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

CANADA
PROVINCE OF SAKATCHEWAN

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

BETWEEN:

SEAN SCHROEDER, ELEANORE SMIROLDO, as LITIGATION GUARDIAN for EDEN BOBYK and ALLISTER CURTIS VEINOT

Plaintiffs

-and-

DJO CANADA, INC., DJO, LLC, McKINLEY MEDICAL LLC, McKINLEY MEDICAL CORPORATION and CURLIN MEDICAL INC.

Defendants

Proceeding under *The Class Actions Act,* SS 2001

THIRD ~~SECOND~~ FRESH AS AMENDED STATEMENT OF CLAIM

(Amended pursuant to the order of Mr. Justice Popescul, dated March 29, 2010)

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"
Deputy Local Registrar

FRESH AS AMENDED 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.

2.1 The Plaintiff, Eden Bobyk, a minor, born September 29, 1992, as represented by her litigation guardian, Eleanore Smiroldo, is a resident of Saskatoon, 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. While there are a number of uses for pain pumps, this action concerns the use of this medical device following shoulder and knee surgery.

5. The Defendant, DJO 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 Defendant, DJO, LLC, is incorporated in Delaware. It has an office at 1430 Decision St., Vista, California, 92081. DJO Canada, Inc. is a wholly owned subsidiary of DJO, LLC. Collectively, these Defendants are referred to as "Donjoy".

7. The Defendants, McKinley Medical LLC, McKinley Medical Corporation and Curlin Medical Inc., are companies incorporated in Colorado. McKinley Medical Corporation and Curlin Medical Inc. are successor companies to McKinley Medical LLC. Collectively, these Defendants are referred to as "McKinley".

8. On December 4, 2003, the Defendant, DJO, LLC, obtained a licence from Health Canada, licence number 63352, to sell pain pumps in Canada under its brand name "Donjoy Pain Control Device". This licence continued until September 30, 2008, when the Defendant, DJO, LLC, cancelled the licence.

9. During the term of this licence, Donjoy sold the Donjoy Pain Control Device to Canadian hospitals and health care providers, including to St. Paul's Hospital in Saskatoon where the Plaintiffs underwent shoulder or knee surgeries after which they were implanted with the Donjoy Pain Control Device.

10. The Defendant, DJO Canada, Inc., was the point of contact for Canadian hospitals and health care providers in purchasing this device. It provided to Canadian purchasers directions for the product's recommended use, safety information, marketing materials, brochures, promotional literature, and research.

11. While Donjoy obtained the regulatory approval of Health Canada to sell the Donjoy Pain Control Device in this country, and while it was the source of information for Canadian purchasers concerning its safety and recommended use, it did not actually manufacture the product, nor did it conduct any independent investigation to confirm the safety of the product before marketing it to Canadians, or subsequently.

12. Rather, Donjoy contracted with McKinley for the manufacturer of the Donjoy Pain Control Device pursuant to a distribution agreement, dated October 1, 2003 (the "Distribution Agreement"). Under this agreement Donjoy was responsible for obtaining and maintaining a licence from Health Canada to sell the product in this country. Donjoy further had the right under the agreement to recall the product, or to take any corrective

action necessary for its safe use, including the right to issue a warning to patients, health care providers, and the regulator concerning the risk of an adverse event caused by the product. McKinley also had the right, upon notice to Donjoy, to recall the product, or to take any corrective action necessary for its safe use, including the right to issue a warning to patients, health care providers and the regulator concerning the risk of an adverse event caused by the product.

13. 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

14. The Defendants marketed the pain pumps to physicians and hospitals as safe and effective for use after surgery. The Defendants failed to recognize and warn however that their pain pumps were unsafe for shoulder and knee surgery when injected directly into the joint space. This joint space is known as the synovial cavity. While the Defendants had tested the safety of the product when injected into the surrounding muscle tissue, the Defendants had all failed to consider the impact of the use of the products on the patient's cartilage, particularly the impact of the use of their product on the cartilage found in the synovial cavity.

15. 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.

16. 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 joint surface, and can result in functional disability. Bone will literally grind upon bone, unmediated by cartilage, causing progressive damage to the joint.

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. Joint replacement surgery, or joint resurfacing surgery, may be attempted to alleviate patient pain, and to restore some limited function to the patient.

The Defendants' Negligence

17. 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.

18. Each of the Defendants was in such a close and proximate relationship to the Plaintiffs and class members as to owe them a duty of care. DJO, LLC obtained the licence by which the product could be sold to Canadians. It represented to Health Canada that the product was safe. Its licence application set out the safety information concerning the product for communication to Canadians doctors and hospitals, as well as its recommended uses. DJO Canada, Inc. was the conduit of that safety information, and recommended uses, to Canadian purchasers. McKinley was the manufacturer and designer of the product. It knew that Donjoy was selling the product in Canada, and it knew the safety information and recommended uses that Donjoy was communicating to Canadian purchasers and to Health Canada. Under the Distribution Agreement, each of the Defendants had the right to take corrective action, including to issue a warning concerning adverse risks causes by the product. Each of the Defendants owed the Plaintiffs and class members a duty to issue such a warning. Each of them failed to do so.

19. The Defendants breached their duties. 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 and knee surgery. The Defendants failed to warn adequately, or at all, against this use. Rather, the Defendants promoted such use. They marketed the product as safe and effective for injection directly into surgery sites. They failed to properly test and identify the risk of chondrolysis from the use of the product.

20. In its application for a licence from Health Canada, the Defendant, DJO, LLC, failed to make any warning or contra-indication against the use of the product in the joint space. Worse, it recommended use of the product "directly" in the surgical site. This would reasonably be understood by doctors and hospitals as endorsing its use in the joint space. The application reads:

> "The system can also be used for continuous infusion of a local anaesthetic directly into the intra-operative site for postoperative pain management."

21. Similarly, in its promotional literature, and in its sales presentations to doctors and hospitals, Donjoy promoted the use of the product "directly" in the surgical site. Again, this would reasonably be understood by doctors and hospitals as endorsing its use in the joint space. Donjoy's sales brochure reads in part:

> "The Donjoy Pain Control Device system provides continuous infusion of a local anaesthetic directly to the surgical site…"

22. 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, or subsequently.

23. 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 and knee surgery.

24. 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 and knee surgery outweighed the risks, and that other, safer means were available to manage patient pain after shoulder and knee 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 and knee surgery when they knew or ought to have known that this was unsafe.

25. The Defendants' common law duties are informed by the *Medical Devices Regulations*, SOR/92/82. Pursuant to s.1 of those regulations, each of the Defendants is a "manufacturer". McKinley is a manufacturer under this section for having designed and assembled the device. Donjoy is a manufacturer under this section for having attached its trade name to the product, and for having labelled it and assigned it a purpose.

26. The regulations impose continuous obligations on the Defendants, commencing at licensing and continuing thereafter. They require the Defendants to ensure the safety of the product before selling it, and to continuously monitor the safety of the product thereafter, monitoring any complaints from doctors, hospitals and patients, keeping up with any new developments in the scientific literature, conducting further testing as necessary, and promptly taking corrective action, including issuing a warning or recall, if new information becomes available which alters the product's risk profile.

27. Pursuant to s.9(2) of the *Medical Devices Regulations*, the Defendants were required to maintain objective evidence to establish the safety of the device. The Defendants breached this section. They failed to adequately obtain such information before licensing and they failed to promptly update such information thereafter.

28. Pursuant to s.10 of the *Medical Devices Regulations*, the Defendants were required to identify the risks of the device, to eliminate or reduce those risks if possible, and to provide safety information with the device concerning those risks which remain. The Defendants breached this section. They failed to identify chondrolysis as a risk and they failed to warn against it, adequately or at all, whether in materials provided with the device, or otherwise.

29. Pursuant to s.11 of the *Medical Devices Regulations*, the Defendants were required to assess the risks of the product against its benefits, and to not sell a product whose risks outweigh its benefits. The Defendants breached this section. Their product provided a benefit of temporary pain relief in circumstances where other forms of pain relief were available. In contrast, chondrolysis is a serious, permanent, crippling condition. The risks of this adverse reaction far outweigh the benefits of the product.

30. Pursuant to s.12 of the *Medical Devices Regulations*, the Defendants were required to ensure that the product was effective for the uses for which it was represented. The Defendants breached this section. The product cannot be seen as effective for use directly in the surgical site at the joint space given the risk of injury.

Strict Liability under *The Consumer Protection Act*

31. The Plaintiffs plead and rely upon *The Consumer Protection Act*, SS 1996, c. C-30.1.

32. The Plaintiffs state that the Defendants are "manufacturers" within the meaning of s. 39(h) of *The Consumer Protection Act*. As the Canadian importer and distributor of a product made outside of Canada by a manufacturer with no place of business in this country, DJO Canada, Inc. is a "manufacturer" of the pain pumps pursuant to s.39(h)(iii) of *The Consumer Protection Act*. As the person who attaches his brand name to the product, and who holds itself out to the public as the manufacturer of the product, including in its filings with Health Canada, DJO, LLC, is a "manufacturer" of the pain

pumps pursuant to s.39(h)(i) and (ii) of *The Consumer Protection Act*. As the person who describes themselves as the manufacturer of the pain pumps in the Distribution Agreement, McKinley is a "manufacturer" of the product pursuant to s.39(h)(ii) of *The Consumer Protection Act*.

33. The Plaintiffs state the pain pumps are a "consumer product" within the meaning section 39(e) of *The Consumer Protection Act*. The pumps are ordinarily used for a personal purpose, namely to provide temporary pain relief to individuals following surgery.

34. 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*.

35. 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.

36. Pursuant to s.48(d) of *The Consumer Protection Act*, there was a positive obligation on the part of the Defendants to specifically warn the Plaintiffs and class members of any defect in the product. The propensity of the pumps to cause a serious adverse affect, chondrolysis, was a defect in the product. The Defendants failed to specifically warn the Plaintiffs and class members, whether directly, or through their health care providers, and the regulator, against this defect.

37. Pursuant to s.48(e) of *The Consumer Protection Act*, the Defendants were required to ensure that their product was reasonably fit for its intended use where they knew or ought to have known what that intended use was, and where they knew or ought to have known that consumers reasonably relied upon the Defendants' skill and judgment. The Defendants knew that the pain pumps were being used for joint surgeries

and that the pumps were being inserted directly into the surgical site. The Defendants, in fact, recommended such use. The Defendants further knew that the Plaintiffs and class members and their health care providers relied upon the Defendants' skill and judgment to ensure that the product was reasonably fit for its intended use. Such reliance was reasonable. The Plaintiffs, class members, their health providers, and the regulator, are not in a position to independently verify the safety of a medical device. They must rely upon the Defendants to ensure that the product is reasonably safe for its intended use. The Defendants failed to ensure that the product was reasonably fit for use directly in the surgical site in joint surgery and they failed to warn against such use.

38. The Plaintiffs plead and rely upon s.70 of *The Consumer Protection Act* and state that the Defendants' breaches of the *Medical Devices Regulations*, as particularized above, constitute evidence that the product was not of acceptable quality and that it was not reasonably fit for its intended use.

39. As a result of the Defendants' 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

40. The Plaintiff, Mr. Schroeder, had surgery on his right shoulder on August 26, 2004. A Donjoy Pain Control Device was used in his surgery. Mr. Schroeder purchased the Donjoy Pain Control Device from the hospital.

41. Thereafter, Mr. Schroeder experienced pain, stiffness and decreased range of motion in his shoulder.

42. Mr. Schroeder had a second surgery on his right shoulder on June 2, 2005. Again, a Donjoy Pain Control Device was used in his surgery. Mr. Schroder purchased the Donjoy Pain Control Device from the hospital.

43. 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.

44. 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.

45. 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.

46. The Plaintiff, Mr. Veinot, underwent surgery on his right shoulder on January 20, 2005. A Donjoy Pain Control Device was used in his surgery. Mr. Veinot purchased the Donjoy Pain Control Device from the hospital.

47. 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 glenuhumeral joint suggesting possible chondrolysis. A right shoulder arthroscopy done on February 10, 2006, confirmed this diagnosis.

48. 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.

49. 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.

49.1 The Plaintiff, Ms. Bobyk, underwent surgery on her right knee on October 25, 2005. A Donjoy Pain Control Device was used in her surgery. Ms. Bobyk's mother and litigation guardian, Ms. Eleanore Smiroldo, purchased the Donjoy Pain Control Device from the hospital on her behalf.

49.2 Thereafter, Ms. Bobyk experienced pain, stiffness and decreased range of motion in her knee. Arthroscopic surgery done on February 27, 2007 found that there was significant loss of cartilage. Ms. Bobyk was diagnosed as having suffered chondrolysis of the knee.

49.3 Ms. Bobyk continues to suffer pain and reduced range of motion and strength in her knee. Her injuries have interfered with her schooling, with her love of sports, and with her sense of confidence and well-being. These injuries have narrowed her future career prospects and have diminished her quality of life. Ms. Bobyk's injuries impede her daily activities and are a source of permanent disability.

Causation and Damages

50. 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.

51. 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

52. 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

53. 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

54. The Defendants functioned as a joint enterprise for the promotion and sale of their brands of pain pumps within Canada. A number of the terms of this joint enterprise are set out in the Distribution Agreement with the Defendants dividing among themselves certain responsibilities for the manufacture and marketing of the product, but with each having an independent right and responsibility to ensure the safety of the product. 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

55. 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

56. 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: "Robt. Gibbings"
Solicitors for the Plaintiffs

This document was prepared by:

SCHARFSTEIN GIBBINGS WALEN & FISHER LLP
Barristers & Solicitors
#500, 111 2nd Avenue South
Saskatoon, SK S7K 1K6
Address for service: Same as above
Lawyer in charge of file: Robert J. Gibbings, Q.C.
Telephone: (306) 653-2838
Facsimile: (306) 652-4747

Co-counsel for the Plaintiffs:

Klein Lyons
Barristers and Solicitors
Suite 1100, 1333 West Broadway
Vancouver, BC V6H 4C1

Phone: 604-874-7171
Fax: 604-874-7180

David A. Klein
Douglas Lennox

Whose addresses for service are same as above

Lawyers in charge of file: as above

TO: DJO Canada, Inc.
2835 Argentia Rd., Unit 5
Mississauga, Ontario
L5N 8G6

AND TO: DJO, LLC
1430 Decision St.
Vista, California, 92081

AND TO: McKinley Medical LLC
4080 Youngfield Street
Wheat Ridge, Colorado 80033

AND TO: McKinley Medical Corporation
4080 Youngfield Street
Wheat Ridge, Colorado 80033

AND TO: Curlin Medical Inc.
4080 Youngfield Street
Wheat Ridge, Colorado 80033