

CANADA
PROVINCE OF SAKATCHEWAN

Q.B. No. 247 of A.D. 2008

IN THE COURT OF QUEEN'S BENCH FOR SASKATCHEWAN
JUDICIAL CENTRE OF SASKATOON

BETWEEN:

SEAN SCHROEDER and ALLISTER CURTIS VEINOT

Plaintiffs

-and-

DJ ORTHO, CANADA INC., DONJOY, INC.,
DJO ORTHOPEDICS, INC., and DJ ORTHOPEDICS, INC.

Defendants

Proceeding under *The Class Actions Act*, SS 2001

STATEMENT OF CLAIM

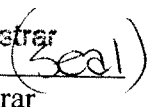
NOTICE TO DEFENDANT

1. The Plaintiffs may enter Judgment in accordance with this Statement of Claim or such Judgment as may be granted pursuant to the Rules of Court unless:

within 20 days if you were served in Saskatchewan,
within 30 days if you were served elsewhere in Canada or the United States of America, or
within 40 days if you were served outside of Canada or the United States of America (excluding the day of service) you serve a Statement of Defence on the Plaintiff and file a copy thereof in the Office of the Local Registrar of the Court for the Judicial Centre above – named.
2. In many cases a Defendant may have the trial of the action held at a Judicial Centre other than the one at which the Statement of Claim is issued. Every Defendant should consult his lawyer as to his rights.

3. This Statement of Claim is to be served within 6 months from the date on which it is issued.

4. This Statement of Claim is issued at the above-named Judicial Centre the 29th day of February, 2008.

J. KERSHAW
A/Deputy Local Registrar 

Local Registrar

STATEMENT OF CLAIM

The Parties

1. The Plaintiff, Sean Schroeder, is a resident of Saskatoon, Saskatchewan.
2. The Plaintiff, Allister Curtis Veinot, is a resident of Rosthern, Saskatchewan.
3. The Defendants are manufacturers, developers, distributors, marketers, promoters and importers of “pain pumps”. These are Class II medical devices under the *Food and Drugs Act*, R.S.C. 1985, F-27. They may only be sold in Canada with the licence and approval of Health Canada.
4. A pain pump is a portable, non-electric device that delivers pain medication directly to the surgical site via a tiny tube, or catheter. Typically, patients wear them for a few days following surgery. The local anaesthetic most commonly used in pain pumps includes bupivacaine (trade name Marcaine), lidocaine and ropivacaine, with or without epinephrine.
5. The Defendant, DJ Ortho, Canada Inc. is an Ontario corporation with its head office at 2835 Argentia Rd., Unit 5, Mississauga, Ontario. It is licenced by Health Canada as an importer of medical devices.
6. The Defendants, Donjoy Inc., DJO Orthopedics, Inc. and DJ Orthopedics, Inc. are related companies incorporated in Delaware. They have an office at 1430 Decision St., Vista, California, 92081. DJ Ortho, Canada Inc. is a wholly owned subsidiary or affiliate to these corporations.
7. The Defendants maintain a licence from Health Canada as the manufacturer of medical devices through an entity, DJO, LLC, including for the manufacturer of a device under the brand name “Donjoy Pain Control Device” The Defendants tested, manufactured and marketed pain pumps in Canada under the brand names “Donjoy Pain Control Device” and the “Painbuster Infusion Kit”.

8. The Plaintiffs bring this action on their own behalf, and on behalf of a class of persons resident in Saskatchewan, and elsewhere in Canada, who used the Defendants' pain pumps and who claim to have suffered injury as a result of such use.

Pain Pumps and Chondrolysis

9. The Defendants marketed their pain pumps to physicians as safe and effective for use after surgery. The Defendants failed to recognize and warn however that their pain pumps were unsafe for shoulder surgery when injected directly into the shoulder joint space. This joint space is known as the synovial cavity. While the Defendants had tested the safety of their products when injected into the surrounding muscle tissue, they had failed to consider the impact of the use of their products on the patient's cartilage, particularly the impact of the use of their products on the cartilage found in the synovial cavity.
10. Local anaesthetics can be toxic to chondrocytes. These are cells found in the synovial cavity which help the body to repair, regenerate and form new cartilage. A pain pump injected into the synovial cavity can administer a sustained dose of local anaesthetic to the cartilage, killing these cells, and preventing regeneration of cartilage.
11. Pain pumps cause a serious adverse reaction known as chondrolysis. This is a painful and debilitating condition involving a loss of cartilage. It entails a premature destruction of the shoulder's joint surface, and can result in functional disability. Symptoms include pain, loss of range of motion, loss of strength, and sensations of popping, grinding and clicking in the joint. Treatment options for chondrolysis may be limited, unsatisfactory and invasive. Shoulder replacement surgery, or shoulder resurfacing surgery, may be attempted to alleviate patient pain, and to restore some limited function to the patient.

The Defendants' Negligence

12. The Defendants owed a duty of care to the Plaintiffs and class members. As the developers, testers, manufacturers, marketers, labellers, and importers of pain pumps, they owed a duty of care to adequately communicate to the Plaintiffs, class members, health care providers and regulators, any serious risk of injury associated with the use of their products, and to ensure that their products were safe and effective for their intended purpose.
13. The Defendants breached that duty. The Defendants knew or ought to have known that their pain pumps can cause chondrolysis when injected into the synovial cavity. The Defendants knew or ought to have known that physicians were using their pain pumps in this manner for shoulder surgery. The Defendants failed to warn adequately, or at all, against this use. The Defendants marketed their products as safe and effective for injection into surgery sites. They failed to properly test and identify the risk of chondrolysis from the use of their products.
14. Animal studies available to the Defendants in 1999, or earlier, indicated that local anaesthetics were potentially toxic to chondrocytes. The Defendants failed to properly review or consider these studies, or draw appropriate conclusions, or conduct their own additional studies before marketing their products.
15. Once brought to market, the Defendants failed to adequately track and monitor adverse reactions to their products, and physician use of their products, and either disregarded, or failed to follow up with necessary diligence, reports from physicians concerning loss of cartilage in patients using their pain pumps after shoulder surgery.
16. The Defendants were negligent in the design, development, testing, manufacturing, licensing, distribution, monitoring, importing, labelling, marketing and sale of their pain pumps. Particulars of negligence are as follows:

- (a) they knew or ought to have known from animal studies, and/or from clinical studies, of the risk of chondrolysis and failed to warn, or adequately warn, the Plaintiffs, class members, health care providers, and regulators;
- (b) they failed to adequately test their products before marketing them;
- (c) they failed to conduct proper post-market surveillance after they began marketing their products;
- (d) they manufactured, licensed, imported, distributed, labelled, marketed and sold pain pumps knowing that the pain pumps could cause chondrolysis and that they were not fit for their intended purpose, and that the benefits of the use of pain pumps in shoulder surgery outweighed the risks, and that other, safer means were available to manage patient pain after shoulder surgery;
- (e) they failed to include in the operator's manual or promotional material for their products any warning, or any adequate warning concerning the risk of chondrolysis, or of the importance of not injecting medication from their pain pumps into the synovial cavity;
- (f) they failed to instruct their employees to properly evaluate, record and advise on complaints of side effects with their pain pumps;
- (g) they failed to accurately, candidly, promptly and truthfully disclose to Health Canada the risk of chondrolysis from their products and they failed to conform to applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, R.S.C. 1985, c. F-27;
- (h) they failed to initiate timely review, evaluation and investigation of the side effects following complaints of injury; and

- (i) they promoted to physicians the use of their products for injection into the synovial cavity in shoulder surgery when they knew or ought to have known that this was unsafe.

Strict Liability under *The Consumer Protection Act*

17. The Plaintiffs plead and rely upon *The Consumer Protection Act*, SS 1996, c. C-30.1.
18. The Plaintiffs state that the Defendants are “manufacturers” within the meaning of s. 39(h) of *The Consumer Protection Act*.
19. The Plaintiffs states the pain pumps are a “consumer product” within the meaning section 39(e) of *The Consumer Protection Act*.
20. The Plaintiffs state that the Defendants are strictly liable for personal injuries caused by the Plaintiffs’ and class members’ use of pain pumps under Part III of *The Consumer Protection Act*.
21. The Plaintiffs further state that the Defendants breached statutory warranties imposed on manufacturers pursuant to Part III of *The Consumer Protection Act*, and in particular, section 48(d) and (e). The pain pumps were not of acceptable quality nor were they reasonably fit for their intended use.
22. As a result of the defendant’s breaches of Part III of *The Consumer Protection Act*, the Plaintiffs and class members are entitled to compensatory damages for their personal injuries pursuant to section 64 of *The Consumer Protection Act* and to punitive damages pursuant to section 65 of *The Consumer Protection Act*.

The Plaintiffs' Injuries

23. The Plaintiff, Mr. Schroeder, had surgery on his right shoulder on August 26, 2004. The Defendants' pain pump was used in his surgery.
24. Thereafter, Mr. Schroeder experienced pain, stiffness and decreased range of motion in his shoulder.
25. Mr. Schroeder had a second surgery on his right shoulder on June 2, 2005. Again, the Defendants' pain pump was used in his surgery.
26. During this second surgery, his surgeon observed a pronounced loss of cartilage in the shoulder joint, and significant chondral damage. Subsequent x-rays confirmed a narrowing of the joint and loss of cartilage. Mr. Schroeder had developed chondrolysis as a result of his use of the Defendants' product.
27. Attempts to treat his injury with anti-inflammatory medications, glenohumeral injections, and physiotherapy were unsuccessful. To alleviate his pain, Mr. Schroeder underwent shoulder replacement and resurfacing surgery on April 20, 2006, during which his humeral head was replaced with a titanium implant.
28. Mr. Schroeder continues to have pain from his injury, and suffers reduced strength and range of motion, despite surgery. He continues to require medication to manage his pain. His injury interferes with his daily activities and is a source of permanent disability and disfigurement. It has impeded his career in the printing business.
29. The Plaintiff, Mr. Veinot, underwent surgery on his right shoulder on January 20, 2005. The Defendants' pain pump was used in his surgery.

30. Thereafter, Mr. Veinot experienced pain, stiffness and decreased range of motion in his shoulder. X-rays taken on or about November 2, 2005 showed quite significant narrowing of the glenohumeral joint suggesting possible chondrolysis. A right shoulder arthroscopy done on February 10, 2006, confirmed this diagnosis.
31. On May 18, 2006, surgery was performed on Mr. Veinot in an effort to alleviate his chondrolysis by resurfacing the humeral head of the shoulder joint.
32. Notwithstanding this treatment, and prolonged physiotherapy, Mr. Veinot continues to have pain and reduced range of motion and strength. It is necessary for him to take pain killers on a regular basis, and also to seek injections of pain medication. Shoulder replacement surgery has been considered. His injuries have interfered with his chosen occupation, for which he is trained and certified, as a welder. His injuries impede his daily activities and are a source of permanent disability.

Causation and Damages

33. As a result of the Defendants' negligence and statutory breach, the Plaintiffs and members of the Class have suffered and will continue to suffer loss. Such loss was foreseeable by the Defendants.
34. Particulars of the loss of damage suffered by the Plaintiffs and class members include the following:
 - (a) pain, suffering, and loss of quality and enjoyment of life;
 - (b) past and future loss of income;
 - (c) loss of earning capacity and future loss of opportunity;
 - (d) past and future cost of care;

- (e) out-of-pocket expenses incurred by the Plaintiffs and class members or for their benefit; and
- (f) medical expenses, including the cost of diagnosis and treatment of their injuries.

Discoverability

35. The cause and nature of their injuries was not reasonably discoverable by the Plaintiffs and class members until, at the earliest, July 3, 2007, and the publication of Hansen et al. "Postarthroscopic Glenohumeral Chondrolysis" in the *American Journal of Sports Medicine*, Vol 10(10).

Punitive Damages

36. The Defendants' conduct in the design, testing, manufacturing, marketing, and sale of the pain pumps, showed a marked disregard for public safety. The Defendants' conduct was of such a wilful nature as to render the Defendants liable for punitive and exemplary damages both under *The Consumer Protection Act* and at common law.

Joint Enterprise

37. The Defendants functioned as a joint enterprise for the promotion and sale of their brands of pain pumps within Canada. Within this joint enterprise, the Defendants individually and jointly researched, tested, developed, marketed, manufactured, imported, promoted, licenced, labelled, monitored adverse reactions to, and placed into the stream of commerce their brands of pain pumps for sale in Canada.

Jurisdiction

38. There is a real and substantial connection between the Plaintiffs, class members, the Defendants, and the subject matter of this litigation. The Plaintiffs plead and

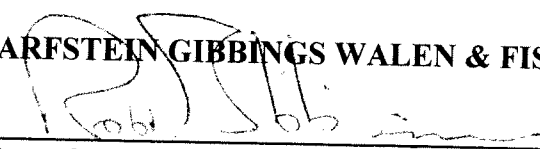
rely upon *The Court Jurisdiction and Proceedings Transfer Act*, S.S. 1997, c. C-41.1, s. 9(g) and (h).

Relief Sought

39. The Plaintiffs claim, on their own behalf, and on behalf of class members:
- (a) an order certifying this action as a class action;
 - (b) general damages;
 - (c) special damages;
 - (d) punitive damages;
 - (e) costs;
 - (f) the cost of providing appropriate notice to class members and administering this proposed class action for their benefit;
 - (g) pre-judgment and post-judgment interest; and
 - (h) such further and other relief as this Honourable Court deems just.

Dated at the City of Saskatoon, in the Province of Saskatchewan, this 29th day of February, 2008.

SCHARFSTEIN GIBBINGS WALEN & FISHER LLP

Per: 

Solicitors for the Plaintiffs

This document was prepared by:

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