

C. Michelle Tribe-Soiseth #1  
Sworn March 4, 2002

No.: S000294  
Vancouver Registry

**IN THE SUPREME COURT OF BRITISH COLUMBIA**

**BETWEEN:**

STEPHEN ALAN HEAD and  
DAVID BOWN

**PLAINTIFFS**

**AND:**

MIRALEX HEALTH CARE INC. and  
HUESON PHARMACEUTICAL CORP.

**DEFENDANTS**

**AFFIDAVIT**

I, C. Michelle Tribe-Soiseth, Barrister and Solicitor, of 2000-595 Burrard Street in the City of Vancouver, Province of British Columbia, MAKE OATH AND SAY AS FOLLOWS:

1. I am an Associate at the law firm of Guild, Yule & Company (“Guild Yule”), defence counsel for the Defendant Miralex Health Care Inc. (“Miralex”) and have personal knowledge of the facts and matters hereinafter deposed to, save and except where the same are stated to be based on information and belief, and where so stated I verily believe them to be true.

2. On January 19, 2000, the Plaintiff, Stephen Alan Head, filed a Writ of Summons and Statement of Claim in the Vancouver Registry of the Supreme Court of British Columbia Action No. S000294 (the “Action”) on Miralex. An Appearance was entered on behalf of Miralex on February

4, 2000. On April 6, 2000 a Consent Order was entered to allow the Plaintiff to add the Defendant Hueson Pharmaceutical Corp. (“Hueson”) as a Defendant. Hueson entered an Appearance on April 19, 2000. The Certification Order in the Action was made on February 7, 2001. A Further Amended Writ of Summons and Statement of Claim, adding the Plaintiff, David Bown, to the Action, was filed on March 28, 2001. Miralex filed its Statement of Defence on April 24, 2001.

3. To date, Hueson has not filed a Statement of Defence.

4. Miralex’s position on the merits of the Plaintiffs’ case, and the issues of causation and damages are particularized and set out in written submissions entitled Stated Case/Mediation Brief (“Mediation Brief”) prepared by counsel for Miralex, Mr. Paul W. Walker, of Guild Yule. Attached hereto and marked as Exhibit “A” to this my Affidavit is a true copy of that Mediation Brief dated January 11, 2002.

5. I have been advised by Mr. Walker, and verily believe, that had this litigation proceeded through the interlocutory phase to trial on the common issues, scheduled to proceed in June, 2003 (and estimated to take three weeks), nearly all, if not all of the insurance limits would very likely be exhausted. If the insurance limits had not been exhausted by the end of the common issues trial, then I am advised that they would be depleted during the damages evaluation phase of the case.

6. Miralex and Hueson obtained the cream that they sold and distributed to class members (“Miralex Cream”) from Manon Pharmaceuticals Ltd. (“Manon”), an Israeli company. Miralex considered issuing third party proceedings against Manon and, therefore, hired an attorney in Tel-Aviv to investigate Manon’s assets. I have been advised by Mr. Walker, and verily believe, that an inquiry was made into Manon’s assets, including but not limited to, real property, sales revenues, and the potential existence of third party liability insurance policies. I have further been

advised, and verily believe it to be true, that it was concluded that Manon did not have readily exigible assets nor any third party liability insurance policy in force.

7. After certification of the Action, it was agreed by all parties that an effort would be made to settle the Action through a form of stated case/mediation with the assistance of Mr. Wilfred J. Wallace, Q.C., formerly a Judge of the British Columbia Court of Appeal. Mr. Wallace was retained by agreement to review medical records, evidence (including expert medical evidence), and hear submissions of all counsel.

8. Five sample claimants (“Sample Claimants”) were chosen from the Class Members known to counsel acting for the Plaintiffs (“known Class Members”) as representative of the various injuries alleged to have been suffered by the class members as a result of the use Miralex Cream. Medical records of the Sample Claimants were obtained and reviewed. In addition, counsel for the known Class Members (“Class Counsel”) presented the complaints of the Sample Claimants in the form of Will Say Statements.

9. There was a full exchange of expert reports on the issues of causation, medical damages, and the potential for damages from the use of the impugned steroid, clobetasol propionate-17 (“Clobetasol”), found in some samples of Miralex Cream.

10. The Plaintiffs’ medical experts in the action were:

a. Dr. Neil Shear; and

b. Dr. Stuart Maddin.

(the “Plaintiffs’ Experts”)

11. Miralex's medical experts were:

- a. Dr. Howard Maibach;
- b. Dr. Frank Parker; and
- c. Dr. David Kendler.

("Miralex's Experts")

12. The Sample Claimants were:

- a. Tammy Kanester;
- b. Robert Lyman;
- c. Danny Prakash;
- d. Jim Stojan; and
- e. Peter Warren.

2. The Plaintiffs' Experts and Miralex's Experts reviewed the medical evidence of the Sample Claimants in relation to their alleged injuries. Prior to their use of Miralex Cream, each of the Sample Claimants suffered from permanent, non-curable, pre-existing skin conditions. A summary of the findings of Miralex's Experts can be found in Parts 12 to 16 of the Mediation Brief (Exhibit "A").

3. Dr. Maibach swore an Affidavit on August 30, 2000, which has previously been filed in this action. Dr. Maibach also prepared reports for Miralex on the following dates:

- a. May 1, 2001;
- b. May 25, 2001; and
- c. November 7, 2001.

(the “Maibach Reports”)

13. Attached hereto and marked as Exhibits B through D, respectively, to this my Affidavit are true copies of the May 1, 2001, May 25, 2001 and November 7, 2001 Maibach Reports, text only without appendices.

14. Dr. Parker swore an Affidavit on September 5, 2000, which has previously been filed in this action. Dr. Parker also prepared reports for Miralex on the following dates:

- a. October 1, 2001;
- b. December 3, 2001; and
- c. January 10, 2002.

(the “Parker Reports”)

15. Attached hereto and marked as Exhibits E through G, respectively, to this my Affidavit are true copies of the October 1, 2001, December 3, 2001 and January 10, 2002 Parker Reports, text only without appendices.

16. Dr. Kendler prepared reports for Miralex on the following dates:

- a. May 14, 2001;
- b. October 10, 2001; and
- c. November 19, 2001.

(the "Kendler Reports")

17. Attached hereto and marked as Exhibits H through J, respectively, to this my Affidavit are true copies of the May 14, 2001, October 10, 2001 and November 19, 2001 Kendler Reports, text only without appendices.

4. Class Counsel had identified 351 known Class Members before the date of mediation, and estimated the class size to be approximately 500 people. Members of the class comprised of residents of British Columbia who are members of the class by virtue of the Certification Order as well as non-residents who have opted into the proceedings.

5. Miralex's position concerning the relevant facts of the Action for the purpose of the stated case/mediation, summarized in Parts 1 and 2 of the Mediation Brief, are as follows:

- a. Hueson was incorporated under the laws of Washington State in 1988;

- b. on or about May 27, 1997, Hueson entered into a distribution agreement (the “Distribution Agreement”) with Manon Pharmaceuticals and Cosmetics (“Manon”), an Israeli company, providing that, *inter alia*, Hueson would be the distributor of a Manon herbal product, Miralex Cream, in Canada, the U.S. and much of Europe;
- c. Hueson began selling Miralex Cream on or about August, 1997;
- d. on or about December 8, 1998, a B.C. numbered company which later became Miralex, was incorporated;
- e. in or about January, 1999, Miralex began the sales and marketing of Miralex Cream;
- f. Miralex obtained a general liability insurance policy providing coverage for residents of North America, which was effective January 18, 1999 (the “Policy”);
- g. Hueson did not obtain any general liability insurance;
- h. Miralex is not responsible by contract or otherwise for the effect of sales of Miralex Cream by Hueson;
- i. on or about September 29, 1999, the Health Protection Branch (“HPB”) advised Miralex that a sample jar of Miralex Cream that it had obtained contained Clobetasol;

- j. on learning of the HPB finding, a contract laboratory was used to evaluate the advice from HPB and not all samples tested had Clobetasol in them and those that did ranged from a concentration as low as 0.28% to 0.93%;
- k. containers of Miralex Cream do not contain lot numbers;
- l. Miralex quarantined all of its inventory of Miralex Cream;
- m. on or about November 10, 1999 Health Canada advised Miralex it was required to issue a Class 1 recall of Miralex Cream in Canada and on or about November 17, 1999, Miralex issued a voluntary recall notice;
- n. on or about November 18, 1999 Health Canada issued a recall notice of its own; and
- o. the alleged injuries the Plaintiffs claimed for were: atrophy (thinning of the skin), purpura (bruising), striae (stretch marks), and flare.

6. The condition of psoriasis generally is discussed in Part 3 of the Mediation Brief. There, it is submitted on behalf of Miralex that psoriasis is a chronic, recurrent skin disease that has unpredictable waxes and wanes which are often unrelated to therapy. It is a life-long condition that is characterized by chronic, recurrent exacerbations and remissions. Factors which increase the risk of developing psoriasis and aggravate the disease include:

- a. family history;
- b. stress;

- c. environmental factors, including chemical exposure;
  - d. injury;
  - e. illness, including common viruses, HIV and Hepatitis;
  - f. infection;
  - g. allergies including common allergies, Idiopathic Chronic Urticaria (hives) and eczema;
  - h. trauma;
  - i. certain medications such as non-steroidal anti-inflammatory drugs and medicines used to treat high blood pressure or depression may trigger an outbreak or worsen the disease; and
  - j. exposure to cold temperatures.
7. The Mediation Brief also states that:
- a. treatment for psoriasis depends upon the severity and location of the symptoms, and include, medicines such as corticosteroids applied to the skin (topical treatment), light therapy (phototherapy), and systemic treatment;
  - b. Clobetasol generally and its use are dealt with in Part 4 of the Mediation Brief. Clobetasol is a Class 1 corticosteroid and has become a treatment of first choice for a wide variety of diseases, including psoriasis. Other uses for Clobetasol include

dermatitis and eczema related to plant exposures, sweat gland disorders, skin pigmentation problems (pemphigoid), dermatitis due to solar radiation, skin conditions related to insect exposure (scabies), pruritic conditions (itching), acne, and hair loss. Most psoriasis patients utilizing corticosteroids, including Clobetasol, do so without clinically significant adverse effects.

8. The issue of the exacerbation of the disease upon the cessation of treatment, commonly referred to as flare, is discussed in Part 5 of the Mediation Brief. The opinions of Miralex's Experts varied as to whether or not flare exists; even so, however, their opinions are consistent with respect to the nature and duration of flare. Miralex's Experts have opined that flare from the cessation of topical application of corticosteroids does not worsen the pre-existing disease process nor does it render the pre-existing disease resistant to therapy. Flare manifests itself by an exacerbation of some or all pre-existing lesions and resolves itself quickly. Dr. Parker opined that, based on his 35 years of clinical practice, flare resolves within a week to two months. Dr. Maibach carried out an extensive review of medical and scientific reports and failed to find evidence of flare in any controlled medical studies. Flare exists in medical science, however, reports of its frequency stem from anecdotal observations which are not based upon controlled studies nor individual case reports. Flare does not mean the cessation of the topical steroid has caused the underlying disease process to worsen or progress, but merely that the symptoms which had abated during topical therapy reappear in their original location and may be more inflamed. Flare is not a permanent condition.

9. The medical principles concerning the potential adverse effects of Clobetasol are discussed in Part 6 of the Mediation Brief. Topical effects which can occur at the site of application of corticoids include striae, atrophy, purpura and flare. Systemic effects, while possible, are unlikely to occur with topical application of a corticosteroid. The only permanent adverse effect which may occur with topical application of Clobetasol is striae which is described by Dr. Maibach, one of Miralex's Experts, as a cosmetic rather than a functional alternation.

10. The 1975 Dr. Carruthers' research project (the "Carruthers Project"), referred to in the April 24, 2001 affidavit of Dr. Stuart Maddin, is reviewed in Part 7 of the Mediation Brief in order to predict the likelihood of class members suffering potential alleged adverse effects due to the topical application of Clobetasol. The Carruthers Project found, with a Clobetasol concentrate of 0.05%, for patients with diseased skin (psoriasis), the safe range of application without adverse effects was likely between 50 to 100 grams per week and it concluded that in most normal people, the "safe" threshold for the amount applied weekly lies between 45 to 90 grams. The Carruthers Project was conducted on subjects with both normal and diseased skin. The subjects with diseased skin used the Clobetasol cream for a duration of 10 weeks to 18 months. Based on the Carruthers Project, Miralex submitted that only individuals who used vast quantities of Miralex Cream containing Clobetasol could have the potential to establish injury beyond *de minimus* in law. This quantity, using the Carruthers Project amounts, was determined to be between 18 to 36 four ounce jars of Miralex Cream containing Clobetasol, per year. Even so, for the purpose of settlement, Miralex suggested a threshold for potential for injury to be use of the equivalent of 7 four ounce jars or more.

11. An analysis of known Class Members for whom sales records exist is conducted in Part 8 of the Mediation Brief. After reviewing sales records of the 351 known Class Members, it was submitted that the total number of those people who could advance a claim for whom the Policy might respond and who bought seven or more four ounce jars, totals a maximum of 18.

12. Parts 9 through 16 of the Mediation Brief deal with the individual claimant profiles of David Bown, Stephen Head, and the Representative Claimants. Miralex's Experts reviewed the clinical records of these individuals and opined, *inter alia*:

- a. Mr. Bown purchased two four ounce jars of Miralex Cream. He did apply Miralex Cream to his external genitalia and his upper right cheek. Miralex's Experts concluded that Mr. Bown did not suffer atrophy or striae. Dr. Parker

opined that Mr. Bown did not suffer any chronic or permanent worsening of his psoriasis;

- b. Mr. Head purchased fifteen four ounce jars, one jar of an undisclosed amount, and two half ounce jars of Miralex Cream. Mr. Head displayed pre-existing stressors to exacerbation of his psoriatic condition including the facts that he was an excessive worrier, he had suffered an outbreak of shingles, he had dramatic weight loss, he had suffered from viral and streptococcal infections and he smoked. Mr. Head's disease had gone through waxes and wanes and had worsened over time. A review of the medical records indicated that Mr. Head's use and cessation of use of Miralex Cream was likely insignificant in the context of his medical history;
- c. Dr. Parker's impression of Ms. Kanester's condition was that her psoriasis ran a variable course and appeared to be as bad if not worse prior to her use of Miralex than it was during or after her use of Miralex Cream. Ms. Kanester failed to seek medical attention for her alleged severe response to cessation of the use of Miralex Cream showing a failure to mitigate any injuries that she may have suffered;
- d. Mr. Lyman purchased a total of 18 jars, all presumed to be four ounce jars, of Miralex Cream between November 1997, and November 1999. Dr. Parker opined that Mr. Lyman had chronic skin atrophy that existed well before Miralex Cream. He has observed that while Miralex might have contributed to Mr. Lyman's problems with atrophy, that atrophy was a long standing pre-existing condition;

- e. The sales records for Mr. Prakash indicate that he purchased two half-ounce jars and seven four-ounce jars between July 5, 1998, and September, 1999. Mr. Prakash was found to have pre-existing complicated case of psoriasis and severe psoriatic arthritis. Mr. Prakash had a history of flare prior to his use of Miralex Cream and was using Prednisone, a systemic steroid. Dr. Kendler concluded that the exacerbations of Mr. Prakash's flare were due to a decreasing in his dose of Prednisone, which occurred at the same time as his discontinuation of Miralex Cream. Dr. Parker stated that the direct cause and effect relationship of Mr. Prakash's flare to Miralex Cream was not clear since his dose of Prednisone was reduced and gold treatments commenced (gold treatments can frequently cause skin reactions);
  
- f. Mr. Stojan purchased one four-ounce jar, three jars presumed to be four ounce jars and one half-ounce jar between April 27, 1998 and April 23, 1999. There was nothing in the clinical records that specifically referred to any adverse reactions from the use or cessation of Miralex Cream;
  
- g. Mr. Warren claims to have used Miralex Cream from December 1997 through to November 1999, consuming seven to eight, presumably four ounce, jars of product. He suffers from palmar psoriasis, one of the most difficult and recalcitrant forms of psoriasis to treat and control. Mr. Warren's medical documentation failed to note any physician visits for worsening and persistence of an exacerbation of his palmar psoriasis apart from October 27, 1999. Dr. Parker opined that pustular palmar psoriasis typically waxes and wanes often without relationship to therapy.

13. The issue of whether or not the damages and causation could be tried prior to liability is dealt with in Part 17 of the Mediation Brief. In the United States, this process is known as reverse

trifurcation and has been utilized in class action proceedings. Reverse trifurcation essentially breaks the trial into three parts: causation, damages, and liability. If the defence wins any part of trial the claim is dismissed. This process is allowed as it encourages settlement. Canadian jurisprudence favours the policy of encouraging settlements and the Canadian courts are interested in keeping themselves free of backlog created by complex litigation. Section 12 of the *Class Action Proceedings Act*, R.S.B.C. 1996, c. 50 gives the Court the discretion to allow a reverse trifurcation of a trial in British Columbia.

14. The issue of causation and damages are discussed in Part 18 of the Mediation Brief. The principles as laid out in *Athey v. Leonti*, [1996] 3 SCR 458 were applied in considering if Miralex's actions caused or materially contributed beyond the *de minimus* range to the Plaintiffs' loss. While Miralex agreed that, if found, causation cannot be apportioned, it stressed that *Athey v. Leonati, supra*, does not state that damages cannot be apportioned when dealing with pre-existing conditions. Plaintiffs are not to be put in a better position than they were had the tort not been committed.

15. The quantum assessment of the Action is reviewed in Part 19 of the Mediation Brief., describing a range of recovery for dermatological injuries to be:

- a. causing minor itching and rashes between \$250 to \$500;
1. causing major dermatitis between \$3,4000 to \$10,000;
2. irritating pre-existing dermatitis between nominal to \$1,000; and
3. bruising alone or minor abrasions and bruising between \$800 to \$1,200.

18. Miralex's counsel could not find any cases where awards were given to striae.

19. Based on the above case law, Miralex submitted that the appropriate quantum for potential injuries suffered by the Plaintiffs are:

- a. striae between \$250 to \$750;
- b. atrophy between \$500 to \$2,000;
- c. purpura between \$250 to \$750; and
- d. flare between \$250 to \$3,000.

20. As a result of the stated case/mediation process, the parties have agreed, subject to the approval of this Honourable Court, to settle the claims of the representative Plaintiffs and members of the class by a total payment of the sum of \$1.4 million being made by or on behalf of Miralex. In exchange, a Release is to be provided that contains language which, *inter alia*, releases both Defendants, and all of their respective administrators, successors, assigns, servants, agents, employees, officers, directors, related and affiliated corporations, insurers, and principals (including Don Hughes, Peter Hughes, and Bryan Moore).

16. I swear this Affidavit in support of an application for Court approval of the settlement agreement referred to in the preceding paragraph, and for no other or improper purpose.

SWORN BEFORE ME at the City of)

Vancouver, Province of British Columbia )  
this 4<sup>th</sup> day of March, 2002. )

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) C. MICHELLE TRIBE-SOISETH

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)  
A Commissioner for taking Affidavits )  
for British Columbia )