all. Ginza also says that the implied terms arise under the Vienna Sales Convention and not under the *Sales of Goods Act 1895*.

15 In each action, Vista and Kontack respectively claim that the goods supplied by Ginza:

(1) were supplied in breach of each of the terms of that agreement;

(2) were not reasonably fit for the purpose for which they were required, contrary to the term of the agreement implied pursuant to s 14(1) of the *Sales of Goods Act 1895* or the Vienna Sales Convention; and

(3) were not of merchantable quality, contrary to the term of the agreement implied pursuant to s 14(11) of the *Sale of Goods Act* or the Vienna Sales Convention.

16 Ginza denies it has acted in breach of the contract. It also raises an issue whether, in the circumstances of the case, if it is has any contractual

liability, the *Sale of Goods (Vienna Convention) Act 1986* applies to the exclusion of the *Sale of Goods 1895* and has the effect of limiting its liability.

17 In the event that the Court should find that there was no agreement concluded between Kontack and Ginza as alleged by Kontack, Kontack further claims that Ginza is liable to it in damages for negligence in respect of the manufacture of the goods. Kontack pleads that Ginza negligently supplied goods to Vista that were not manufactured according to the requirements of the TGA and were not sterile.

18 Vista also claims, in the alternative, that Ginza is liable to it in damages for negligence in this same respect.

19 Ginza denies that it is liable to either Vista or Kontack in tort.

20 In a separate counterclaim in the Ginza action, Vista claims that Ginza is liable to pay it the sum of $AUD19,337 on account of commissions due to it pursuant to a commission agreement and as a result of the sale of contact lens care goods by Ginza to the Choonwae Pharma Corporation of Korea. Ginza admits that liability but pleads it is entitled to set off against the sum claimed the amount of the claim of Ginza in the Ginza action.

21 In the event that Vista makes out its claim for damages in the Ginza action in contract or in tort, Vista claims that it is effectively entitled to reduce Ginza's claim to zero and is also entitled to damages under the following heads of damage:

(1) the invoiced costs of recalled goods;

(2) the lost profit margin on the resale of goods to retailers;

(3) the direct costs of recalling goods;

(4) lost reputation, goodwill and future sales.

22 Kontack claims similar entitlements.

The issues

23 In these circumstances, the following issues fall for determination:

(1) Was there any relevant agreement at material times between Kontack and Ginza?

(2) Was the agreement between Vista and Ginza, and any agreement found to exist between Kontack and Ginza,

breached by the failure of Ginza to meet the express term of the contract that the goods should be "manufactured according to the requirements of the TGA"?

(3) Further, or alternatively, was the agreement between Vista and Ginza, and any agreement found to exist between Kontack and Ginza, breached by reason of a failure of Ginza to comply with the express term of the contract that the goods should be "sterile"?

(4) Further, or alternatively, was the agreement between Vista and Ginza, and any agreement found to exist between Kontack and Ginza, breached by reason of a failure of Ginza to comply with the implied terms of the contract that the goods should be of merchantable quality and fit for the purpose required?

(5) Does the *Sale of Goods (Vienna Convention) Act 1986* apply to the agreement between Ginza and Vista, and any agreement found to exist between Ginza and Kontack, to the exclusion of the *Sale of Goods Act 1895*; and if it does so, does it have the effect that Vista and Kontack are only entitled to reduce the price with respect to those batches of goods which were actually tested and found to be not sterile?

(6) If there was no agreement between Kontack and Ginza as alleged, is Ginza liable to Kontack in damages for negligence?

(7) If Vista is entitled to damages, what is the extent of its entitlement?

(8) If Kontack is entitled to damages for negligence against Ginza, what is the extent of its entitlement?

Background

24 The circumstances in which the parties to this action came to do business are not materially in dispute. In the early 1990s, Dr Alfred Grauaug, who is and was then a medical practitioner, was involved in the design of medical equipment for use in the care of newborn children (neonatal care). He was a director of Mercury Electronics Pty Ltd, which company then employed Mr Ted Lee. Through Mercury Electronics, Dr Grauaug met Mr Albert Chia and his sister, Mrs Jenny Khan, who were directors of Ginza. Their dealings initially concerned the neonatal

electronic equipment that Mercury Electronic was manufacturing in Australia. Mr Chia was involved in setting up a hospital in Borneo. In the course of discussions, Dr Grauaug and Mr Lee began to consider the prospect of importing into Australia contact lens solutions manufactured by Ginza in Singapore.

25 It seems that meetings involving Dr Grauaug and Mr Chia concerning this business opportunity were initially held in Singapore, but were ultimately concluded in Australia. Dr Grauaug recalled that he met with Mr Chia in Australia as well as in Singapore and it was his recollection that the final decision about importing contact lens solution manufactured by Ginza was made when he met with Mr Chia, with or without Mr Lee, in the Parmelia Hilton Hotel in Perth. Dr Grauaug said that he and Mr Chia "shook hands on the concept". Dr Grauaug determined that Mercury Electronics was not the right business vehicle for the distribution and sale of contact lens solutions in Australia. As a result, Vista was incorporated in about 1990. Dr Grauaug and Mr Lee then proceeded to represent Vista in its dealings with Ginza. Dr Grauaug became both a director and shareholder of Vista.

26 Dr Grauaug and Mr Lee appreciated at the outset of this new venture that the importation of contact lens solution into Australia was regulated by the Australian Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* (Cth). Mr Lee learned from representatives of the TGA in Canberra that contact lens solution was a notifiable device, with the result that Vista required TGA approval of the labels on the bottles of solution it proposed distributing for retail sale in Australia. According to Mr Lee, this was all that the TGA required by way of regulation at the commencement of Vista's dealings with Ginza.

27 Mr Lee visited Singapore on several occasions to discuss with Mrs Khan packaging, labelling and other issues relating to the venture. Vista then began importing Ginza's products in about 1991. At this time, Kontack had not been incorporated.

28 Thereafter, it appears that Ginza faxed price lists to Vista from time to time. On one occasion at least, Mrs Khan visited Perth to discuss with Mr Lee the issue of outstanding accounts then owing by Vista to Ginza.

29 In 1992, Vista was notified by the TGA that contact lens solution had become a listed product under the *Therapeutic Goods Act*. Mr Lee met with representatives of the TGA in Canberra and also spoke to them by telephone concerning the TGA's requirements. He was informed that the

TGA now required contact lens solution to be manufactured in accordance with the Code of Good Manufacturing Practice (the Code) promulgated under the Act. He obtained a copy of the Code from the TGA. He was also advised that, in order for Ginza's products to be listed in Vista's name, Vista was required to be the "sponsor" under the Act and to submit a "plant master file statement" to the TGA in relation to Ginza's plant in Singapore. He was also advised that Ginza's plant would need to be audited by a TGA auditor from time to time.

30 Mr Lee telephoned Mrs Khan and informed her of the advice that he had received from the TGA. In November 1992, Mr Lee travelled to Singapore to discuss those requirements with Mrs Khan and he then gave Mrs Khan a copy of the Code which he had obtained from the TGA. On 7 November 1992, on behalf of Vista, Mr Lee signed a document headed "Agreement", which was prepared by Ginza to ensure the confidentiality of all information provided by Ginza to Vista for the purpose of being submitted by Vista to the TGA in partial satisfaction of the TGA's requirements. At that time, Mrs Khan and Mr Lee discussed the Code. Mr Lee then prepared a "plant master file statement" on the basis of information given to him by Mrs Khan, and Mrs Khan signed it on Ginza's letterhead.

31 Information, including this plant master file statement, was then provided by Vista to the TGA in Canberra. In late 1992, Ginza's contact lens solution products, of which Vista was the sponsor under the *Therapeutic Goods Act*, were listed under the Act, thereby authorising their sale in Australia.

32 In about March 1993, the first audit of Ginza's plant in Singapore was conducted by the Australian TGA for the purposes of the *Therapeutic Goods Act*. The first audit was conducted by Ms Caroline Woodruff of the TGA. Mr Lee was present during that audit. During the audit, Ms Woodruff, Mrs Khan and Mr Lee discussed in some detail the requirements of the Code. They also discussed the requirement that Vista, as the sponsor under the Act, was responsible for all testing in Australia if any complaint were made in Australia regarding Ginza's products.

33 Initially, all product manufactured by Ginza for Vista was manufactured under the "Vista" brand name. However, over time, the same product was marketed under different names, such as "Green Spot" and "AMCAL". In about 1993, before Kontack Pty Ltd was incorporated, Vista also began using the "Kontack" brand name. The circumstances in which the Kontack brand name came to be used and Kontack Pty Ltd came to be

incorporated are discussed below, as they are relevant to the issue of whether Kontack Pty Ltd and Ginza contracted at material times for the supply of contact lens solution bearing the "Kontack" brand name.

34 In October 1995, a second audit of Ginza's plant was conducted by Ms Woodruff for the TGA. In her report of 8 November 1995, she detailed certain deficiencies in the manner of manufacture then utilised by Ginza. Later, in November 1995, Mrs Khan, on behalf of Ginza, confirmed that Ginza had brought about changes to its manufacturing process to address the deficiencies identified by Ms Woodruff in her audit report.

35 The business operated by Vista in importing Ginza contact lens solutions into Australia, and wholesaling or distributing them throughout Australia, appears to have developed without any particular event until 1997. In February 1997, Vista provided random samples of "Green Spot Preserved Saline Solution", batch number 40811B, to the TGA for testing, as required by the TGA. This was the first time random samples of Ginza's products had been supplied to the TGA for testing. On 4 July 1997, this Green Spot solution was found by the TGA to have failed sterility testing and to be contaminated with bacteria. The TGA then recommended recall of the Green Spot product (the first recall). This was the first time the TGA had issued a recall, as they were empowered to do under the Act, in respect of a Ginza product.

36 On 11 July 1997, the TGA required a further audit of Ginza's plant in Singapore. From that point on, relations between the parties to this action soured and soon enough their commercial relationship ceased. The reasons why this happened are canvassed in detail below. However, in short, on 10 September 1997 the TGA recommended an immediate recall of all Ginza product manufactured in 1997 (the second recall); and on 6 November 1997, TGA requested a recall of all Ginza's products manufactured in December 1996 (the third recall). On 9 December 1997, Ginza, through its solicitors, demanded that Vista make payment of unpaid invoices for 1997. On 10 December 1997, solicitors acting for Vista sought damages against Ginza by reason of the supply of contaminated product.

37 In the first instance, Ginza issued proceedings in the District Court of Western Australia for payment of unpaid invoices. Vista then filed its defence and counterclaim seeking damages in excess of the jurisdiction of the District Court of Western Australia and the matter was referred to the Supreme Court. Kontack commenced a separate action against Ginza for damages, having regard to the view it and Vista took that there had, at

material times, been separate supplies of the recalled goods by Ginza to Vista and to Kontack.

Was there an agreement between Kontack and Ginza?

38 In the Kontack action, Kontack alleges in par 4 of the statement of claim that, in or about February 1995, the parties entered into an agreement whereby Ginza agreed to sell and Kontack agreed to purchase contact lens solution manufactured and supplied under the "Kontack" label in Singapore.

39 The particulars of the Kontack agreement pleaded are that the agreement was partly oral, partly in writing and partly to be inferred from the course of trade between those parties. To the extent that it was made orally, it is alleged that in or about February 1995 in a telephone conversation between Mrs Jenny Khan on behalf of Ginza and Dr Grauaug on behalf of Kontack, Dr Grauaug told Mrs Khan that Kontack had been incorporated for the purpose of taking over all business hitherto conducted by Vista concerning the importation of contact lens solution for supply to supermarket chains in Australia under the Kontack brand. The particulars provided in par 4 further indicate that Dr Grauaug then informed Mrs Khan that Kontack would contract with Ginza on terms identical to those existing with respect to the agreement between Vista and Ginza which was then already in place.

40 Insofar as the Kontack agreement is to be inferred from a course of trade, the particulars state, in short, that the course of trade commenced on 21 February 1995 with the plaintiff placing orders with the defendant for the supply of contact lens solution under the "Kontack" brand and thereafter the plaintiff making further orders periodically and the defendant filling such orders.

41 While it is pleaded that this agreement was also partly in writing, no particulars of the writing are provided. Nor were they led in evidence.

42 Ginza denies that any such contract was ever orally concluded between the parties or established by course of trade. It says that the only course of trade was the continued lodgment of purchase orders by Vista, including in respect of goods bearing the "Kontack" brand name. Ginza says that the evidence supports its position.

43 The evidence in support of the agreement pleaded and particularised between Kontack and Ginza was provided almost entirely by Dr Grauaug.

At all material times, he was a director of Vista and the person who caused the incorporation of Kontack and was responsible for its business direction and management. He believed that he and his wife were directors of Kontack. However, it became plain during the course of the evidence, particularly following the evidence of Mr Whiting, the accountant to Vista and Kontack that, since its incorporation, Mr Whiting and his wife were the directors and shareholders of Kontack and had been since its incorporation. They remained so as at the date of trial.

44 Kontack was, on the evidence, formed in response to a concern expressed to Dr Grauaug by certain pharmacy and optometry retailers in South Australia that supermarkets were selling the same brand name goods that were distributed to them by Vista. Dr Grauaug said that he intended, by establishing Kontack Pty Ltd, that goods carrying the "Kontack" brand name should be distributed to supermarkets alone by an entity that was not in any formal sense connected with Vista or with him.

45 Dr Grauaug explained in his statement of evidence that after he decided to incorporate Kontack Pty Ltd, he spoke to Mrs Khan at Ginza and informed her that in South Australia there had been complaints from pharmacy and optometry chains. He said that the substance of the conversation with Mrs Khan was that he told her that Kontack had been incorporated for the purpose of taking over all business hitherto conducted by Vista concerning the importation of contact lens solution into Australia for supply to supermarket chains under the "Kontack" brand. Dr Grauaug says he offered to purchase contact lens solution manufactured by Ginza so as to enable Kontack to import the contact lens solution into Australia for supply to supermarket chains under the Kontack brand. Dr Grauaug says that he further stated to Mrs Khan that Kontack Pty Ltd would contract with Ginza on terms identical to those existing with respect to the agreement between Ginza and Vista. He said that the first purchase order lodged pursuant to this agreement was placed on 21 February 1995. Thus, in his statement of evidence, Dr Grauaug substantially replicated the particulars to the pleaded contract as set out above.

46 Mrs Khan said she did not believe any such discussion occurred, although plainly Ginza became aware of the existence of Kontack as an entity as a result of discussions I accept did take place between Dr Grauaug and Mrs Khan at about this time.

47 In cross-examination, Dr Grauaug agreed that contact lens solution carrying the brand name "Kontack" had been manufactured by Ginza and imported into Australia and sold by Vista for some years prior to the

incorporation of Kontack Pty Ltd. In respect of the claimed agreement between Kontack and Vista, it was put to Dr Grauaug that what he was saying to the Court was that "the contractual arrangements with Vista and Ginza insofar as Kontack products were concerned ceased at the time you made this new agreement with Jenny Khan and a new contractual arrangement came into existence between Ginza and Kontack Pty Ltd". Dr Grauaug responded by, saying, "No, I'm not saying that." Dr Grauaug then explained (at t/s 194):

> "What we were doing with Kontack Pty Ltd was a marketing exercise and we did run the companies separately - that in many instances invoices were sent on Vista letterhead. Ginza often addressed correspondence and invoices to Vista but they should have been addressed to Kontack and sometimes they were addressed to Kontack Pty Ltd but we internally arranged the financial dealings so that Kontack was running as a separate entity."

48 Dr Grauaug added that, when Kontack was incorporated:

> "No major change had occurred. I informed Mrs Khan as to why Kontack Pty Ltd was set up and, in fact, we asked her at one stage to bill separately. This wasn't always the case and it didn't worry us very much because we had a very good relationship with them and, as I said earlier, we always arranged the payments appropriately and subsequently fixed up the paperwork internally."

49 Dr Grauaug was then asked directly in cross-examination (t/s 195) whether there was an agreement in or about February 1995 between him and Mrs Khan whereby Ginza agreed to stop supplying Kontack products to Vista as it had been doing for three years, and to commence supplying those products to Kontack Pty Ltd, or did such an agreement not take place. To that question, Dr Grauaug responded: "I'm not sure." He then added that:

> " … we did actually ask Mrs Khan to separately invoice Kontack Pty Ltd and on occasions she did."

50 It appears that the request to which Dr Grauaug was referring, was a facsimile transmission from Ms Alison Sage, Acting Manager, Marketing and Sales, of Vista to Mrs Khan at Ginza dated 2 July 1996 concerning the subject, "Statements of Account". In this fax, the following request was made:

> "Jenny,
>
> We have entered a new financial year and this gives us new ideas to implement.
>
> In future, at the end of each month, please issue two separate Statements - one for VISTA and one for Kontack.
>
> Hope this is possible - please advise."

51 The evidence of Dr Grauaug, particularly in cross-examination, when read with the documentary request of Ms Alison Sage of 2 July 1996, does not tend to support the claim of Kontack that there was concluded in about February 1995 an express oral agreement whereby Ginza would thenceforth supply Kontack Pty Ltd with the goods described as "Kontack Goods". Rather, the evidence suggests that, while Ginza, through Mrs Khan, became aware that Vista intended marketing Kontack brand name goods through a separate entity in Australia known at Kontack Pty Ltd, the agreement between Ginza and Vista that pre-existed the incorporation of Kontack Pty Ltd, continued to govern the supply of Kontack brand goods by Ginza to Vista. At the least, nothing in this evidence leads to a conclusion that an agreement in the terms pleaded and contended for by Kontack was ever concluded.

52 To the extent that from time to time Statements of Account were issued to Kontack Pty Ltd, as they were, does not alter this conclusion. Nor does this conduct necessarily require the conclusion that an agreement was concluded by course of trade. The provision of statements from time to time appears to have been consequent upon Ms Sage's request of 2 July 1996. The invoices that Ginza sues upon in the Ginza action are eight in number. All but one are in respect of Kontack brand name goods (the exception being invoice 97/0706 dated 7 June 1997 which is in respect of "Vista" goods). All eight invoices are dated between 15 March 1997 and 11 July 1997; that is to say, after the date of Ms Sage's facsimile. All eight invoices were addressed to Vista, not Kontack.

53 The relevant statements of account adduced in evidence are dated 31 July 1997, 31 May 1997 and 30 June 1997, 30 April 1997, 31 March 1997, 28 February 1997. There is also a number of purchase orders given by Kontack Pty Ltd to Ginza for Kontack brand name goods, being those annexed to exhibit V5, namely, purchase order number 29, dated 16 January 1997, purchase order number 23, dated 20 December 1996, and another that appears to be a purchase order dated 20 March 1997 and duly amended by two attached documents of the same date. However, these

latter purchase orders do not appear to be the subject of the invoices the subject of the Ginza claim.

54 While there may be some particular instances, not the subject of the Ginza action, that permit of the argument that Kontack contracted separately with Ginza for the supply of particular goods, I am not satisfied, on the balance of probabilities, in relation to the invoices the subject of these actions, that those invoices were the subject either of purchase orders lodged by Kontack or invoices rendered by Ginza to Kontack or an oral agreement between Ginza and Kontack, as alleged by Vista and Kontack. Rather, the evidence points the other way, suggesting that the agreement or course of conduct between Vista and Ginza that pre-existed the incorporation of Kontack, continued to govern the supply of Kontack brand name goods to Vista after the incorporation of Kontack Pty Ltd.

55 As Senior Counsel for Ginza pointed out, any contractual arrangement between Ginza and Kontack that required the effective importation into Australia by Kontack Pty Ltd of contact lens solutions would have required Kontack to be the "sponsor" for the purposes of importation of such products into Australia under the *Therapeutic Goods Act*. At all times, Vista was the sponsor, not Kontack. This tends to support the conclusion that, in relation to all the goods the subject of the invoices in the Ginza action, Vista was responsible for their importation into Australia and was contractually liable to Ginza for their supply. Whatever may have been the contractual or other business relationship between Vista and Kontack in relation to distribution and sale of such goods within Australia, it did not affect the contractual basis on which Ginza supplied the Kontack brand name goods to Vista.

56 I consider that the provision of statements of account by Ginza to Kontack in respect of Kontack brand goods was most probably in response to the request of Ms Sage in her facsimile to Mrs Khan dated 2 July 1996 for Ginza to "issue two separate Statements". In that fax, Ms Sage expressed the "hope" that "this is possible". This language does not bespeak a contractual entitlement to separate statements, but merely an expectation that Ginza would act in a way that would facilitate the internal administrative or other contractual arrangements between Vista and Kontack in Australia once the goods were imported by Vista. Indeed, such a view accords with the understanding of the arrangement expressed by Dr Grauaug in his evidence in cross-examination and referred to above.

57 I find, therefore, that there was no agreement as pleaded between Ginza and Kontack in respect of any of the goods supplied pursuant to the

invoices sued on by Ginza in the Ginza action or otherwise the subject of Kontack's action. At all material times, such goods were supplied by Ginza to Vista.

58 The consequence of this finding is that, subject to its defences and claims to a right of set-off, Vista is liable to Ginza for the total sum of the goods supplied and which are the subject of the Ginza action, totalling $Singapore139,550.32.

59 Another consequence of this finding is that Kontack's claim for damages for breach of contract in the Kontack action must necessarily fail. However, Kontack also claims damages for negligence against Ginza. I will return to that claim in tort later in these reasons.

Were the goods manufactured in accordance with the requirements of the TGA?

60 It is agreed by the parties to the Ginza action that, pursuant to the agreement between Ginza and Vista, Ginza was obliged:

(1) to supply goods that were manufactured according to the requirements of the Therapeutic Goods Administration (TGA);

(2) to supply goods that were sterile;

(3) to supply goods that were of merchantable quality; and

(4) to supply goods fit for the purpose for which they were supplied.

61 It is accepted by the parties (subject to Ginza's argument concerning the effect of the Vienna Sales Convention on the assessment of damages), in my view correctly, that if the goods supplied were not sterile, they would also not be of merchantable quality or fit for the purpose for which they were required. Thus, the critical terms of the agreement are those set out in pars (1) and (2).

62 Whether the first pleaded express term of the contract was breached requires an answer to the question whether the goods supplied by Ginza to Vista were manufactured "in accordance with the requirements of the TGA". The "TGA" in this context means the "Therapeutic Goods Administration". The TGA is the Commonwealth government agency that administers the *Therapeutic Goods Act 1989*, even though it is not expressly referred to in the *Therapeutic Goods Act*. The Act refers to "the Department", which is not defined in the Act. The "Department" is a

reference to the Department of State of the Commonwealth that is administered by the Minister: *Acts Interpretation Act (1901)* (Cth) s 19A(3). As of July 1997, the Commonwealth Department of Health and Family Services appears to have been the relevant department. It appears at material times to have acted under the guise of or through the unit known as the "Therapeutic Goods Administration". The Act also refers to the "Secretary", which is a reference to the Secretary of the Department: s 3(1) of the Act. These matters appear to be matters of common ground and no party suggests anything turns on them in these proceedings.

63 In order to answer the question whether the goods supplied by Ginza to Vista were "manufactured in accordance with the TGA", it is necessary first to understand something of the workings of the *Therapeutic Goods Act* and the relevant "requirements" or the TGA at material times in respect of the "manufacture" of contact lens solution.

64 At all times during the period December 1996 to 22 July 1997, s 36(1) of the *Therapeutic Goods Act* provided that the Minister may, from time to time, "determine written principles to be observed in the manufacture of therapeutic goods for use in humans". Section 36(2) then set out matters to which the manufacturing principles may relate, and provided that "the manufacturing principles may include codes of good manufacturing practice". The expression "good manufacturing practice" is often reduced to the acronym "GMP". Pursuant to these statutory powers, the Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Products, August 1990 (the Code) was promulgated. As it applied at material times, it was tendered in evidence.

65 It is not in contest between the parties that the goods the subject of these actions were manufactured at its premises in Singapore by Ginza at various times in December 1996 and during 1997 prior to 22 July 1997, at which time the third TGA audit of the factory of Ginza in Singapore was conducted by Mrs Shelley Tang of the TGA.

66 The Code, as it then applied, at page 2801 set out certain "manufacturing principles determined under the *Therapeutic Goods Act 1989*". As to the "Place and method and manufacture", cl 4 provided as follows:

> "4. Therapeutic goods must be manufactured:
>
> (a) in buildings that are located, designed, constructed and used:

(i) to suit the operations carried out in them; and

(ii) to ensure protection of the goods from contamination; and

(iii) to permit efficient cleaning and maintenance; and

(iv) to minimise the rise of manufacturing error; and

(b) in an environment, in or with equipment and with precautionary measures that:

(i) ensure a standard of hygiene appropriate to the class of goods being manufactured; and

(ii) minimise the risk of contamination of therapeutic goods that are materials, components, or products used or manufactured at the premises; and

(c) in accordance with procedures that are clearly defined by the manufacturer."

67 As to "Quality assurance", cl 6 provided as follows:

"6(1) A manufacturer must establish and implement an effective system of quality assurance that:

(a) is designed to achieve consistent quality in the therapeutic goods manufactured; and

(b) includes safeguards and controls designed to prevent the occurrence of foreseeable errors or process failure; and

(c) involves the active participation of both management and operation personnel.

(2) If the therapeutic goods manufactured by the manufacturer are of the type for which there is no quality assurance system specified in the Codes, the manufacturer must use a system that incorporates the principles of section 4 of

Australian Standard AS3901-1987/ISO 9001-1987, entitled 'Quality Systems for Design/Development, Production Installation and Servicing', as in force on the day on which this determination commences.

(a) If the therapeutic devices manufactured by the manufacturer are of a type for which there is no quality assurance system specified in the Codes, the manufacturer must use a system that incorporates the principles set out in the European Standard EN 46001:1993 entitled 'Specification for Applications of EN 29001(BS) 5750:Part 1' to the manufacture of medical devices: published by British Standards Institution."

68 As to "Documentation", cl 7 provided:

"7 A manufacturer must establish and maintain a system of documentation, document control and recording that:

(a) provides a complete history of each:

(i) item; or

(ii) batch; or

(iii) quantity of therapeutic goods produced in specified time periods; manufactured at the premises; and

(b) establishes a traceable connection between:

(i) ingredients and the components or component materials used in manufacture of goods; and

(ii) the manufactured product."

69 As to "Sterile therapeutic goods", cl 9 provided:

"9(1) Therapeutic goods that are required to be, or are represented as being, sterile must be manufactured:

(a) in separate, contained areas in the premises that have:

(i) high standards of hygiene; and

(ii) a system of control of particulate contaminants that is appropriate to the class of goods being manufactured; and

(b) with special care and attention to detail; and

(c) in accordance with procedures established by the manufacturer.

(2) The Manufacturer must establish procedures, and have equipment available, to monitor adequately:

(a) the microbiological status of the environment of the production areas; and

(b) the microbiological burden of goods that are to be sterilised."

70 The Code's manufacturing principles further dealt with matters of "Complaints" (cl 8), "Compliance with Application for Registration" (cl 10), "Expiry Dates" (cl 11) and "Sub-contracting" (cl 12).

71 The Code included, as Appendix C, a document which at material times was dated "July 1981, edited August 1990" and was described as "Guidelines on Tests for Sterility".

72 The way in which the *Therapeutic Goods Act* applied at material times to the goods manufactured by Ginza and supplied to Vista was as follows. The Secretary was obliged to maintain a register, known as the Australian Register of Therapeutic Goods (the Register), for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans: s 17(1). The Register contained two parts, one relating to goods to be known as registered goods and the other relating to goods to be known as listed goods: s 17(3). The regulations prescribed the therapeutic goods, or the classes of therapeutic goods, that were required to be included in each part of the Register: s 17(4)(a).

73 Regulation 11 of the *Therapeutic Goods Regulations 1990* provided that, for the purposes of s 17(4)(a) of the Act, the therapeutic goods, or classes of therapeutic goods, specified in Pt 1 of Sch 4 must be included in the part of the Register for listed goods.

74 Schedule 4 identified those therapeutic goods required to be included in the part of the Register for listed goods. Part 1 was headed "Listable Goods". Item No 2 was, by a process of interpretation and elimination, relevant to the goods manufactured by Ginza and supplied to Vista at material times. It relevantly provided:

> "Therapeutic goods required to be included in the part of the Register for listed goods
>
> Schedule 4 Part 1 Listable Goods
>
> Item No
>
> Therapeutic goods
>
> 1 Therapeutic goods manufactured in Australia for export only other than good exempt under Reg 12.
>
> 2. Therapeutic devices other than devices to which:
>
> (a) item 3, 4 or 5 of Pt 1 of Sch 3 applies; or
>
> (aa) Pt 2 of Sch 3 applies; or
>
> (b) item 1, 2, 3, 4, 5, 7 or 11 of Sch 5 applies; or
>
> (c) item 1, 1A, 3, 4, 5, 7, or 8 of Sch 5A applies.
>
> 3. … "

75 Contact lens care products fell within the category "therapeutic device" as defined in s 3(1) of the Act. As they did not fall into any of the "other than" categories (eg, items 3, 4 or 5 of Pt 1 of Sch 3, item 1, 2, 3, 4, 5, 7 or 11 of Sch 5 or items 1, 1A, 3, 4, 5, 7 or 8 of Sch 5A) referred to in Item No 2 of Pt 1 of Sch 4 of the Regulations, they were "listable".

76 It is not in contest between the parties that the contact lens solution manufactured by Ginza was a "therapeutic device" which was required to be "listed" on the Australian Register of Therapeutic Goods in order for Vista and Kontack to be able to sell the product in Australia.

77 At material times, a person who, *inter alia*, imported therapeutic goods into Australia was a "sponsor" as defined by s 3(1) of the *Therapeutic Goods Act*. Under s 26A(4) of the Act, the sponsor was required to be listed on the Register. It was an offence for a sponsor to import listable goods if they were not listed, by virtue of s 20. It was

therefore necessary for Vista in order to import into and distribute within Australia the goods manufactured by Ginza, to apply to list the goods on the Register.

78 Dr John Cable, Director of the Conformity Assessment Branch of the TGA at material times, said in his evidence that, for a range of goods, including contact lens solutions, which were required to be "listed" on the Register at the material times, the determination of the Minister under s 36(1) of the Act in relation to the Code specified that the manufacture of such goods should be undertaken in accordance with the standards applicable to the product and the quality systems principles set out in standards known as EN46002/ISO 90002. European Standard EN 46001 is expressly referred to in cl 6 of the Manufacturing Principles set out in the Code as noted above. As explained by Mrs Tang in her evidence, for all practical purposes in the circumstances of this case EN46002 and EN46001 were identical. I accept that is so.

79 As a matter of practice, as Dr Cable explained, compliance with the Manufacturing Principles is ascertained by the TGA through the review of information submitted by the sponsor (for example, by provision of a "plant master file") and by carrying out regular onsite audits. Each audit involves a detailed examination of the operation and procedures of the manufacturing plant and includes a detailed review of the quality systems and the batch documentation.

80 Dr Cable further explained that, because Ginza's plant was located in Singapore, Vista, as sponsor, was required to establish that Ginza complied with the Manufacturing Principles by arranging for an audit of Ginza's plant by a GMP auditor employed by the TGA's audit and licensing section.

81 It is not in contest that the TGA issued a Certificate of Listing of Vista's goods on the Register in November 1992 and that subsequently three audits of Ginza's manufacturing premises were conducted by TGA auditors; in 1993, 1995 and in 1997.

82 Mrs Tang, an auditor from the TGA, conducted the third audit of Ginza's manufacturing plant in Singapore on 22 July 1997. A draft of her audit report was made available to Ginza and Vista soon after the audit and was formalised by a written "GMP audit report" signed by Mrs Tang as Principal Microbiologist, TGA laboratories, dated 28 July 1997.

83 The consequence of the third audit and report, as stated in Mrs Tang's GMP audit report, was that the company was "assessed as having an unacceptable level of GMP compliance. It has been recommended that

product for the Australian market no longer be sourced from this company". The reference to "this company" is a reference to Ginza.

84 The background to the circumstances in which the third audit occurred is of some relevance to the matters in issue and the question whether or not the material terms of the agreement between Vista and Ginza were complied with or breached.

85 In June 1997, the TGA laboratories conducted random sample testing of contact lens solution manufactured by Ginza. Mrs Tang explained that the tests were sterility tests conducted in accordance with the guidelines prescribed by the TGA, as set out in Therapeutic Goods Order No 11, which is similar to Appendix C of the Code. The TGA laboratories' report on sterility confirmed that one of the products manufactured by Ginza in respect of which Vista was the sponsor, "Green Spot Preserved Saline Solution" batch number 40811B, failed sterility testing.

86 Mrs Tang, by letter dated 4 July 1997 (attachment B to exhibit B15), wrote to Vista on behalf of the TGA advising of the contamination in batch number 40811B, and that such contamination demonstrated a serious breakdown in the sterility control procedures in the manufacturing process of the contact lens solution.

87 As a result of this sterility testing, Vista was instructed by TGA to quarantine all existing product manufactured by Ginza and to recall all Green Spot Preserved Saline Solution from batch number 40811B, to what is described as the "consumer level". This required the wholesaler to recall product from consumers who had acquired the product from a retailer. An alternative form of recall is to the "retail level", as a result of which a wholesaler need only recover the product from the retailers to whom the product has been distributed. The retail level recall is obviously less onerous from a sponsor's point of view.

88 Mrs Tang, in order to establish whether Ginza was manufacturing contact lens solution in compliance with the Code, immediately made arrangements with Ginza to permit her to conduct an audit of the company's manufacturing plant in Singapore. She duly attended Ginza's Singapore premises and plant and conducted an audit on 22 July 1997. There is no dispute that Mrs Tang attended the premises and plant on that day. However, Ginza disputes, or at the very least questions, the extent to which Mrs Tang carried out an audit in the manner in which such audits are typically conducted by TGA auditors.

89 Mrs Tang stated that the purpose of her audit was to assess Ginza's method of manufacturing practice against the prescribed quality standard EN46002 and ISO9002. While the Code, as noted above, in dealing with the manufacturing principle of quality assurance, makes express reference to European Standard EN46001, Mrs Tang explained that the use of European Standard EN46002 was at that time permissible. That standard was intended to supersede EN46001 and had been approved by the Therapeutic Goods Committee and was in general use for listed products. She explained that it was a subset of EN46001 and generally regarded as a "more lenient standard". As a result, auditors believed they could use it, even though it had not officially been put in place as a manufacturing principle for listed devices at that time. She said that it did not matter, in fact, whether EN46001 or 46002 was consulted because the provisions were the same for her audit purposes. She stated that she found during the audit that Ginza's manufacturing processes did not employ the required level of manufacturing control and sterility assurance. Her main concern related to the absence of any quality system process and the lack of any validation of sterilisation processes.

90 As to the quality system, Mrs Tang referred to the Code's requirements that there be a comprehensive system for quality management of all therapeutic goods manufactured. She said the quality system should relate to every aspect of manufacture and testing that will ensure that the lens solution meets the required quality criteria. In her assessment, formed during the audit, Ginza did not have in place any formally established or documented quality system.

91 As to document control, Mrs Tang referred to the "fundamental requirement" under the Code for the storage and retention of documents and records relevant to the quality assurance programme. She said that in order for Ginza to meet this requirement, Ginza should have had complete records pertaining to each batch of solution, including original data such as laboratory notebooks, which are retained for at least one year after the expiry date of the batch. As a result of her audit, Mrs Tang considered Ginza had no proper system in place for the storage and control of essential documents in the manufacture and quality assurance process.

92 In connection with purchasing, Mrs Tang stated that where possible, starting materials should be purchased from approved or certified suppliers and starting materials should be purchased to established specifications in order to meet the Code's requirement. She considered Ginza should have had in place adequate purchasing documentation making reference to certified suppliers and to required specifications. In her audit, Mrs Tang

found that Ginza had no system in place for ensuring that all materials purchased conformed to the specified requirements for ensuring the quality and sterility of the product manufactured.

93 In relation to process control, Mrs Tang stated that the Code required a system of process control to address the risk of contamination or cross-contamination from things such as the starting materials (including water from the environment and the uncontrolled release of dust, gases, vapours, sprays, or organisms from materials or products in process) or from residues in equipment and from operators and their clothing. In her audit, Mrs Tang found Ginza had no documentation which addressed the process parameters relevant to contamination control. By way of example, she noted Ginza had no documentation to address the bioburden of containers used in the manufacturing process.

94 Mrs Tang also found in the audit that proper documentation, which should have been in place to address the microbiological contamination of non-sterile products in order to meet the Code's requirement, was not in place. She explained, by way of example, that microbiological contamination of non-sterile products would be minimised by a quality assurance system documented to address matters such as training, effective operating, cleaning and sanitation procedures, microbiological sampling and testing of starting materials and final products, monitoring of process water and the periodic microbiological monitoring of the process environment.

95 Mrs Tang further stated that the microbiological load of product should be as low as practicable prior to sterilisation. The bioburden of all products used should be assessed and monitored relevant to the efficiency of the method of sterilisation to be used. She stated that Ginza was responsible for carrying out validation of the effectiveness of the sterilisation of equipment, components and product used in the manufacturing process. Ginza should have ensured that the sterilisation process or all product containers was adequately validated, but she found this was not done. Mrs Tang explained that "validation" is the action of proving that the sterilisation process used in the manufacture or control can reliably achieve the desired and intended results.

96 Mrs Tang also stated that aseptic processing and filling equipment procedures and environments should be validated for overall performance at the time of qualification and at regular intervals. Test runs with suitable sterile agents which will not inhibit microbiological growth are passed through the routine procedures up to the sealing of filled containers. At the

time of her audit, Mrs Tang considered Ginza had not adequately validated its aseptic filling process.

97 Mrs Tang also considered process monitoring required the validation of materials such as spore strips and recovery broths, which would indicate the presence of microbiological contamination. She found in the audit that in Ginza's case the spore strips and recovery broths used for process monitoring were out of date and their continued use had not been validated or documented. Further, she found there was no monitoring or control of process parameters such as biological indicators.

98 In respect of inspection and testing, Mrs Tang stated that a test for sterility should be carried out on a sample of each batch. She found Ginza did not conduct sterility testing on each batch of product manufactured.

99 As to quality records, Mrs Tang stated it is important in any quality assurance programme that adequate records are maintained, particularly of batch numbers, so that the manufacturing process in respect of particular batches is adequately documented. She said this is particularly so with respect to ensuring that any contaminated batch can be properly traced. Mrs Tang stated that her audit of Ginza's premises revealed that the traceability of the product batches was compromised because the batch record sheets did not record the full details of sub-batches. She said that she observed during the audit that Ginza had adopted a practice where it would manufacture a batch, but would only document the sub-batch. The documentation used to record batches and sub-batches did not adequately provide the traceability of product batches recorded in the batch record sheets.

100 Mrs Tang said that, a short time after commencing the audit, she formed the clear view that Ginza had an unacceptable level of GMP compliance. Her overall assessment of Ginza's manufacturing practice was that it was "poor" and "fell well short of the required standard". She said that early in the conduct of the audit the deficiencies were so apparent that there was little point in completing an entire audit of the plant. She concluded - or aborted - the audit after approximately two hours.

101 Following the audit conducted by Mrs Tang on 22 July 1997, the TGA received the results of the sterility testing carried out by certain private laboratories accredited by the TGA at the request of Vista on a number of other batches of Ginza products. The results showed that a number of samples were not sterile. Those tests were conducted in Australia by Microtech Laboratories Pty Ltd and Consulchem Pty Ltd. In the light of

her audit, and after receiving the results of these tests, Mrs Tang's view was, and she recommended to Dr Cable, that no further product should be sourced from Ginza, and that all 1997 product imported into Australia by Vista be recalled (the second recall). Upon receipt of the results of further testing showing that a batch of December 1996 product was also contaminated, she further recommended that all December 1996 product manufactured by Ginza and imported into Australia and distributed by Vista be recalled (the third recall).

102 After these proceedings were commenced, further tests on certain samples of Ginza's product were carried out by Ms Cristina Farrar of Princess Margaret Hospital in Perth at the request of both Vista and Ginza. These also disclosed contamination of a number of samples.

103 Ginza attacks the sufficiency or adequacy of the procedures or techniques adopted by these various agencies or laboratories in the conduct of the tests they undertook. Counsel for Vista, however, says that notwithstanding that attack, it was never put to the expert microbiologists called from these various organisations and who gave evidence in the proceedings, nor was there any evidence called on behalf of Ginza to suggest, that the findings of contamination were actually wrong. It is submitted on behalf of Vista that the highest Ginza's case could be put was to say that the statutory regulations that set out certain procedures or techniques were not strictly complied with. The nature of this evidence and Ginza's objections to it are dealt with in more detail below. In the event, I have accepted Vista's submissions on this point.

104 The tests of a number of samples carried out by Microtech, Consulchem and at Princess Margaret Hospital show contamination. In the case of the tests conducted by Microtech, 15 of the 18 batches failed. In the case of the tests conducted by Consulchem, six out of eight samples tested failed. Similarly, of 70 samples tested by Ms Farrar at PMH, 48 failed.

105 The question of whether the goods were "manufactured according to the requirements of the TGA" is not the same as the question of whether such goods were "sterile" upon their supply to Vista. For example, it does not necessarily follow from proof that the goods, or some of them, were not sterile that they were not manufactured according to the requirements of the TGA, although there might be a higher probability that this is so in such a case. Nor does it necessarily follow from proof that the goods were not manufactured according to the requirements of the TGA that the goods supplied were not sterile, although this may increase the risk of the goods not being sterile. The factual matrix in which these two questions must be

considered, however, is common and facts going to the determination of the one question may bear on the determination of the other.

106 What is clear is that the contractual term that the goods should be "manufactured according to the requirements of the TGA" was intended, as far as possible, to ensure that the goods would in fact be sterile. Similarly, the TGA's procedures are intended to ensure sterility of products following manufacture, without such procedures themselves being guaranteed to be "fail-safe". This was emphasised by a number of the expert witnesses, particularly those who were employed by the TGA at material times. They said the testing of supplied goods for lack of sterility, that is, "contamination", only assists in ensuring that the TGA's requirements are satisfied. The finding that a particular product sample is "contaminated", or that it cannot be confirmed as sterile, does not mean all other products (eg, from the same batch or a contemporaneous of products) are not sterile. For this reason, sterility testing was described by Mrs Tang as a "blunt instrument". It is an indication that there may be a problem with the manufacturing process.

107 Dr Cable stated that sterility testing "is not determinative of whether a product has been manufactured in accordance with acceptable sterility control procedures." He added: "It is simply a test which would confirm a breakdown or failure of such procedure in respect of a particular container from the batch which is contaminated." He added:

> "Sterility, therefore, cannot be guaranteed by the sterility testing that might occur at the end of the manufacturing process. It must be built into the manufacturing and control procedures which occur during processing of the batch. In my experience, greater reliance must be placed on appropriate techniques and procedures throughout the manufacture of the product, including the validation of the manufacturing procedures and adoption of a quality systems approach to manufacture in accordance with the principles of EN46002 rather than simply relying on sterility test made on a sample of each batches as the sole criterion for establishing the sterility of the batch [*sic*]."

108 Vista relies on the sequence of events described above, culminating in the third audit by Mrs Tang in July 1997, and the results of the third audit itself, as well as the subsequent testing of samples of the goods, to demonstrate that the goods manufactured and supplied by Ginza were not manufactured according to the requirements of the TGA.

109 On the face of the evidence set out above, Vista's contention is well made. Mrs Tang's view was that the manufacturing processes at Ginza left much to be desired, so much so that her audit in July 1997 took less than two hours. The audit was of a relatively short duration, not because it was a cursory audit, but because Mrs Tang considered the inadequacies in Ginza's processes were demonstrable. As a result, she found that the manufacturing process was "unacceptable" for the various reasons set out in detail above.

110 Mrs Tang is well qualified and experienced as a microbiologist, with an aggregate of 17 years' experience. She was also well qualified to conduct the audit in question, having been so acting with the TGA for 10 years at the time of the third audit. Notwithstanding the suggestion put to her by Senior Counsel for Ginza that she should have confined her audit strictly to microbiological issues, plainly Mrs Tang was qualified and experienced as a TGA auditor and entitled to range beyond strictly microbiological matters depending on the circumstances and in her discretion. The suggestion put to Mrs Tang that she had her mind closed to the possibility of an unacceptable audit outcome was expressly denied by her and not made good by the evidence. The Court accepts that Mrs Tang was at all times open to be swayed against the audit determination she eventually made.

111 A further claim that Mrs Tang was presented with information relevant to the audit which she refused to consider, was unambiguously rejected by her. The Court accepts Mrs Tang's statements that, had she been invited to peruse any relevant materials or other information, she would have done so. In particular, the Court does not accept Mr Richard Chia's evidence that he produced the "Validation master plan" (exhibit G6) to Mrs Tang in the course of her audit, to which she effectively turned her face. The evidence disclosed that there was no document in existence in July 1997 known as the "Validation master plan". As exhibited, it is a voluminous document. Mr Chia's evidence was that he produced a very few pages of an SOP (standard operating procedure) for the validating of environment bioburden testing - in fact, two pages only. He could not recall what else he had shown to Mrs Tang, although he insisted he had produced to her other documents as well. His evidence did not support a much stronger claim that a document, approaching in content and volume the substance of the materials tendered in evidence as exhibit G6, was produced by him to Mrs Tang, let alone ignored by her in the course of her audit. I do not accept that he did.

112 Similarly, a suggestion that Mrs Tang became tearful or emotional in the course of conducting a stressful audit whereby she effectively aborted

the audit without completing it in a more exhaustive way, was denied by her. Whether or not Mrs Tang ever became "misty eyed", as Mr Chia put it in his evidence, or actually cried, as his sister Mrs Khan claimed, I doubt. Dr Grauaug, who was also present at the audit, denied she had become tearful in the course of the audit. He was also given access to Mrs Tang's draft audit report later in the course of her Singapore audit visit. The creation by Mrs Tang of a draft audit report (which was largely the same as the final report that went into evidence) contemporaneously with the conduct of her audit at Ginza's premises in Singapore is hardly consistent with the claim or suggestion that Mrs Tang was emotionally ill-equipped to conduct or complete the audit, or that she failed in substance to do so.

113 Having observed Mrs Tang give her evidence, having heard her address pointed questions concerning her experience and the manner in which she conducted her audit, as well as having heard her provide the reasons why she conducted the audit and what she found, I have no hesitation in finding Mrs Tang a sound and reliable witness. Where her evidence is in conflict with that of others as to the circumstances and manner in which she conducted her audit at Ginza's premises in July 1997 and as to what she found during the audit, I accept Mrs Tang's account of events.

114 The question of relevance to the pleaded breach of contract, is whether the audit findings of Mrs Tang on 22 July 1997 indicate a failure of Ginza to manufacture the goods supplied to Vista in the period between December 1996 and July 1997 in accordance with the requirements of the TGA, or whether Mrs Tang's audit merely had a present and prospective effect by indicating a failure or inability to manufacture goods in accordance with the requirements of the TGA as of and from 22 July 1997.

115 In my opinion, it should be inferred from Mrs Tang's audit findings, on the balance of probabilities, and having regard to the results of the testing done at Microtech, Consulchem and Princess Margaret Hospital (which are considered further below), that the deficiencies she noted in her audit report applied to the manufacture of goods throughout the whole of the period December 1996 to July 1997. Each of the matters identified in Mrs Tang's audit report as an unacceptable practice or process has an historic aspect to it that makes it improbable that each deficiency first occurred only at some particular, indeterminate date or dates during the period December 1996 to 22 July 1997. Rather, each deficiency identified reflects a matter of historic neglect. Each plainly constituted a state of affairs at the times the goods in question were manufactured by Ginza

during the whole of the period December 1996 to 22 July 1997 inclusive, and I so find.

116 The Intertech Global Access report prepared in September 1997 for and at the request of Ginza, and which Ginza was reluctant to publish to the TGA or Vista at material times prior to these proceedings, strongly confirms the view expressed by Mrs Tang in her audit report in July 1997, and confirms the view I take, that the requirements of the TGA were not met at material times from December 1996 to the time of that audit in July 1997. Mr Comar, who gave evidence, was a co-author of that report with Mr Steve Williams of Intertech Global Access. The report resulted from an inspection of Ginza's premises in late July and early August 1997. The review was undertaken by an examination of the company's documentation and records, interviews with relevant personnel and following an inspection of Ginza's manufacturing facility. The authors also had regard to the audit report prepared by Mrs Tang. They did not dissent in any respect from the audit findings made by Mrs Tang in her report. Indeed, Mr Williams and Mr Comar advised Ginza that the site was not in a position successfully to pass a TGA audit at that time or in the near future. The deficiencies with the manufacture and quality control procedures at Ginza's premises identified by them were numerous and were said to indicate a range of possible causes of contamination of products, summarised as follows:

(a) The manufacturing processes had not been validated to ensure that the prescribed Sterility Assurance Level (SAL) could be attained by this system. The standard for this process is an SAL which results in less than one faulty product per million units manufactured.

(b) The process water and distribution system was inadequately controlled and monitored both in frequency and by inappropriate methods.

(c) The chemical and microbiological quality control procedures were not validated and inadequate for the application.

(d) The manufacturing control procedures could not guarantee that a sterile product was being manufactured consistently and with the appropriate SAL.

117 Mr Comar said that detection of contamination with absolute certainty would require the examination of every bottle of contact lens solution of every batch manufactured by Ginza using media capable of supporting the

growth of all possible contaminants. In his view this was "neither practical nor economic."

118 Ginza says that, notwithstanding Mrs Tang's audit findings on behalf of the TGA, no "requirement of the TGA" can be identified in respect of which the manufacture by Ginza failed to comply. It is true that nowhere in the Code does one find an express requirement by the TGA that particular, detailed processes or procedures, of the type Mrs Tang identified as required, be done. However, that is not to say there was no "requirement of the TGA" that was relevant at material times pursuant to which such particular, detailed processes or procedures should have been done.

119 As noted above, the regulatory scheme of the *Therapeutic Goods Act* administered by the TGA, relies in part on the general requirements of the Act and the Code and the various standards, such as EN 29001, it incorporates or applies by reference. This system in practice may be said to have an element of subjectivity to it, if one wishes to characterise the regulatory system in that way. However, Mrs Khan understood the regulatory process was of this nature. She recognised that the audit process buttressed the regulatory system, so far as exportation of the goods in question from Singapore to Australia was concerned; she frankly admitted this in cross-examination and the evidence of Mr Lee tends to confirm her understanding of the nature of the regulatory system. She clearly understood that the TGA would audit Ginza's manufacturing practices and processes in order to determine whether the requirements of the TGA were being met. Those requirements, in turn, were to be found in the Code and the various standards it referred to, especially those to do with sterile product manufacture.

120 As an aspect of Ginza's contention in this regard, Ginza claimed it was entitled, at all material times, to rely upon the TGA's first and second audits conducted by Ms Woodruff in 1993 and 1995. When those audits were conducted, they identified certain matters which were then responded to by Ginza. It followed, argued Ginza, that, at the times the goods in question were manufactured by Ginza in the period December 1996 to 22 July 1997, it could not be said that Ginza had failed to manufacture the goods contrary to any express requirements laid down by Ms Woodruff in her audit reports. This may be so, but it does not assist in answering the question whether the goods supplied were manufactured in accordance with the requirements of the TGA. Such a contention merely reformulates the earlier contention and does not answer the question. It is also built on a false premise as to the nature of the audit process and role.

121 An audit is not, and was not intended by the TGA at any material time, to be a substitute for a licensing process in which approval subject to express conditions is provided to a manufacturer by a regulatory agency. If it were, the contentions of Ginza would have weight. Either the approval and conditions were met at material times or they were not. If they were met, manufacturing would plainly be "in accordance with the licence and conditions". If they were not met, manufacturing would not be "in accordance with the licence and conditions".

122 An audit report, however, cannot be equated with a licence, with or without conditions. Mrs Tang described the audit process in the following terms:

> "We always take the position that an audit is not a shopping list of problems or deficiencies. An auditor goes in, sees certain things, makes a report. We always write as a standard clause in our report that this is not to be taken as a shopping list, it may be indicative of other problems, and that the company should ensure that they fully comply with the code.
>
> ….
>
> … an audit is a sampling process. You cannot look at every process during an audit. You may pick out certain points but it's quite accepted that an audit done in the time allowed cannot pick up everything that may be wrong with a company. They may pick up four or five points. There may be 10 or 12 that they didn't find.
>
> … that's partly the reason why we try to send different auditors each time."

I accept that this describes the purpose of an audit and the audit process undertaken by Mrs Tang and Ms Woodruff on the occasions they conducted audits of Ginza's premises and plant, and I find that Ginza, through Mrs Khan, appreciated the nature of a TGA audit and the role of an auditor in those same terms.

123 In these circumstances, notwithstanding the first and second audits conducted by Ms Woodruff, Ginza was, at all material times, subject to an obligation, by virtue of the first express term of its contract with Vista, to manufacture the supplied goods in accordance with the requirements - including the general requirements set out in the Code - of the TGA. The first and second audit reports conducted by Ms Woodruff neither released

Ginza from that obligation nor the need to continue to satisfy the requirements - both general and specific - of the TGA, including those set out in the Code. The contractual obligation was to manufacture, not in accordance with audit reports issued from time to time by the TGA, but "in accordance with the TGA's requirements".

124 Accordingly, I find that Ginza did not manufacture the supplied goods in accordance with the requirements of the TGA, as the first express term of the contract between Ginza and Vista required. As a result, Vista is entitled to damages against Ginza for breach of this first express term of the contract.

125 This finding, however, as noted, does not necessarily mean that the goods supplied were not sterile. I now turn to the question of breach of the second express term.

Were the goods sterile?

126 The evidence and history relating to the contamination of the supplied goods has been recounted above. A schedule of batches manufactured by Ginza for Vista during the period December 1996 to July 1997 is attached to these reasons. It conveniently summarises the evidence going to contamination of the goods. The schedule was produced to the Court in the course of argument by Senior Counsel for Ginza. It is not suggested on behalf of Vista and Kontack that the primary information disclosed in it is incorrect.

127 Vista says that, while only certain batches of product manufactured in the relevant period have been found to be not sterile (marked "Fail" on the schedule), the evidence as a whole entitles the Court to infer, on the balance of probabilities, that the goods supplied were not sterile.

128 Ginza, on the other hand, challenges much of the evidence said to support either particular findings of sterility or an inference of sterility in respect of all the goods supplied in the relevant period and the subject of Ginza's claim.

129 The submissions of Ginza in this regard emphasise the difference noted above between a term that goods supplied should be "sterile" and a term that requires the goods to be manufactured in accordance with the requirements of the TGA. This is not a case where all the goods supplied, or even all batches of the goods supplied, have been tested and found either to be not sterile or to have an indeterminate result.

130 It is understandable in a contractual relationship of the type that existed at material times between Ginza and Vista, that not every item of the goods supplied, that is to say, not every bottle, or indeed every batch of solution that found its way into the bottles supplied, should need to be tested in order to establish that the goods supplied were not sterile. It is not contested by Ginza that in an appropriate case evidence may lead to an inference that goods supplied are not of the quality contracted for. Ginza's argument is that, in this case, the evidence is insufficient to support the drawing of such an inference.

131 Where evidence shows a sufficient number of batches of product to have been contaminated, in circumstances where the contamination appears to be widespread and serious, and there are no explanations offered which could reasonably lead to the conclusion that the contamination occurred after the supply of the goods, it is open to a Court to infer that the whole of the goods supplied were contaminated; ***Marimpex Mineralol Handelsgesellschaft MBH v Louis Dreyfus et Cie Mineralol GmbH*** [1995] 1 Lloyd's Rep 167 provides an example, albeit in a different factual context. The question always is, what, in the circumstances of the case, constitutes evidence of a sufficient number of batches. In ***Marimpex***, contamination of 10 per cent of a cargo of oil was sufficient.

132 In my opinion, on the evidence led, it is more probable than not that the supplied goods were not sterile. The contentions put by Vista why, on the balance of probabilities, the evidence supports such a finding are, in my view, compelling.

133 In February 1997, as noted above, the TGA tested certain samples of Green Spot batch 40811B product. On 4 July 1997, Mrs Tang, in her capacity as Chief Microbiologist at the TGA, wrote to Vista to advise that the samples tested in relation to batch 40811B were contaminated. This led to the July 1997 third audit conducted by Mrs Tang. The result of this test on its own plainly is insufficient to provide a reliable basis upon which to conclude that all other items of the product manufactured before or after that batch (in 1994) were not sterile.

134 What then occurred, however, strongly points to sterility of the product in the period December 1996 to July 1997 in question. In August 1997, Microtech Laboratories Pty Ltd were asked by Vista to test a number of samples of batches of Ginza product. The result of testing, according to Microtech, was that of 18 of the batches tested, 15 failed sterility testing. The 15 that failed were as follows: 72406A, 72506A, 72506C, 72606A, 72506B, 72606C, 72406B, 70707B, 70907A, 70606C, 70507A, 72306C,

70606A, 71103B, 71103C. These descriptions provide a code to the individual batches of product. For example, the description "72406A" indicates that the batch in question was batch A manufactured on 24 June 1997. That described as "72506C" was batch C manufactured on 25 June 1997, and so on.

135 The schedule attached to these reasons discloses the results of all testing. It can be seen that batches of solution manufactured in March, April, June and July 1997 failed Microtech's testing.

136 In October 1997, Microtech was further engaged by Vista to perform sterility testing on further batches of contact lens solution manufactured by Ginza, most of which were manufactured in 1996 or 1997. The great majority of the batches tested, according to Microtech, passed sterility testing, save for "AMCAL Visaclear Preserved Saline" batch number 61812C, that is from batch C manufactured by Ginza on 18 December 1996.

137 Also in August 1997, following the sterility testing and results Vista had obtained from Microtech Laboratories, Consulchem, analytical and consultant chemists and microbiologists, was requested by Vista to conduct sterility tests on a number of samples of contact lens solution. Consulchem received 12 cartons, each containing 20 plastic bottles of solution, from Vista. Of the nine cartons tested for sterility, according to Consulchem six failed the sterility test. In the opinion of Ms Carol Young, microbiologist and director of Consulchem, who supervised the sterility testing, the testing indicated that there was "contamination across the batches". As the schedule shows, the samples were from batch numbers manufactured in March and June 1997.

138 After these proceedings were commenced, Ms Cristina Farrar, medical scientist at the Women's and Children's Pathology Department of Microbiology, Princess Margaret Hospital for Children in Subiaco, Perth, Western Australia, was requested to conduct sterility testing on samples of the supplied goods. On 7 August 1998, 20 units of batch number 72406A were provided by Vista for testing and all 20 units were tested for sterility. On 27 August 1998, at Ginza's request, Ms Farrar was provided with a further quantity of contact lens solution for testing. The quantities and batch numbers of those were: 72406C (20 units), 72506A (20 units), 72406A (20 units), 72506B (20 units) and 72506C (20 units). Ms Farrar said that each batch tested did not pass the test for sterility as defined in Australian Code of Good Manufacturing Practice. Seventy units were tested and 48 failed, indicating, according to her, "gross contamination".

Again, these samples were from batch numbers manufactured in 1997. The schedule discloses that six of the "Fail" results were in respect of batches manufactured in June 1997.

139 Following the testing by Microtech Laboratories, Vista wrote to Dr John Cable, Director, Conformity Assessment Branch of the TGA, by letter dated 5 September 1997 (exhibit V1 attachment L). In the letter, signed by Dr Grauaug, Vista said of the Microtech results available as of that date:

> "These are the first in a total of 38 batches that have been sent to Microtech. There are some positive and negative results. These products remained quarantined in our warehouses and have not been released to the public. A further 12 batches have been sent to Consulchem Pty Ltd in Victoria and these results are expected on 18 September.
>
> I am concerned with these results especially as some contradict the results from tests carried out at Singapore General Hospital … "

At this point, data to hand from Dr Charles Tang of the Singapore General Hospital suggested there was no contamination of product manufactured at about the same time.

140 By letter dated 12 September 1997, and apparently faxed to Dr Cable, Dr Grauaug drew to Dr Cable's attention the facts that Vista had:

> "• ceased importation of goods from Ginza Pte Ltd
>
> • arranged an alternate manufacturer from Italy and are progressing with TGA requirements on this as quickly as possible
>
> • We have arranged testing of batches held in quarantine and the results show that the 1997 stock is contaminated, (months of production range from April through to July) but the 1996 stock is not contaminated. Seventeen (17) batches of 1996 stock have been tested, having been produced in April, May, August and December of that year. Three (3) have been tested by TGA and fourteen (14) by Microtech and the results were given to me 11.30 WST today. (See table enclosed.) The seventeen (17) includes one batch tested by both laboratories.

> There is, thus, no evidence that the 1996 stock is contaminated and all the data supports the fact that some event has contributed to the contamination being confined to some period in 1997. Ginza has engaged Australian consultants to investigate the causes of this contamination and they will be in Singapore this week."

141 By letter dated 16 September 1997, Dr Cable wrote to Dr Grauaug at Vista in these relevant terms:

> "I note the results of sterility tests, provided by Microtech Laboratories, of 17 batches of product manufactured during 1996, and your contention that, based on these results, there is no evidence that stock manufactured during this period is contaminated.
>
> As discussed, the TGA is concerned that the manufacturing procedures employed by Ginza are sub-standard and that the level of compliance with the principles of good manufacturing practice is such that there could be little confidence in the microbial status of the products manufactured during 1996.
>
> Accordingly, I am reluctant to accept that the test results presented for the 17 batches manufactured during April, May and August, establish that *all batches* made during 1996 are free from contamination." (emphasis in original)

142 By a further letter dated 16 September 1997, Vista, by Dr Grauaug, wrote to Dr Cable at TGA and provided a copy of an interim report from Consulchem indicating that Vista multipurpose solution 60605A, a product manufactured in May 1996, was sterile on day 13 and therefore unlikely to become contaminated by day 14. Dr Grauaug then expressed the opinion that:

> "There are thus 18 batches from 1996 which have passed sterility tests. This is a substantial representative spread of products manufactured in 1996.
>
> We now wish to release 1996 from quarantine as there is no justification in holding this stock any further. Please fax your confirmation as soon as possible."

143 As a result of these representations, Dr Cable of the TGA by letter to Dr Grauaug of Vista dated 23 September 1997 indicated that the TGA

agreed to the release from quarantine of a number of batches of Vista and Kontack products as set out in that letter. These comprised various batches of March, April, May, June, July, August and one batch of December 1996 product. Dr Cable continued to express concern about the quality of products manufactured in the latter part of 1996 on the grounds that "the change to the manufacturing conditions which has led to widespread contamination of the products manufactured in 1997 might equally have occurred in the latter part of 1996 and affected these batches". The reference to the "change to the manufacturing conditions" is not further explained in this letter.

144 In a further letter from Dr Cable to Dr Grauaug dated 6 November 1997, Dr Cable recounted some of the history of testing of products following the third audit by Mrs Tang in July 1997. Dr Cable again noted that subsequent testing of products manufactured during 1997 had established that 15 of 18 batches tested were contaminated. This is plainly a reference to the Microtech Laboratories testing. Dr Cable referred to the fact that the decision to restrict the previous recall of products to batches manufactured in 1997, "was made on the basis of your contention that the contamination was likely to be due to a change in the manufacturing conditions which occurred during the holiday shut-downs in December 1996 and January 1997". This helps to explain the comment in the earlier letter and indicates that Dr Grauaug was the source of the belief Dr Cable there expressed. There is no evidence to establish that contamination was due to any such event.

145 In his letter dated 6 November 1997, Dr Cable further notes that, as a result of the failure of AMCAL saline batch 61812C to pass a sterility test, as confirmed in Dr Grauaug's fax of 22 October 1997 - at a time prior to shut-down periods - the "quality of all batches manufactured during December 1996" was brought into question.

146 Dr Cable went on to state in his letter:

> "Since the samples you have sent for sterility testing have been taken from warehouse stock, it is not possible to ascertain whether the sample is representative of the manufactured batch.
>
> The failure of Batch No 61812C casts doubt upon the microbiological quality of all batches manufactured during December. For the reasons explained above, only exhaustive testing of all containers will provide an assurance of sterility …

> It is therefore recommended that all batches manufactured by Ginza Pte Ltd during December 1996 and which have been imported into Australia, be recalled to consumer level."

147 In his evidence, Dr Cable explained that success in detecting microbiological contamination of goods is dependent, *inter alia*, on statistical considerations. Generally, the odds are against detecting contamination where a small proportion of the units in a batch is contaminated. Detection of contamination with absolute certainty would require the examination of every bottle of contact lens solution in every batch manufactured by Ginza using media capable of supporting the growth of all possible contaminants.

148 Dr Cable provided a table of the probabilities of detecting a contaminated bottle through the conduct of a single sterility test on a sample from a batch relative to the percentage of the units in the batch that are contaminated. In the case of the sterility test results provided by Microtech Laboratories, where 15 out of 18 batches were tested, Dr Cable said this indicates that there is a "very high likelihood that a significant percentage of containers in each batch were contaminated. The fact that so many batches failed through the retesting would also indicate that there was systematic contamination". I accept his evidence.

149 Dr Cable emphasised that sterility cannot be guaranteed by the sterility testing that might occur at the end of the manufacturing process and for this reason it must be built into the manufacturing and control procedures which occur during processing of the batch. Sterility testing, however, is useful in detecting a gross failure of the manufacturing process, such as may be related to contamination arising from technical malfunction, human error or mix-up, or where contaminated items may be used in the manufacturing process.

150 Dr Cable's evidence therefore goes to establish that, while he did not have evidence before him that all batches of all Ginza products imported into Australia by Vista and manufactured in the relevant period were contaminated or had failed sterility testing, he could not be satisfied that such products were free from contamination and that this concern led to his decisions, not only to recall all 1997 product (the second recall), but ultimately to recall all batches manufactured by Ginza during December 1996 (the third recall). On the basis of the information before him, Dr Cable on behalf of TGA, took an informed regulatory decision. He did not, and he did not have to, determine conclusively that the product the subject of the recall notices was contaminated, that is to say, was not sterile.

It was sufficient for his purposes to be concerned that all such product was not sterile.

151 The question for the Court, however, is whether the evidence is also sufficient to permit the Court to draw an inference, on the balance of probabilities, that the December 1996 and 1997 goods manufactured by Ginza, and the subject of the parties' claims here, and which were the subject of the recall notices, were in fact not sterile. It is not enough for the Court to conclude that Dr Cable acted reasonably in a regulatory sense, in order to infer this fact on the balance of probabilities.

152 In my view, the evidence of contamination of Ginza product given on behalf of the TGA and the three laboratories discloses widespread and gross contamination of the batches submitted. I am of the opinion that the extent and level of that contamination leads to the proper inference that the whole of the goods supplied, which are the subject of the Ginza action, were not sterile. The testing done by Microtech Laboratories in August 1997 was in respect of 18 batches manufactured at various dates in March, June and July 1997. The nine cartons of product tested for sterility by Consulchem in August 1997, of which six failed, were manufactured in March and June 1997. The product the subject of sterility testing at Princess Margaret Hospital in August 1998 included product manufactured on various dates in June 1997. On the other hand, of a number of batches of solution manufactured by Ginza in 1996 and 1997 that were sterility tested in October 1997 by Microtech Laboratories, only a batch from December 1996 failed the testing. While the evidence shows that some product manufactured during 1997 "passed" sterility testing, and that some batches manufactured in January, February and March 1997 were not subjected to testing, the only proper inference to be drawn from the evidence, and an inference which is consistent with the interpretation placed on the same data by Dr Cable, albeit for the purpose of making an informed regulatory decision, is that, as a whole, the product supplied by Ginza in the relevant period was, on the balance of probabilities, not sterile.

153 As a result, Vista is also entitled to damages against Ginza for breach of this second express term of the contract.

The reliability of the sterility tests

154 I mentioned above that Ginza mounted a substantial effort to discount the sterility testing conducted by the three laboratories in Australia. Ginza submits that the sterility test results produced by Microtech Laboratories, Consulchem and Princess Margaret Hospital cannot be relied upon for the

purpose of determining whether or not the supplied goods were "manufactured according to the requirements of the TGA" or whether or not the goods were sterile. Ginza's contention is directed to the issue of whether the tests conducted by Microtech, Consulchem and Princess Margaret Hospital were carried out in accordance with the standard prescribed by Therapeutic Goods Order 11 (TGO 11) or Appendix C of the Code. It is appropriate here to set out the reasons why I am not persuaded by Ginza's arguments in this respect.

155 Appendix C of the Code is a set of "Guidelines on Tests for Sterility". TGO 11 is an order made pursuant to s 13 of the *Therapeutic Goods Act 1966,* apparently continued under the *Therapeutic Goods Act 1989*. TGO 11 is dated 4 December 1983. TGO 11 is described as a "Standard for Sterile Therapeutic Goods". It provides the "Standard for substances and articles, of which goods for therapeutic use consist, that are labelled as sterile or sterilised or otherwise purport to be sterile or to have been sterilised, shall be determined in accordance with the tests specified in this Order". At page 18 of TGO 11, a summary of the interpretation of the test results as specified in cl 20 of the order is set out. It provides for conclusions of "Pass", "Indeterminate Result", "Invalid Test" and "Fail".

156 The Guidelines on Tests for Sterility, Appendix C of the Code, which are dated "July 1981, edited August 1990", appear to postdate the date of the TGO 11. The evidence shows Appendix C is usually relied upon by accredited testing laboratories when conducting sterility testing. One issue put to the witnesses from the three laboratories concerning TGO 11 and the Code, was whether validation had been undertaken prior to the sterility testing. It was suggested to each witness that failure to so validate was contrary to both TGO 11 and the Code. Another issue put to these witnesses concerned whether results which were said either to have "failed" or not to have "passed" should have been treated as "indeterminate" requiring repeat testing. A further issue put to these witnesses was whether these test results could be considered relevant if the laboratory did not have information concerning the batch size or production history of the samples they were asked to test.

157 As to the role played by TGO 11 or appendix C in sterility testing, Mrs Tang of the TGA said that if a company challenges the result of the test that the TGA has done, the company must follow TGO 11. Mrs Tang said TGO 11 is binding on the TGA and is a reference test. The initial testing carried out by the TGA in respect of batch number 40811B was done in accordance with TGO 11.

158 Mrs Tang commented on the requirement of both TGO 11 and Appendix C that if one obtains an indeterminate result, a repeat test is required to verify same. The TGO 11 and Appendix C suggest that until a repeat test is conducted and the same result obtained, a "Fail" should not be recorded. She said that, while TGO 11 and Appendix C so provide, the reasoning behind the requirement is scientifically not very sound and that, since the sterility testing rules were changed more recently, it is no longer the case. She conceded, however, that it was the case at the time the tests the subject of scrutiny in this action were conduct.

159 Mr Jay, of Microtech, said that the relationship between Appendix C and TGO 11 at the time his laboratory conducted sterility testing was confusing, and that it still is. The Code requires Appendix C to be followed for the test of sterility. He said TGO 11 was issued by the TGA and it had some extra requirements in it. As far as he was concerned, TGO 11 prescribed the method of sterility testing that the TGA use when they conduct tests. He said that in practice, in industry, Appendix C was utilised by manufacturers and in practice his laboratory utilised Appendix C unless the client required testing under TGO 11.

160 Mr Jay acknowledged that, under both TGO 11 and Appendix C, the requirement is that: "Both sampling and testing requirement are therefore different from the therapeutic goods order which must be applicable in situations where there is no knowledge of batch size or production history." He accepted that he relied on Appendix C even though he had not been provided at any relevant time with information concerning batch size or production history of the batches his laboratory tested. He said that, notwithstanding the above requirement, it was practice within the industry and in his own laboratory to use Appendix C unless directed by the client to use TGO 11. In this case, he received a request from Vista to do sterility testing and that is what he did.

161 Mr Jay accepted that, in a number of instances, Microtech recorded a "Fail" when, if Appendix C were literally applied, it should have recorded an "indeterminate result" and then conducted repeat testing. However, he did not recall Vista delivering extra batches of product for repeat testing. He said that "industry may or may not repeat a test". If the required number of samples were produced for repeat testing and the client required it, it would be done. In this instance, it was not required.

162 Ms Farrar, from Princess Margaret Hospital, explained in some detail the nature of the sterility testing she undertook. She also indicated that she conducted testing by reference to Appendix C of the Code. It was

suggested to her that, by reason of the data she obtained, a test result of "indeterminate" required a repeat test to be conducted before the test result "fail" could be entered. She agreed that she had not performed the test she conducted strictly according to either Appendix C or TGO 11 in that respect.

163 However, Ms Farrar indicated that she had been asked to test two different products, a Vista product and a Kontack product. She was asked by Vista to test 20 samples, which she did individually. She was then asked by Mr Lee, on behalf of Ginza, some three or four weeks later, to conduct independent testing of some products that had been earlier tested in the Eastern States and which Ginza feared were not true and accurate. Ms Farrar told Mr Lee that normally the Code requires that either 10 per cent of the batch or 10 samples of the batch should be tested. She explained that most manufacturers will pool the products and have one test result. The problem with that, she explained, was that you do not know the degree of contamination in a product. To determine the degree of contamination in a product, it would be necessary then to test each of the 10 units individually. In that way, it was possible to say precisely what the level of contamination is. She told Mr Lee that if he believed that Ginza's product was, indeed, sterile and wanted results to prove it, then he should test them individually. Mr Lee agreed on behalf of Ginza to that course. Ms Farrar then tested the samples provided by Mr Lee individually. He provided a carton of boxes, being a carton of each batch, for testing. Each carton had 20 units in it. Mr Lee requested Ms Farrar to select out 10 units at random from the 20 in the box and test them individually. She pointed out to Mr Lee that she only had limited stock of filter units, which is one of the apparatus used for testing, and if he wanted them to be tested individually and he needed the results rapidly, she could assist him, but he would have to purchase the units for her. He indicated that he did not desire to purchase the units and would wait. He was happy to wait until they were able to test all the units individually. She went ahead on that basis. She then selected out 10 units and tested them all individually. Accordingly, she produced 50 results for Ginza.

164 In total, Ms Farrar tested 20 samples for Vista and 50 for Ginza, that is, 70 in total. Forty-eight of the 70, according to Ms Farrar, appeared to be suffering "gross contamination".

165 Ms Young, from Consulchem, was also asked whether her laboratory conducted the relevant sterility testing by reference to Appendix C of the Code or TGO 11. She indicated that the laboratory followed Appendix C. She indicated that her understanding is that, while the requirements of the

two are similar, laboratories have always worked from the Code of GMP, which is appendix C. She said: "We've always as a laboratory audited by TGA used directly their publication which was Appendix C at that time."

166 As with other witnesses, Ms Young did not evince any knowledge of the batch size or the production history of the samples she was asked to test. This was not considered by her to be relevant to the reliability of the analysis that her laboratory provided. Ms Young said, "At the time when we were asked to do the work we said that we would do the testing under Appendix C, … That method is what we employed and at the time this was presented to Vista and accepted by Vista."

167 Concerning whether repeat testing was conducted when a sample appeared to have failed sterility testing, Ms Young indicated that she telephoned Vista and told them of the failure, and said that there was provision to repeat the test with double the number of samples. She was told that Consulchem "were the repeat test laboratory", as testing had been conducted previously elsewhere. She was told Consulchem was not required to repeat the tests.

168 When asked whether she agreed that, under Appendix C, the test is deemed to be "indeterminate" unless there has been repeat testing, Ms Young said, "No I do not." She explained that she considered that to take another view was to be "playing with semantics". Ms Young stated:

> "The test is definitely a fail if you get growth. We got growth. The test was a fail. The findings as to the entire batch, whether it passes sterility or not, is indeterminate which is why we contacted Vista, said we had a fail, 'Could you please forward more samples to us so that we could test double the number and substantiate that finding?' whereupon we were told there was no need to, it was just a double check."

169 Ms Young added that she was very well aware of the fact that if one looks at the probability of finding a failure the second time round, it rests of very shaky scientific grounds and, in fact, that is no longer valid in sterility testing. She indicated that it was always an option and, in the past, it was considered fair to say to the manufacturer: "You're on shaky ground as far as one test. You have the option of testing again, but we have to let you know that we've got pretty strong evidence that there's a failure."

170 Ginza submits that, because the sterility testing so conducted was not strictly in accordance with TGO 11, or for that matter with Appendix C, either the results concerned should be discounted or the results that were

recorded as "Fail" should be treated as "Indeterminate", with the consequence that the number of "Fail" results should be considerably reduced.

171 In my view, the sterility test results produced by Microtech, Consulchem and Princess Margaret Hospital should be accepted for what they show in the schedule to the reasons. In each case, the tests were conducted by or under the supervision of experienced scientists. In each case, regard was had to the testing procedure laid down in Appendix C of the Code. In each case, the scientists have said that the need for repeat testing stands on shaky scientific ground. This was confirmed by Mrs Tang from the TGA. In each case, the witnesses verified the industry-wide acceptance of the results of such a method of testing. There is no reason, in my view, to doubt the authenticity and reliability of the test results produced by each of these laboratories. Those results marked as "Fail" should be accepted as test results which indicate that, in all probability, the samples tested were contaminated; that is to say, they were not sterile.

172 Indeed, the parties themselves, at material times, were prepared to accept the form of testing undertaken by the laboratories. In particular, when Mr Lee, on behalf of Ginza, approached Ms Farrar at Princess Margaret Hospital, the method and manner of sterility testing was explained by Ms Farrar and expressly accepted by Mr Lee, on behalf of Ginza. It does not serve Ginza well now to challenge the reliability of the test results from a form of testing it acceded to.

173 In all of these circumstances, I am not satisfied that the scientific data put in evidence by the scientific witnesses on behalf of the three laboratories should be rejected, as Ginza contends. On the contrary, I find it compelling evidence to support the contention that the sterility tests show gross contamination across the batches tested, supporting the finding that the requirements of the TGA governing their manufacture were not met and the goods were not sterile.

174 The only evidence that appears to militate against such a view is that presented by Dr Charles Tang (no relation to Mrs Shelley Tang of the TGA) of the Singapore General Hospital. Save for batch 40811B, he did not detect any batch which failed sterility testing. I accept, on the basis of Dr Tang's evidence and the evidence generally before me, that, save for batch 40811B that was manufactured in 1994, there is little or no evidence that any other goods manufactured until December 1996 were contaminated. However, the question is whether it is proper to draw an inference on the basis of the sterility test results of Microtech, Consulchem

and Princess Margaret Hospital, and the test results of the TGA, in relation to the December 1996 and 1997 period up until July 1997, that the product manufactured was contaminated.

175 In that regard, it is appropriate to note Mr Comar's testimony that, at the time he and Mr Steve Williams conducted the inspection of Ginza's premises for the purposes of preparing the Intertech Global Access report of September 1997, they were aware that tests performed by the Singapore General Hospital were reported as having been satisfactory. Both prior to and during his visit to Singapore, Mr Comar sought, through Ginza, to obtain method validation documents for the test procedures utilised at Singapore General Hospital. No documentation was ever supplied to him or Mr Williams concerning the validity of the methods used. Several attempts were made to visit the Singapore General Hospital as part of the Intertech audit, but they were unsuccessful. As of November 1999, Mr Comar had not seen any evidence that the methods utilised by the Singapore General Hospital were either validated or performed to appropriate international standards.

176 On behalf of Ginza, it is said that no inference concerning lack of sterility can be drawn because the test results constitute too small a sample. It is also said that Vista has had most or all of the recalled product in its possession and control for several years, yet has not undertaken any satisfactory level of testing. It is said there is no reasonable explanation for its failure to do so and the inference should be drawn that the results of tests on those products would not have assisted Vista's case: ***Spence v Demasi*** (1998) 48 SASR 538 at 547. It is said the Microtech invoices show that the cost of testing is small. It is further submitted that, at the outset, Vista accepted the responsibility of undertaking the testing of any batches of recalled products.

177 I do not accept Ginza's submission. The level of testing appears to me, in all of the circumstances, to be satisfactory. There must reasonably be practical and economic limits to the extent to which testing, in such circumstances, can and should be undertaken. There is no evidence to suggest Vista and Kontack refused or refrained from undertaking any reasonable testing of available product. On the other hand, there is evidence that Mrs Khan of Ginza arranged for further testing to be conducted by another Australian laboratory, AMS. The results were not produced in evidence. It is reasonable to assume their production would not have advanced Ginza's case.

178 Ginza further submits that if it were possible to draw an inference that the goods in question were not sterile, a number of facts militate against such a finding, including that Ginza's process of manufacture was a sophisticated system designed to ensure sterility which had been approved by the TGA in May 1993 and again in October 1995 in the course of the first and second audits; that Vista has not been able to point to anything that occurred in December 1996 which might justify its stance, for example, Ginza did not stop production over Christmas in 1996; that there are a number of possible explanations for a product failing a sterility test, as Dr Charles Tang had noted in his witness statement on which he was not cross-examined; that the detection of micro-organisms in some and not all of Ginza's products is difficult to reconcile with the result of the efficacy tests conducted by Dr Charles Tang, on which he was not cross-examined; there is no evidence of a single complaint from a customer of any problem with Ginza's product manufactured between the second audit in October 1995 and the third audit in July 1997; that Vista continued to accept solution manufactured by Ginza for the Korean market; and that it was not suggested to Dr Tang in cross-examination that the product manufactured after July 1997 was not sterile.

179 As to the first of these propositions, which is probably the most important, I have already set out above my reasons for concluding that Ginza failed to meet the first express term of the contract, namely, that the product should be manufactured in accordance with TGA requirements. In my view, the evidence adduced through Mrs Tang concerning what she discovered during her third audit of the plant of Ginza in July 1997 does not support the conclusion that Ginza's process at material times was either sophisticated or calculated to ensure sterility.

180 It may be true to say that nothing in particular has been pointed to by Vista or otherwise in the evidence to suggest a reason why there may have been a sterility problem as of December 1996. However, the facts before me are as they are and the results of Mrs Tang's audit in July 1997 and the results of the sterility testing conducted by the three laboratories, taken with the failure of the sample manufactured in 1996, together lead me to accept that, on the balance of probabilities, the manufacturing process of Ginza from December 1996 onwards failed to comply with TGA's requirements. Those requirements, as previously noted, were designed and calculated to ensure the sterility of product. Those requirements are also designed in the knowledge that it may often prove difficult to point to any particular event that has caused contamination. The evidence of Mrs Tang and Dr Cable confirms this view. It is not to be thought surprising, therefore, that no particular event has been identified in the evidence either in December

1996 or later, that, of itself, explains the sterility test results conducted by the TGA and the three laboratories.

181 Accordingly, while there might be a number of other possible explanations why a product might fail a sterility test, there is nothing on the evidence which suggests to me that the possible explanations put forward by Dr Charles Tang negative the drawing of the inference, on the balance of probabilities, in this case.

182 While Dr Charles Tang may not have found any grounds to doubt the efficacy of the product he tested, I do not doubt, as I have found, the authenticity and reliability of the sterility tests conducted by the TGA and the three laboratories in Australia that have been lead in evidence.

183 The fact that there may be no evidence of a single complaint from a customer, is hardly to the point. No scientific evidence was led to suggest that non-sterile products would inevitably cause users difficulties. Rather, the evidence before me suggests that the requirements of the TGA are designed to create the greatest level of customer satisfaction possible within Australia.

184 The fact that Vista continued to accept solution manufactured by Ginza for the Korean market, in which it then had an interest through the Choonwae Pharma Corporation, may be explained on a number on bases, not the least of which were, as suggested, a belief on the part of Vista that the product was not so contaminated that it would actually cause consumer complaints, as well as a commercial desire to continue to sell the product, regardless of the difficulties with the Australian TGA. It may be that the latter motivation lacks some degree of moral efficacy, but it does not provide a ground for declining to draw the inference I have drawn.

185 The state of product manufactured after July 1997, in my view, is not material to the matters in issue in these proceedings.

Were the goods "fit for the purpose" and of "merchantable quality"?

186 In light of my finding that the goods were not sterile, and given the concessions of the parties noted above (and subject to consideration of the argument of Ginza that the Vienna Sales Convention applies so as to affect any reduction in price to which Vista may be entitled), I also find that the goods were not fit for the purpose for which they were supplied.

Does the Sale of Goods Act 1895 or the Sale of Goods (Vienna Convention) Act 1986 apply to the contract?

187 The *Sales of Goods Act 1895* was enacted in order to codify the law relating to the sale of goods. It has counterparts throughout Australia. It is understood that the *Sales of Goods Act 1895* applies to contracts of sale of goods made in Western Australia.

188 The *Sale of Goods (Vienna Convention) Act 1986* was enacted to give effect within Western Australia to the United Nations Convention on Contracts for the International Sales of Goods (Vienna Sales Convention). By s 5 of the Convention Act, the provisions of the Vienna Sales Convention set out in Sch 1 to the Act have the force of the law in Western Australia. Section 6 provides that the provisions of the Convention prevail over any other law in force in Western Australia to the extent of any inconsistency. This would appear to mean that, for example, to the extent that the Vienna Sales Convention makes provision inconsistent with that made by the *Sales of Goods Act 1895*, the provisions of the Convention prevail.

189 Article 1 par (1)(a) provides that the Convention applies to contracts of sale of goods between parties whose places of business are in different States, when the States are Contracting States. In this case, the place of business of Ginza at all material times was in Singapore and that the place of business of Vista at all material times was in Australia. I have found above that the contract of sale of goods in question in this case was between Ginza and Vista only. In other words, there is in this case a contract of sale of goods between parties whose places of business are in different States, the States relevantly being Singapore and Australia. It is common ground that each State is a Contracting State. In those circumstances, the Vienna Sales Convention applies to the contract of sale of goods that I have found to exist between Ginza and Vista.

190 By the pleadings in the Ginza action and by the submissions of the parties, each of Ginza and Vista accept that the implied terms pleaded going to fitness for the purpose and merchantable quality find expression both in the *Sales of Goods Act 1895* and in the Vienna Sales Convention. This is substantially so.

191 For example, in a manner not unlike s 14 of the *Sales of Goods Act 1895*, the Vienna Sales Convention deals with the question of conformity of the goods with the contract. In particular, by Article 35 par (1), the seller must deliver goods which are of the quantity, quality and description required by the contract and which are contained or packaged in the manner

required by the contract. By par (2), except where the parties have agreed otherwise, the goods do not conform with the contract unless, *inter alia*, they:

(a) are fit for the purpose for which goods of the same description would ordinarily be used;

(b) are fit for any particular purpose expressly or impliedly made known to the seller at the time of the conclusion of the contract, except where the circumstances show that the buyer did not rely, or that it was unreasonable for him to rely, on the seller's skill and judgment.

192 The Vienna Sales Convention also specifies remedies for breach of contract by the seller. Article 45 par (1) provides that, if the seller fails to perform any of his obligations under the contract or this Convention, the buyer may:

(a) exercise the rights provided in Articles 46 to 52;

(b) claim damages as provided in Articles 74 to 77.

By par (2), the buyer is not deprived of any right he may have to claim damages by exercising his right to other remedies.

193 Article 50, which is discussed in further detail below, provides, *inter alia*, that if the goods do not conform with the contract and whether or not the price has already been paid, the buyer may reduce the price in the same proportion as the value that the goods actually delivered had at the time of the delivery bears to the value that conforming goods would have had at that time.

194 Article 74 provides that damages for breach of contract by one party consist of a sum equal to the loss, including loss of profit, suffered by the other party as a consequence of the breach. Such damages may not exceed the loss for which the party in breach foresaw or ought to have foreseen at the time of the conclusion of the contract, in the light of the facts and matters of which he then knew or ought to have known, as a possible consequence of the breach of the contract.

195 By virtue of Article 45, a buyer can both rely on Article 50 in order to claim the right to reduce the price of goods supplied, as well as on Article 74 in order to claim damages for breach of the contract. In that regard, the provisions of the Convention appear similar to those of s 52, and especially s 52(4), of the *Sales of Goods Act 1895*. The latter subsection permits a buyer to set up a breach of warranty in diminution or extinction of

the price as well as maintain an action for damages for breach of warranty if further damage has been suffered by a buyer beyond that diminution or extinction of the price. In this action, this is how Vista has pleaded its case.

196 On the face of it, the terms of the Convention would appear to govern all relevant issues to the exclusion of the *Sales of Goods Act 1895*.

Vista's right to reduce the price of the goods

197 In these circumstances, therefore, Vista is entitled to reduce the price of the goods supplied by Ginza and the subject of the Ginza action from that claimed to zero pursuant to the Vienna Sales Convention Article 50, which reflects s 52(1)(a) of the *Sales of Goods Act 1895*. This outcome reflects the proportion the value the goods actually delivered had at the time of the delivery (effectively no value) to the value that conforming goods would have had at that time (the sum claimed by Ginza in the Ginza action).

198 Ginza says that the effect of Article 50 and 51(1) of the Vienna Sales Convention is such that Vista is only entitled to reduce the price with respect to those batches of product that were tested and found to have been contaminated. I do not consider the Convention operates in the manner contended for.

199 Article 50 of the Convention provides that:

> "If the goods do not conform with the contract and whether or not the price has already been paid, the buyer may reduce the price in the same proportion as the value that the goods actually delivered had at the time of the delivery bears to the value that conforming goods would have had at that time. However, if the seller remedies any failure to perform his obligations in accordance with article 37 or article 48 or if the buyer refuses to accept performance by the seller in accordance with those articles, the buyer may not reduce the price."

Article 51(1) provides that:

> "If the seller delivers only a part of the goods or if only a part of the goods delivered is in conformity with the contract, articles 46 to 50 apply in respect of the part which is missing or which does not conform."

200 In my opinion, the effect of these two Articles is not as contended for by Ginza. Article 50 does not provide that only the costs associated with

the recall of the particular goods actually tested and proved to be contaminated, are recoverable. Article 50 simply provides that, where such goods do not conform to the contract, the buyer may reduce the price in the same proportion as the value "that the goods actually delivered" had at the time of delivery bears to the value that the conforming goods would have had at that time. The question that is raised for consideration in this action is which, if any, of the goods were conforming goods. Where, by reference to the evidence, the Court concludes that all the goods in issue should be taken not to be conforming goods, then Article 50 has the effect, as I have found, that the price of the goods in question should be reduced to zero.

201 The result of the application of Article 50, in the circumstances as I have found them, means that Ginza cannot succeed in its claim.

202 On the other hand, Vista is entitled to its remedies, not only under Article 50 in this way, but also for damages assessed in accordance with Article 74 of the Vienna Sales Convention.

203 A further question remains as to whether Ginza is liable to Vista and to Kontack in damages for negligence.

Is Ginza liable to Vista in damages for negligence?

204 Ginza agreed to manufacture sterile lens solution for distribution in Australia by Vista, with the additional understanding that goods distributed under the "Kontack" brand name would also be distributed by Kontack. Ginza knew that such goods had to be manufactured in accordance with the requirements of the Australian TGA in order to qualify for importation by Vista into Australia or for sale within Australia.

205 In light of the above findings, I consider that Ginza was not only bound by an express term of the contract between it and Vista to supply goods that would be manufactured according to the requirements of the Australian Therapeutics Goods Administration and that such goods would be sterile, but that it also owed Vista a duty of care to provide goods to Vista that were manufactured in accordance with the requirements of the TGA and that were sterile.

206 In light of the above findings, it follows that Ginza breached each duty of care it owed in these terms to Vista and is liable in damages for negligence to Vista as a result.

Is Ginza liable to Kontack in damages for negligence?

207 I have found that Kontack did not conclude an agreement with Ginza as alleged. Accordingly, Kontack is unable to sustain a claim in damages for breach of contract.

208 However, Kontack argues that it is entitled to have damages in negligence in a similar sum. For the reasons set out above in relation to Vista's entitlement to sue in tort, I accept that that is so. At all material times, Ginza, through Mrs Khan, was aware that Kontack Pty Ltd had been incorporated by Dr Grauaug as a corporate vehicle for the marketing of "Kontack" brand goods in Australia and that Kontack was itself the wholesaler or distributor of Kontack brand products within Australia. Mrs Khan of Ginza was well aware of the close relationship between Vista and Kontack and the reason why Kontack had been formed separately to sell Ginza product within Australia. Indeed, as noted above, on occasion invoices and statements were issued by Ginza directly to Kontack for the supply of certain goods, although not those in issue in this action.

209 In those circumstances, I find that Ginza owed Kontack duties of care to provide goods to Vista under the "Kontack" brand name, that were manufactured in accordance with the requirements of the TGA and that were sterile.

210 I also find that the duty of care in each respect was breached, for the same reasons I have set out above as to why the terms of the contract with Vista, to similar effect, were breached.

211 Accordingly, Ginza is primarily liable to Kontack for damages in tort.

Vista's and Kontack's damages

212 In light of the facts as I have found them, Vista was entitled, if not obliged, to recall the goods that it did recall. Vista, in my view, acted responsibly in its dealings with the TGA, both before and after the third recall. In practical and commercial terms, it had no alternative but to act in the way that it did.

213 By reason of the finding that there was no relevant contract between Kontack and Ginza in respect of the goods identified in the Kontack action, only Vista is entitled to damages for breach of contract. However, each of Vista and Kontack are entitled to damages for the negligence of Ginza. Vista's damages, in my view, in a case such as this, will be the same

whether measured in contract under Article 74 of the Vienna Sales Convention or in tort.

214 Damages are claimed under the following heads of claim:

(1) The invoiced costs of recalled products, that is to say, invoices raised by Ginza for which Vista was liable.

(2) Lost profit margin on the resale of the product concerned.

(3) Direct costs of recalling product.

(4) Lost reputation, goodwill and future sales.

Each head of damage constitutes something which Ginza ought to have foreseen at the time of making the contract, should it breach the contract, save in respect of head (3) so far as Kontack is concerned. I will deal with each head of claim in turn.

Invoiced costs of recalled products

215 Vista: I have found that the products duly recalled by the TGA were manufactured by Ginza in breach of its contract with Vista and also negligently.

216 The invoiced costs of those products recalled by Vista was in the sum of $AUD163,557.45. However, the invoices include invoices 97/0304 and 97/3006 in a total sum of $AUD31,635, which were never paid by Vista and which comprised part of Ginza's claim. As Vista is entitled to reduce Ginza's claim on account of these invoices (as set out above), they cannot also comprise part of the damages awarded to Vista. Accordingly, Vista is only entitled to damages under this head of damage in the sum of $AUD131,922.45.

217 Ginza further argues that damages under this head should be further reduced by a sum of $AUD6,516.64, on the basis that Dr Grauaug conceded in cross-examination that his calculation of such damages involved a double-counting. I do not accept that this is the case. Dr Grauaug explained in his evidence that, if one totalled all of the AMCAL Visiclear MPS500ML bottles that had been counted in the stocktake, the number was 23,117. If one then totalled the AMCAL Visiclear MPS500ML bottles that were listed in the damages summary in exhibit V22, including the last item on that list which was said to have been counted twice, the total was 21,867. It appears, therefore, that Vista has, in fact, claimed less recalled AMCAL Visiclear MPS500ML stock than the

stocktake listed. This leads me to conclude there has been no double-counting as alleged.

218 Kontack: Because I have found there is no contractual relationship between Ginza and Kontack, it follows that Kontack cannot make a claim in respect of the invoiced costs of products recalled by it, because it was not invoiced by Ginza for those products. However, Kontack is entitled to damages in tort under this head in respect of such invoiced goods.

219 The invoiced cost of those products bearing the Kontack brand name the subject of this action was $AUD73,330.40. However, these invoices included invoices 97/0504, 97/0706 and 97/1107 in respect of Kontack brand name goods which have never been paid either by Vista or Kontack. Accordingly, the claim for damages under this head should be reduced by a sum of $AUD48,724.90.

220 Kontack is entitled to damages under this head, therefore, in the sum of $AUD24,605.60.

Lost profit margin on resale of recalled products

221 Vista: As to the lost profit margin on the resale of products to retailers in Australia, the amount claimed by Vista action is $AUD79,232.78.

222 Of this sum, Ginza says that Dr Grauaug conceded that $AUD4921.28, being the figure in the last line of exhibit V22, was a double-counting of sums claimed in that exhibit. For the reasons set out above, I do not accept there has been any relevant double-counting.

223 Ginza also claims that Dr Grauaug admitted that commission was paid on the total price of the goods, that is, the total of Ginza's invoiced price and that it has been included in the calculation of alleged lost profit. The commission is said to have been between 10 and 15 per cent and payable on Vista and Kontack brands. Ginza says these amounts have not been accounted for; and there is no documentary evidence that the commissions were in fact paid to the agents concerned. Ginza says the only evidence that they had been paid came from Dr Grauaug in re-examination, but he did not point to any documents showing accounts from the agents or confirmation of payment to them. Thus, it is said by Ginza that, after taking account of commissions payable on Vista and Kontack brands, and having regard to the fact that there is no primary evidence in relation to Dr Grauaug's assertion that commissions have been paid, appropriate deductions have to be made from Vista's alleged loss of profit to provide a true figure.

224 On behalf of Vista and Kontack, it is submitted that there should be no deduction in the award of damages under this head because of the commission paid. Ginza and Kontack claim they are entitled to the gross profit margin on the sale of their respective products because the commission and all other expenses in relation to the sales were paid by Vista and Kontack respectively. Dr Grauaug said in evidence that the commission in respect of sales was, in fact, paid. This assertion is said to be supported by the Vista and Kontack financial statements in vol 6 of the trial bundle which confirm that the commissions were paid. I accept that this is so. Trial bundle page 2500 shows that in the financial year 1997, Vista paid commission of $AUD8074. Trial bundle page 2518 shows that in the financial year 1998, Vista paid commission of $AUD9127. Trial bundle page 2608 shows that in the financial year 1997 Kontack paid commission of $AUD25,923. Trial bundle page 2622 shows that in the financial year 1998, Kontack paid commission of $AUD3911. Thus, in 1997, Kontack paid $AUD25,923 in commission on gross sales of $AUD183,692: as to the latter sales see trial bundle page 2608. This represented approximately 15 per cent of gross sales. In relation to Vista in 1997, Vista paid $AUD8074 in commission on $AUD538,947 of gross sales (see trial bundle page 2500). However, Vista was not required to pay commission on sales of such brand names as AMCAL, Soul Pattinson and Blue Circle.

225 I accept the submission of Vista and Kontack to the effect that commission, therefore, was only payable in relation to the "Vista" brand name and "Kontack" brand name goods. The Vista branded goods represented a small amount of total sales. The Kontack brand name goods were only sold by Kontack. Vista appears to have sold a small amount of product under the "Vista" brand name, where commission was paid. And also to have sold other brands, such as AMCAL, Soul Pattinson and Guardian, where no commission was payable.

226 The evidence suggests that the commissions referred to by Dr Grauaug were in fact paid. For example, trial bundle page 2500 shows that, for the financial year 1997, Vista paid commission of $AUD8074 and the amount of $AUD4921.28, challenged by Ginza as not having been paid, would appear to be part of this sum.

227 Kontack: Under this head of damage, Kontack claims lost profits of $AUD115,650. I accept the submission of Ginza that Vista cannot now claim in contract for lost profits in respect of goods sold by Kontack, a separate company from itself, and must abide by the legal and contractual arrangements it created for itself. Vista accepts that, if the Court does not find a contract between Kontack and Ginza, then it is not open to Vista to

convert that loss of profits claimed in the sum of $AUD120,571.88 to a Vista loss of profits claim. However, Ginza is liable to Kontack for damages for negligence under this head of damage.

228 Ginza submits, however, that, if it is liable for such damages, the claimed lost profit of $AUD115,650.20 should be reduced by the sum of $AUD28,347.09. This latter sum is said to represent commission allegedly paid at 15 per cent on the total price of all Kontack products in accordance with exhibit V22. However, for the reasons I have set out above, I am not satisfied that the submission is correct. I am satisfied on the balance of probabilities that the commissions in question were paid by or on behalf of Kontack and I am satisfied that Kontack is entitled to the gross profit margin on the sale of its products. It was obliged to pay commissions to achieve the sales and in the calculation of damages should not be obliged to forfeit the recovery of those commissions which were, in effect, wasted expenditure.

229 I find, therefore, that under this head of damage Kontack is entitled to the sum of $AUD115,650.20.

Direct costs of recalling products

230 Vista: The direct obligation to recall the products was imposed on Vista by the TGA and I find that only Vista is entitled to claim for those costs directly incurred in recalling the products.

231 In relation to the direct cost of recalling products, the sum incurred by Vista is in the sum of $AUD105,521.68.

232 Ginza also submits that Dr Grauaug admitted that the expenses listed on page 43 of his witness statement for Blue Circle, $AUD25,866 have not been paid. The essence of the submission of Ginza is that there is no presently incurred sum, nor is there a sum that is, in all probability, likely to be incurred.

233 It is correct to observe that this sum has not been paid. However, in my view, there is a present liability in respect of the Blue Circle debt and no reason to consider that it has been forgiven by the creditor. Indeed, the Blue Circle debt is the subject of a judgment debt in the Victorian Magistrates' Court. The fact is that Vista has been in receivership for some time and this event may well have led to the creditor not pressing for satisfaction of the outstanding judgment debt.

234 Ginza also says that Vista is not entitled to claim as damages a sum of $AUD8678.47 still owing to Sigma (formerly AMCAL) for public relations consultancy fees and solicitors' fees. I accept that items of expense included in the Sigma demand on account of public relations consultancy fees and solicitors' fees would not, on the face of it, be recoverable against Vista, and that solicitors' legal costs could only become recoverable to some extent, in any event, once an action had been commenced. There is nothing to suggest that the action has been commenced.

235 Accordingly, the entitlement of Vista to damages under this head is in the sum of $AUD105,521.68 less the claimed Sigma expenses of $AUD8678.47, being the sum of $AUD96,843.21.

236 Kontack: I find that Kontack is not entitled to any portion of the $AUD389.20 claimed under this head of damage.

Claim for loss of goodwill

237 As to the head of loss relating to loss of reputation, goodwill and future sales, Vista claims a sum of between $AUD158,000 and $AUD178,000. In its written opening, Vista claimed that amount. Kontack also claimed damages under the same head of damage in its pleading, but did not particularise any sum. Mr Thompson, called by Vista to give expert evidence concerning the extent of such business losses, treated Vista and Kontack as one and the same entity for the purposes of his calculations. Mr Thompson's view was that any potential purchaser would purchase Vista and Kontack as a group and the businesses should be valued collectively. It seems that only Vista's claim for damages under this head was being pressed at trial.

238 No doubt it is correct to observe that, in the particular circumstances governing the shareholding, control and management of Vista and Kontack, the prospective purchaser of the business of Vista would expect to acquire the business of Kontack as well. However, that does not mean, as a matter of law, that the value of the goodwill of Vista necessarily comprehends the value of the goodwill of Kontack. It may simply mean that the value of the goodwill that a prospective purchaser might be prepared to pay would be the composite value of the two businesses.

239 Mr Thompson made no attempt to distinguish between the businesses of Vista and Kontack and no evidence was adduced to attribute to Kontack any goodwill value. Nor was any formula or other evidence adduced to

suggest any means of breaking-down the value attributed to Vista by Mr Thompson so that it reflected goodwill values for each of Vista and Kontack.

240 For present purposes, given the finding I have made that Ginza is liable to Kontack for lost profit margin on the resale of product in tort, it is reasonable to conclude that Ginza should also be liable under this head of damage to Vista in contract and tort and to Kontack in tort, if such a loss is proved. The real question is, having regard to the disclosed business activities of Vista and Kontack, what evidence is there of damage under this particular head of claim.

241 Mr James Ronald Thompson, of Jarot Business Assessments, gave expert evidence in support of this head of the claim of Vista and Kontack for damages. His evidence was the subject of close cross-examination by Senior Counsel for Ginza. In relation to the claim for damages under this head, which might simply be called "goodwill", Ginza says that Vista, and by extension Kontack, had no right at any material time to such damages because it had no right to continuity of supply from Ginza. Ginza, it says, could have determined the arrangements that were in place at its whim, as Dr Grauaug of Vista conceded in his evidence. If Ginza had simply decided to stop supplying Vista with product, Vista would have been in the same position as it was presently. It could not insist on continuity of supply from Ginza.

242 Similarly, Ginza argued that no contractual arrangements existed between Vista and any of its retail outlets. If those outlets had ceased selling Vista stock at any time, Vista would simply have collapsed. Ginza contends that no representative of any of the retail outlets was called to give evidence as to why these ceased sourcing Vista's products and, by implication, no inferences can be drawn.

243 In any event, Ginza claims Vista's claim ignores the fact that it found another supplier and dealt with that supplier until October 1998, some 12 months after Ginza's product was recalled. The evidence showed that Esoform, an Italian company, was relied on by Vista for about a 12-month period to supply an alternative contact lens solution for its Australian business. In those circumstances, Ginza argues it is not possible causally to relate the collapse of Vista's business to Ginza rather than Esoform. It also argues that Mr Thompson should have taken Vista and Kontack's trading relations with Esoform in this period into account when assessing the "goodwill" value of the business.

244 In my view, it is relevant to take into account the fact that Vista and Kontack had no right to continuity of supply of product from Ginza at all material times. However, given the subsistence of the relationship between Vista and Ginza from the early 1990s until late 1997, it is reasonable to conclude that none of the parties had any real expectation, other than that the arrangements in place in July 1997, prior to the third audit, would continue indefinitely into the future.

245 It is also fair to observe that Vista did make arrangements with Esofrom, as an alternative supplier of contact lens solution, following the breakdown of its arrangements with Ginza in late 1997. However, the fact that it obtained supplies for 12 months before its business collapsed does not, in my view, mean that there can be no causal link between the collapse of Vista's (and Kontack's) business and the breaches of contract or tortious duties I have found. Vista, obviously, did what it could to obtain alternative supplies so that its business did not collapse. However, its efforts to find a suitable alternative supplier were not successful. The damage done to the business of Vista (and Kontack) by Ginza's breach of contract (and duty of care) took their toll, notwithstanding the attempt by Vista to replace Ginza with Esoform as a reliable supplier. In my opinion, the breach of the contract and the tortious conduct were capable of constituting material causes of whatever loss of goodwill was ultimately suffered by Vista and Kontack.

246 In that respect, Ginza submits that the evidence of Mr Thompson should not be relied on in an assessment of the claim for loss of goodwill made by Vista and Kontack. In my view, much of the expert evidence provided by Mr Thompson does not assist in measuring the extent of the business losses of Vista and Kontack. Mr Thompson was substantially reliant on information provided to him by Dr Grauaug concerning the nature and conduct of the business, although Mr Thompson insisted he made some independent assessments based on his understanding of the business at the time operated by the companies.

247 Mr Thompson, for example, proceeded on the basis that Vista had a 10 per cent share of the contact lens solution market in Australia at material times. This information was given to him by Dr Grauaug. Dr Grauaug ultimately conceded in cross-examination that Vista had nothing like a 10 per cent share of that market. Dr Grauaug accepted that a market share of about 2 per cent was more accurate. Mr Thompson agreed that, if he had been told the market share was 1 per cent or 5 per cent, it would have had a material effect on his conclusions.

248 Mr Thompson described Vista as a wholesale business, but said this was the only business importing contact lens solutions of which he had any personal knowledge. Ginza submits that the characterisation of Vista as a wholesaler was incorrect. In fact, it should be characterised as a distributor. Mr Thompson's report is said to be based on Vista being a wholesaler. For example, Mr Thompson derived the rate of return on investment (ROI) from his belief that Vista was a wholesaler. If one accepts the claimed distinction between a wholesaler and a distributor, then there is substance in the contention that the assessments made by Mr Thompson were fundamentally flawed, as they were based on a false premise.

249 In many respects, I consider there is force in the submission made on behalf of Ginza in this respect. Vista was not the manufacturer, obviously, of the Ginza products. It simply imported them into Australia and then distributed them. However, it was a wholesaler in the conventional sense that it sold those goods to retailers. I do not think that any significant distinction can be drawn between the act of distribution for profit and the act of wholesale, in these circumstances. The point really is that initially made on behalf of Ginza, that Vista and Kontack had no right to continuity of supply. They were not the manufacturers and could not guarantee contracts of supply to retailers within Australia. Nor did they have any control over a retail outlet's decision whether or not to take their product. They constituted examples par excellence of the "middleman"; and, in this case, a middleman without any apparent commercial leverage. All of these factors would be taken into account by any prudent purchaser of a business such as that operated by Vista and Kontack and would materially affect the rate of return on investment that such a purchaser would consider appropriate.

250 Mr Thompson was asked to specify what comparable businesses he had previously assessed and valued that would give substance to his testimony as to the goodwill value of this business. He was unable to describe any single business which was comparable to Vista. When asked what analysis of the future prospects of the business he had undertaken, Mr Thompson said that he worked on information given to him, the fact that the product was a simple one, the fact that it was a wholesaling business, and what he thought would appeal to the buyer.

251 It appeared from cross-examination that Dr Grauaug did not tell Mr Thompson that Vista's relations with Esoform had broken down or that its product had been recalled by the TGA. Nor did Dr Grauaug tell him that Vista had continued operating until the end of 1998, and that it had only ceased operating when Esoform's product was recalled.

252 The 40 per cent return on investment figure that Mr Thompson used in his calculation of the goodwill value was a figure based on his subjective assessment of Vista's performance. He acknowledged that, even after implementing certain "add-backs", the combined Vista/Kontack net profit in 1996/97 was only $42,000. On that basis, he accepted there was no goodwill value in the business. He said, however, that his goodwill value assessment was based on his view as to the projected higher profits the business would, in all probability, earn in the future. However, he acknowledged his opinion was based on a number of assumptions. When asked what analysis he had undertaken in deriving his opinion that the growth of sales could have been anywhere between 30 per cent and 70 per cent, he indicated he did not undertake any analysis and instead relied on his experience. In the event, he averaged the range to suggest that 50 per cent sales growth would be appropriate.

253 Mr Thompson could not produce any worksheets or calculations in respect of the view set out in his report and conceded there were none. When the profits for the three previous years, namely, 63 per cent, 4 per cent and 80 per cent were put to him, he acknowledged that, instead of the business growing, it could have receded to a much lower figure.

254 In short, Mr Thompson took the view that this was a business which was soon to reap the benefits of its careful establishment and that, given its present market share - 10 per cent, as he (incorrectly) understood it - significant growth in profits could be enjoyed from an expenditure base which would be little increased on that disclosed for the 1996/97 year. This appears to me to be a generously optimistic assessment of the likely future of the business expansion of Vista and Kontack as of the 1998 year. It was also one that had no actual regard to the performance of Vista and Kontack during the period it was supplied with similar goods by Esoform, although not too much should be made of this period of trading which was effectively after the event of the difficulties in late 1997.

255 Counsel for Vista and Kontack submitted that "it is very easy to attack Mr Thompson's evidence, but equally difficult to show a flaw in his background, experience and expertise derived in real life as a business valuer who has conducted over 2000 business valuations in 15 years". Mr Thompson, he suggested, "knows what he is talking about". However, counsel also accepted that the key issue to the goodwill valuation made by Mr Thompson was his assumption that sales in the 1998 year would be likely to rise by an average of 50 per cent. Counsel submitted that the course of dealings between Dr Grauaug and the Coles Supermarket chain in 1993, and later with the Woolworths chain, suggested that there was real

potential for the combined sales of the two companies to increase dramatically.

256 For my part, I cannot be satisfied that the assumption made by Mr Thompson that, in the 1998 financial year, the combined sales of Vista and Kontack would increase by an average of 50 per cent, or anything like it, is well placed. There is nothing in the evidence before me to justify any such view. Indeed, there is a paucity of evidence before me to suggest any sales growth scenario is realistic. If one were to assume, for the sake of hypothesis, even a 10 per cent growth in combined sales of the two companies, it is apparent from an extrapolation of Mr Thompson's evidence, that a prudent purchaser of the combined businesses would be reluctant to pay any or any substantial sum on account of their alleged goodwill value.

257 In all the circumstances, given that this was a business that depended upon the personal relationships between Dr Grauaug and Ginza, was still in its relatively formative stages, had a small market share (about 2 per cent) and was an importing business that depended upon goodwill between Ginza and Vista to ensure continuity of supplies, and having regard to the actual financial performance of Vista and Kontack at material times, I am not prepared to award any damages on account of the alleged loss of goodwill of the combined businesses of Vista and Kontack. To do so, on the evidence before me, would constitute an entirely speculative exercise, something I should not undertake.

Conclusion and orders

258 In the event, the claim of Ginza in the Ginza action and its counterclaim and claim for set-off in the Kontack action should be dismissed.

259 In the Ginza action, by application of Article 50 of the Vienna Sales Convention (or, for that matter, by application of s 52(1) of the *Sale of Goods Act 1895*, if that Act were relevant) the purchase price claimed by Ginza should be reduced to zero. Indeed, the same result is arrived at if the counterclaim of Vista for damages in contract and tort is set off, as it should be in a case such as this where there is a close connection between Ginza's claim and Vista's counterclaim (see ***Casella v Costin Pty Ltd***, unreported; SCt of WA; Library No 5416; 22 June 1984, per Wallace J with whom Burt CJ agreed)) against the claim of Ginza for the unpaid price of the goods supplied.

260 In the Ginza action, Vista is entitled to damages, calculated as follows:

261 *Vista*:

Invoiced costs of recalled products:	$AUD131,922.45.
Lost profit margin on resale of recalled products:	$AUD 79,232.78.
Direct costs of recalling products:	$AUD 96,843.21.
Loss of goodwill, etcetera:	Nil
Total:	$AUD307,998.44

262 Vista is also entitled to judgment on its claim under the commission agreement in the sum of $AUD19,337.00.

263 In the Kontack action, Kontack is entitled to damages, calculated as follows:

264 *Kontack*:

Invoiced costs of recalled products:	$AUD 24,605.60
Lost profit margin on resale of recalled products:	$AUD115,550.20
Direct costs of recalling products:	Nil
Loss of goodwill, etcetera:	Nil
Total:	$AUD140,155.80

265 The appropriate orders therefore should be:

(1) In the Ginza action, the claim of Ginza should be dismissed. However, on its counterclaim, Vista is entitled to damages for breach of contract and in negligence in the total sum of $AUD307,998.44. Vista is also entitled to interest on such

damages at the rate of 6 per cent per annum, pursuant to s 32 of the *Supreme Court Act 1935* (WA), calculated from 10 December 1997 (when formal demand for damages was made following the third recall of the goods in question) until judgment.

(2) In the Ginza action, Vista is also entitled to judgment against Ginza on its counterclaim in the sum of $AUD19,337, pursuant to the commission agreement concerning the sale of contact lens care goods by Ginza to the Choonwae Pharma Corporation of Korea. Vista is also entitled to interest on such sum at the rate of 6 per cent per annum pursuant to s 32 of the *Supreme Court Act 1935*, calculated from 4 December 1998 (when demand therefor was made) until judgment.

(3) In the Kontack action, on its claim, Kontack is entitled to damages against Ginza for negligence in a total sum of $AUD140,155.80. Kontack is also entitled to interest on such damages at the rate of 6 per cent per annum, pursuant to s 32 of the *Supreme Court Act 1935*, calculated from 10 December 1997 until judgment. Ginza's counterclaim and claim to set-off should be dismissed.

(4) Vista and Kontack are also entitled to an order for their costs of the action. I will hear from the parties as to the appropriate terms of the costs order or orders.

SCHEDULE OF BATCHES MANUFACTURED BY GINZA PTE LTD FOR VISTA CORPORATION PTY LTD DURING DECEMBER 1996 AND 1997 OR OTHERWISE RECALLED

Ginza Invoice No. (Bold denotes the subject of Ginza's claim)	Date of invoice	Purchase order (where the subject of Ginza's claim)	Product	Batch nos.	Date of manufac-ture	Tested by TGA	Tested by Dr Charles Tang	Tested by Microtech	Tested by Consulchem	Tested by PMH
94/2511	25.11.94		Green Spot Saline	40811B	08.11.94	FAIL	FAIL			
			Green Spot MPS	43110B	31.10.94					
96/2612	26.12.96		Amcal Saline 500ml	61712A 61712B 61712C 61812A 61812B 61812C	17.12.96 17.12.96 17.12.96 18.12.96 18.12.96 18.12.96		PASS	INDETERM INATE		
			Amcal MPS 120ml	61312A 61412A 61612A	13.12.96 14.12.96 16.12.96			PASS		
97/0101	01.01.97		Opta-Care Saline 500ml	62412C 62612A 62612B 62612C 62712A 62712B	24.12.96 26.12.96 26.12.96 26.12.96 27.12.96 27.12.96	 PASS PASS 	 PASS	*PASS* *PASS*		
			Opta-Care MPS 500ml	62012C 62112A 62312A 62312B 62312C 62412A 62412B	20.12.96 21.12.96 23.12.96 23.12.96 23.12.96 24.12.96 24.12.96	 PASS 	 PASS	 *PASS*		
97/0102	02.01.97		Soul Pattinson Saline 500ml	61210A 62712C 72801A 72801B 72801C 72901A 72901B	12.10.96 27.12.96 28.01.97 28.01.97 28.01.97 29.01.97 29.01.97					
			Soul Pattinson MPS 240ml	72401A 72401B 72501A 72701A 72701B	24.01.97 24.01.97 25.01.97 27.01.97 27.01.97		 PASS			

						TGA	Dr Charles Tang	Microtech	Consulchem	PMH
97/2702	27.02.97		Soul Pattinson MPS 500ml Soul Pattinson Saline 500ml	71902A 71902B 71902C 72002A 72002B 72002C 72102A 72102B 72102C 72202A 72402A 72402B 72402C	19.02.97 19.02.97 19.02.97 20.02.97 20.02.97 20.02.97 21.02.97 21.02.97 21.02.97 22.02.97 24.02.97 24.02.97 24.02.97					
97/0103	01.03.97		Amcal MPS 500ml	72502A 72502B 72502C 72602A 72602B 72602C	25.02.97 25.02.97 25.02.97 26.02.97 26.02.97 26.02.97					
97/0803	08.03.97		Chemmart Saline 480ml	70403A 70403B 70403C 70503A 70503B 70503C 70603A 70603B	04.03.97 04.03.97 04.03.97 05.03.97 05.03.97 05.03.97 06.03.97 06.03.97					
97/1403	15.03.97		Kontack Saline 480ml	70603B 71003A 71003B 71003C 71103A 71103B 71103C	06.03.97 10.03.97 10.03.97 10.03.97 11.03.97 11.03.97 11.03.97			 FAIL FAIL	 FAIL PASS	
97/1503	15.03.97		Kontack MPS 480ml	71203A 71203B 71203C	12.03.97 12.03.97 12.03.97					
97/0304	04.05.97		Vista eye comfort 25ml	72003A	20.03.97		PASS			
97/0404	05.04.97		Kontack Protein Remover 50ml Kontack Cleaner 35ml	70104A 72703A	01.04.97 27.03.97					
97/0504	05.04.97		Kontack MPS 480ml	73103A 73103B 73103C 70104A 70104B 70104C 70204A 70204B 70204C	31.03.97 31.03.97 31.03.97 01.04.97 01.04.97 01.04.97 02.04.97 02.04.97 02.04.97			 FAIL PASS		

						TGA	Dr Charles Tang	Microtech	Consulchem	PMH
97/0706	07.06.97		Kontack MPS 480ml	70306A 70306B 70306C 70406A 70406B 70406C 70506A	03.06.97 03.06.97 03.06.97 04.06.97 04.06.97 04.06.97 05.06.97					
			Kontack Saline 480ml	70506B 70506C 70606A	05.06.97 05.06.97 06.06.97			FAIL FAIL		
97/2606	28.06.97		Amcal MPS 500ml	72006A 72006B 72006C 72106A 72306A 72306B 72306C	20.06.97 20.06.97 20.06.97 21.06.97 23.06.97 23.06.97 23.06.97		PASS			
97/3006	30.06.97		Vista Saline 500ml	72406A 72406B 72406C 72506A 72506B 72506C 72606A 72606B 72606C 72706A	24.06.97 24.06.97 24.06.97 25.06.97 25.06.97 25.06.97 26.06.97 26.06.97 26.06.97 27.06.97		PASS	FAIL FAIL FAIL FAIL FAIL FAIL FAIL FAIL	FAIL FAIL FAIL PASS FAIL FAIL	FAIL FAIL FAIL FAIL FAIL
			Kontack Protein Remover 50ml	71106A	11.06.97					
			Kontack Cleaner 35ml	70906A	09.06.97					
97/1107	11.07.97		Kontack MPS 480ml	70707B 70707C 70807A 70807B 70807C 70907A 70907B 70907C	07.07.97 07.07.97 08.07.97 08.07.97 08.07.97 09.07.97 09.07.97 09.07.97			FAIL FAIL		
			Kontack Saline 500ml	70606B 70606C 70507A 70707A	06.06.97 06.06.97 05.07.97 05.07.97			 FAIL FAIL		
97/1008	10.08.97		Kontack Lens Lubricant 25ml	71007A	10.07.97		PASS			