

99-CV-181819 CP [TORONTO]

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

KEVAN DRADY AND KATHRYN ANNE TAYLOR

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA AS REPRESENTED BY
THE MINISTER OF HEALTH, THE ATTORNEY GENERAL OF CANADA

and

BAXTER HEALTHCARE CORPORATION,
BAXTER INTERNATIONAL INC., INAMED CORPORATION,
TMJ IMPLANTS INCORPORATED, DOW CORNING CORPORATION,
MEDTRONIC XOMED SURGICAL PRODUCTS INCORPORATED,
SMITH MEDICAL CANADA INCORPORATED,
BRISTOL MYERS SQUIBB COMPANY,
RELIGIOUS HOSPITALLERS OF SAINT JOSEPH OF THE HÔTEL DIEU OF
KINGSTON, MOUNT SINAI HOSPITAL,
UNIVERSITY HEALTH NETWORK (FORMERLY TORONTO GENERAL
HOSPITAL),
DR. A.K. WYLLIE, DR. GERALD BAKER and DR. W. DOBROVOLSKY

Proceeding under the *Class Proceedings Act*, 1992

AMENDED THIRD PARTY CLAIM

TO THE THIRD PARTIES

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by way of a
third party claim in an action in this court.

The action was commenced by the plaintiff against the defendant for the relief claimed in
the statement of claim served with this third party claim. The defendant has defended the

AMENDED THIS 19/04 PURSUANT TO CONFORMEMENT A
MODIFIÉ CE 19/04 RÈGLE 26.02 (A)
 THE ORDER OF L'ORDONNANCE DU DATED / DATÉ LE 19/04
REGISTRAR GREFFIER
SUPERIOR COURT OF JUSTICE COUR SUPÉRIEURE DE JUSTICE

AMENDED THIS 04/20/04 PURSUANT TO CONFORMEMENT A
MODIFIÉ CE 04/20/04 RÈGLE 26.02 (A)
 THE ORDER OF L'ORDONNANCE DU DATED / DATÉ LE 04/20/04
REGISTRAR GREFFIER
SUPERIOR COURT OF JUSTICE COUR SUPÉRIEURE DE JUSTICE

action on the grounds set out in the statement of defence served with this third party claim. The defendant's claim against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS THIRD PARTY CLAIM, you or an Ontario lawyer acting for you must prepare a third party defence in Form 29B prescribed by the Rules of Civil Procedure, serve it on the lawyers for the other parties or, where a party does not have a lawyer, serve it on the party, and file it, with proof of service, WITHIN TWENTY DAYS after this third party claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your third party defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a third party defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your third party defence.

YOU MAY ALSO DEFEND the action by the plaintiff against the defendant by serving and filing a statement of defence within the time for serving and filing your third party defence.

IF YOU FAIL TO DEFEND THIS THIRD PARTY CLAIM, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date

October 1st, 2004

Issued by

J. Grant
Local registrar

Address of
court office

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TO:

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M4T 2Y3

Per: John B. J. Legge
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Solicitors for the Plaintiffs

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Deerfield, Illinois, USA
60015-4633
- AND TO: BAXTER INTERNATIONAL INC.
One Baxter Parkway
Deerfield, Illinois USA
60015-4633
- AND TO: INAMED CORPORATION
5540 Ekwil Street
Santa Barbara, CA, U.S.A.
93111-2936
- AND TO: TMJ IMPLANTS INCORPORATED
17301 West Colfax Avenue, Suite 135
Golden, Colorado
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- AND TO: DOW CORNING CORPORATION
2200 West Salzburg Road
P.O. Box 994
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USA 48686-0994
- AND TO: MEDTRONIC XOMED SURGICAL PRODUCTS INCORPORATED
6743 Southpoint Drive
North Jacksonville, Florida U.S.A.
32216-0980
- AND TO: SMITH MEDICAL CANADA INCORPORATED
301 Gough Road
Markham, Ontario
Canada, L3R 4Y8
- AND TO: BRISTOL MYERS SQUIBB COMPANY
345 Park Avenue
New York, New York, USA
10154-0037

AND TO: RELIGIOUS HOSPITALLERS OF SAINT JOSEPH OF THE HÔTEL
DIEU OF KINGSTON
166 Brock Street
Kingston, ON
K7L 5G2

AND TO: MOUNT SINAI HOSPITAL
600 University Ave.
Toronto, Ontario
M5G 1X5

AND TO: UNIVERSITY HEALTH NETWORK (FORMERLY TORONTO
GENERAL HOSPITAL)
200 Elizabeth St.
Toronto, ON
M5G 2C4

AND TO: DR. A.K. WYLLIE
295 Avenue Road
Kingston, Ontario
K7M 1C8

AND TO: DR. GERALD BAKER
Dundas Medical Centre
220 Dundas Street West, Suite 306
Whitby, ON
L1N 8M7

AND TO: DR. W. DOBROVOLSKY
14310 111 Ave
Suite 107E, Coronation Plaza
Edmonton, AB
T5M 3Z7

AND TO: Lerners LLP
Barristers and Solicitors
2400-130 Adelaide Street West
Toronto, Ontario
M5H 3P5

Per: James Newland
Tel: (416) 867-3076
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Solicitors for the Ontario Health Insurance Plan

CLAIM

1. The defendant claims against each third party:
 - (a) Contribution and indemnity in respect of any amount or amounts which it may be found liable or called upon to pay to the plaintiffs in the main action;
 - (b) Pre-judgement interest pursuant to section 128 of the *Courts of Justice Act*, R.S.O. 1990, Chap. C. 43;
 - (c) Post-judgement interest pursuant to section 129 of the *Courts of Justice Act*, R.S.O. 1990, Chap. C. 43;
 - (d) Costs of the main action on the substantial indemnity scale;
 - (e) Costs of this third party proceeding on the substantial indemnity scale; and
 - (f) Such further and other relief as this Honourable Court may deem just.

2. The defendant, the Attorney General of Canada ("AGC"), is sued in the main action as a representative of Her Majesty the Queen in Right of Canada.

3. The plaintiffs in the main action have brought a claim for damages against the AGC, arising out of injuries which the plaintiffs allegedly sustained with respect to the safety of devices used in the temporomandibular joint ("TMJ"). The details of the plaintiffs' allegations are more fully set out in the Statement of Claim.

4. The AGC has delivered at Statement of Defence in the main action and has denied any responsibility to the plaintiffs for the damages claimed.

5. The defendant repeats and relies upon the allegations set out in his Statement of Defence in the main action.

6. The third party manufacturers are incorporated with their head offices located as set out below:

BAXTER HEALTHCARE CORPORATION
One Baxter Parkway
Deerfield, Illinois, USA
60015-4633

BAXTER INTERNATIONAL INC.
One Baxter Parkway
Deerfield, Illinois USA
60015-4633

INAMED CORPORATION
5540 Ekwill Street
Santa Barbara, CA, U.S.A.
93111-2936

TMJ IMPLANTS INCORPORATED
17301 West Colfax Avenue, Suite 135
Golden, Colorado
80401

DOW CORNING CORPORATION
2200 West Salzburg Road
P.O. Box 994
Midland, Michigan
USA 48686-0994

MEDTRONIC XOMED SURGICAL PRODUCTS INCORPORATED
6743 Southpoint Drive
North Jacksonville, Florida U.S.A.
32216-0980

SMITH MEDICAL CANADA INCORPORATED
301 Gough Road
Markham, Ontario
Canada, L3R 4Y8

BRISTOL MYERS SQUIBB COMPANY
345 Park Avenue
New York, New York, USA
10154-0037

7. The third party hospitals are public hospitals duly licensed, pursuant to the laws of the Province of Ontario, and at all material times were located as set out below:

RELIGIOUS HOSPITALLERS OF SAINT JOSEPH OF THE HÔTEL DIEU
OF KINGSTON
166 Brock Street
Kingston, ON
K7L 5G2

MOUNT SINAI HOSPITAL
600 University Ave.
Toronto, Ontario
M5G 1X5

UNIVERSITY HEALTH NETWORK (FORMERLY TORONTO GENERAL
HOSPITAL)
200 Elizabeth St.
Toronto, ON
M5G 2C4

8. The following third party doctors are doctors licensed to practise in the Province of Ontario, and are alleged by the plaintiffs to have been the treating doctors of Kevan Drady, and at all material times held themselves out to be accredited specialists in oral surgery, carrying out their practise in the following locations:

DR. A.K. WYLLIE
295 Avenue Road
Kingston, Ontario
K7M 1C8

DR. GERALD BAKER
Dundas Medical Centre
220 Dundas Street West, Suite 306
Whitby, ON
L1N 8M7

9. According to particulars furnished by the plaintiffs, the third party doctor, Dr. W. Dobrovolsky, performed the surgery on Kathryn Taylor.

MANUFACTURERS

10. The third party manufacturers have been at various times since 1976 engaged in Canada in the business of developing, designing, testing, patenting, researching, manufacturing, marketing, supplying and selling to wholesalers, distributors, and retailers for resale to hospitals, surgeons, medical practitioners, and the general public, devices for use in surgery for the treatment of TMJ disorders.

11. Each of the third party manufacturers owed the plaintiffs, the AGC and the public, a duty to use reasonable care in researching, designing, developing, testing, marketing, supplying and selling these devices. The third party manufacturers failed to meet this duty.

12. Particulars of the negligence of the third party manufacturers are as follows:
 - (a) Negligently designing and manufacturing devices of substandard or inappropriate materials which were inadequate to protect against the breakdown of the devices;
 - (b) Negligently designing and manufacturing the devices using materials which the third party knew or should have known were potentially toxic in the human body;
 - (c) Failing to test the devices in a manner which would fully disclose the nature of the short and long-term risks associated with the use of the devices in the human body;
 - (d) Failing to report test results or problems with the devices that disclosed the nature of the risks associated with the use of the devices in the TMJ;
 - (e) Failing to cease manufacture and recall the devices when they knew or should have known the risk of injury by the devices.

13. Any damages arising from these devices manufactured by the third party manufacturers, which is not admitted but specifically denied, are as a result of negligent

misrepresentation by the third party manufacturers or their failure to disclose information to the AGC, in which event the third party manufacturers are liable to the defendant in damages.

14. The third party manufacturers made misrepresentations to the plaintiffs and to the defendant regarding the quality and character of the devices by representing that the devices were safe for use in the human body.

15. The third party manufacturers were at all times legally responsible for the safety of the devices, which they marketed or sold in Canada and for complying with *The Food and Drugs Act*, *The Food and Drug Regulations* and *The Medical Devices Regulations*. The third party manufacturers have the obligation, are in the best position and are the only entities that have the ability and responsibility to present evidence and defend the allegations made in respect to the safety and efficacy of their individual products. At all material times they had all the research, development and test data and the expertise necessary to establish the safety and efficacy of their products.

16. The misrepresentations were made with the intent that the plaintiffs and the AGC would rely upon them.

17. The third party manufacturers knew or ought to have known that the misrepresentations were false.

18. The plaintiff and the AGC acted in reliance on the misrepresentations by the third party manufacturers.

19. The AGC is entitled, should it be found liable to the plaintiffs, to contribution and indemnity from the third party manufacturers, resulting from their negligence and misrepresentation and to the costs of defending the plaintiffs' claim and prosecuting this third party claim.

20. Full particulars of the third party manufacturers' negligence and misrepresentations are within the knowledge of the third party manufacturers. The defendant will provide further and better particulars after full disclosure of documents and completion of examination for discovery.

DOCTORS AND HOSPITALS

21. The third party doctors and hospitals owed, at all material times, a duty to the plaintiffs to exercise all due care, skill and diligence in and about professional services rendered to them. The AGC states that the third party doctors used devices on the plaintiffs that they knew or ought to have known were unsafe.

22. The final decision on the implantation of a TMJ device and the selection of a specific device are made by the person implanted. These decisions are made after receiving all appropriate information concerning the risk of implantation, and after reviewing the patient's health history, current medical condition, diagnosis, prognosis and numerous other individual issues, and after reviewing the range of medical options available. The delivery of this information and discussion is the responsibility of the implantee's third party doctor. This discussion is implantee specific and at all material times this medical information and care was the duty of the third party doctor.

23. The TMJ device implantees' third party doctors are responsible for informed consent issues, including, but not restricted to:

- (a) effectiveness of a TMJ device for that recipient;
- (b) selection of a specific device model;
- (c) surgical complications including infection and device wear;
- (d) the risk of device wear or breakdown; and
- (e) the risk of further arthritic changes within the joint.

24. The responsibility for ensuring that the TMJ implantation surgery is performed competently and that any devices used are safe is that of the third party doctors and hospitals. Furthermore, it is the responsibility of the third party doctors to ensure that follow up appointments are made and on-going vigilance, care and treatment are conducted.

25. The defendant is entitled to assume that the third party doctors will maintain a reasonable standard of professional care in informing themselves of the developments within their area of medical specialty, including reading any warnings directed to them with respect to medical devices habitually used in their area of practice. The defendant places reasonable reliance upon the third party doctors to do so and to take all reasonable steps necessary to ensure the safety of the patients, to whom they, as health professionals, owe a duty of care.

26. The defendant is entitled to assume that the third party hospitals will maintain a reasonable standard of professional care in maintaining records concerning the purchase

and use of medical inventory, including medical devices, so as to permit the effective identification and tracking of devices surgically implanted into patients at their facility. The defendant places reasonable reliance upon the third party hospitals, to do so and assumes they will take all reasonable steps necessary to ensure the safety of patients to whom they owe a duty of care.

27. The third party hospitals owed a duty to the plaintiffs to ensure that all devices used were safe and that the treating third party doctor was aware of any concerns regarding the devices. The AGC states that on occasion device selection may have been made on an *ad hoc* basis by the third party hospital where the implantation took place and without the benefit of consultation with the implant recipients or their medical advisors. In such cases, it was the responsibility of the said hospital to have taken reasonable steps to ensure that the device was authorized for sale in Canada and that it was fit for its intended purpose.

28. The third party doctors and hospitals conducting the implantation are in the best position to record and track medical devices used during an individual patient's procedure and are obligated to do so, in order to meet the standard of care applicable to them as health professionals, for appropriate follow-up treatment. The AGC states that the third party hospitals failed in this responsibility.

29. The defendant places reasonable reliance upon the third party doctors and hospitals to recall patients in a timely manner, upon receiving actual knowledge of a problem or danger associated with a medical device they have surgically implanted.

30. As hereinbefore pleaded, the third party manufacturers are responsible to ensure compliance with regulations, prior to sale in Canada. The third party doctor or hospital purchasing a medical device for human implantation has a duty to take reasonable steps to ensure that the product is authorized for sale in Canada.

31. A medical professional or facility that knowingly purchases a non-compliant medical device for the purpose of human implantation, assumes the risk associated with doing so and the responsibility for communicating any attendant medical risk to the patient, as part of the process of obtaining informed consent.

32. A health care professional or medical facility that knowingly uses a medical device in an application, which is beyond the use for which it has been authorized for sale in Canada, assumes the risks associated with doing so and the responsibility for communicating any attendant medical risk to the patient, as part of the process of obtaining informed consent.

33. The damages sustained by the plaintiffs, if any, were the result in whole or in part of the negligence of the third parties.

34. The AGC pleads and relies upon the provisions of sections 19 of the *Food and Drugs Act*, R.S.C. 1985, Chap. F-27 as amended and the *Negligence Act*, R.S.O. 1990, c. N-1, as amended.

35. The AGC proposes that this Third Party Claim be tried together with the main action in the City of Toronto, in the Province of Ontario.

SERVICE OUTSIDE OF ONTARIO

36. The AGC pleads and relies on Rule 17.02(g)(h)(o) and (p) of the Rules of Civil Procedure, allowing for service ex juris of the foreign third parties. Specifically, the Third Party Claim may be served without a court order outside Ontario in that the claim is:

- (a) In respect of a tort committed in Ontario;
- (b) In respect of damages sustained in Ontario arising from a tort or breach of contract wherever committed;
- (c) Against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario; and
- (d) Against a person resident or carrying on business in Ontario.

^{October 1st}
Date of Issue: 30th day of September 2004

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Per: Christopher A. Amerasinghe Q.C.

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Law Society No. 15521T
Solicitors for the Defendant, The Attorney
General of Canada

JRARDY AND TAYLOR - AND THE ATTORNEY GENERAL OF CANADA
Plaintiffs - Defendant

AND BAXTER HEALTHCARE CORPORATION ET AL
Third Parties

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding Commenced at Toronto

AMENDED THIRD PARTY CLAIM

Department of Justice
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Solicitors for the Defendant, The Attorney General of
Canada