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5 Of Attorneys for Plaintiff Martin R. Jaramillo

6 **UNITED STATES DISTRICT COURT**
7 **NORTHERN DISTRICT OF CALIFORNIA**
8 **SAN JOSE DIVISION**

9 **MARTIN R. JARAMILLO,**

Case No. **04421 PVT**

10 Plaintiff,

11 vs.

COMPLAINT

12 **DJO, LLC**, a Delaware Corporation;
13 **DJO, INC., FKA DJ ORTHOPEDICS,**
14 **INC.,** a Delaware Corporation;
15 **MCKINLEY MEDICAL, L.L.C.,** a
Colorado Corporation; **MOOG, INC.,** a
New York Corporation; **CURLIN**
MEDICAL, INC., and **DOES 1 through 10,**

Personal Injury; Strict Products Liability;
Negligence (28 U.S.C. §1332)

16 Defendants.

DEMAND FOR JURY TRIAL

17 Plaintiff alleges:

18 **JURISDICTION AND PARTIES**

19 1.

20 Plaintiff Martin R. Jaramillo was at all relevant times a resident and citizen of the County
21 of Monterey and the State of California. The defendants are all corporate residents of states
22 other than California, and all of them conducted substantial business in California. The District
23 Court has subject matter jurisdiction over this case because of the diversity of the parties,
24 pursuant to 28 U.S.C. §1332, and the amount in controversy exceeds \$75,000.
25
26
27

1 **INTRADISTRICT ASSIGNMENT**

2 2.

3 The plaintiff in this action resides in Monterey County, and the location of the surgeries
4 performed on plaintiff were in Santa Clara county.

5 **The Plaintiff**

6 3.

7 Plaintiff Martin Jaramillo is a 45 year-old man who at all relevant times was a resident of
8 Monterey, California.

9 **The Defendants**

10 4.

11 Defendants DJO, LLC and DJO, Incorporated, formerly known as DJ Orthopedics, Inc.,
12 (collectively referred to as "DJO defendants") are Delaware corporations. Their principal place
13 of business is in Vista, California. DJO defendants conducted regular and sustained business in
14 California by selling and distributing their products in California, as described below.

15 5.

16 Defendant Curlin Medical, Inc. ("Curlin") is a company incorporated under the laws of
17 the State of Delaware, having its principal place of business in California. Curlin was acquired
18 by defendant Moog, Inc. on or around August 2006. Curlin conducted regular and sustained
19 business in California by selling and distributing its products in California, as described below.

20 6.

21 Defendant McKinley Medical, L.L.C. ("McKinley") is a company incorporated
22 under the laws of the State of Colorado. Its principal place of business is in Wheat Ridge,
23 Colorado. McKinley conducted regular and sustained business in California by selling and
24 distributing its products in California, as described below. Based on information and belief,
25 McKinley developed, manufactured, and marketed pain pumps. Plaintiff is informed and
26 believes that the pain pump device was distributed, marketed, and sold by defendants DJO,
27 Incorporated, DJO, L.L.C., formerly known as DJ Orthopedics, L.L.C.

1 7.

2 Defendant Moog, Inc. ("Moog") is a company incorporated under the laws of the State of
3 New York. Its principal place of business is in East Aurora, New York. Moog is a global
4 corporation that designs and manufactures aircraft, industrial and medical device products.

5 8.

6 The true names and capacities of defendants Doe 1 – 10 are unknown to plaintiff, who
7 therefore sues them by fictitious names until such time as he can identify them, and then amend
8 his complaint. Plaintiff is informed and believes that the Doe defendants are liable in strict
9 liability or negligence, or both, for the injuries alleged herein, and that the acts and omissions of
10 the Doe defendants were substantial and proximate contributing causes of plaintiff's injuries and
11 damages.

12 **FACTS COMMON TO ALL CLAIMS**

13 9.

14 At all relevant times, defendants DJO, Curlin, McKinley and Moog designed,
15 manufactured, and distributed a product called a "pain pump," a medical device intended to
16 deliver, via catheter, continuous doses of pain relief medication directly into the shoulder joint
17 space. The pain pumps deliver anesthetic pain medication directly into the operative site for 48
18 hours or more immediately following shoulder surgery. At all relevant times, the Doe defendant
19 analgesic/anesthetic medication manufacturers designed and manufactured Marcaine
20 (bupivacaine) and distributed it for use in orthopedic surgery, specifically for arthroscopic
21 surgery. The Doe defendants' anesthetic products were commonly used in pain pump devices,
22 including the pain pumps used following plaintiff's shoulder surgery.

23 10.

24 The pain pumps are designed and intended to be used with commonly used anesthetics
25 such as lidocaine or marcaine, with or without epinephrine, in volumes of 250 cc's or more, over
26 two days or more. The continuous injection of such medications at such doses over time directly
27 into the shoulder joint, however, can cause serious and permanent damage to the cartilage of the

1 shoulder joint. Plaintiff's pain pump was inserted post-operatively, and through the pump he
2 received dangerous doses of continuously injected medication into his shoulder joint. Plaintiff
3 suffered, as a result, a condition called "chondrolysis," characterized by the complete or nearly
4 complete loss of cartilage in the shoulder joint and a narrowing of the space between the bones in
5 the shoulder joint—an irreversible, disabling, and extremely painful condition.

6 11.

7 Plaintiff suffered a shoulder injury in approximately December 2003, and his medical
8 care providers recommended surgery to treat the injury. Plaintiff underwent arthroscopic
9 shoulder surgery at the Bascom Surgery Center in Campbell, CA on April 21, 2004. At the
10 conclusion of that surgery, plaintiff's surgeon inserted a pain pump in such a manner that pain
11 medication was infused directly into plaintiff's shoulder joint capsule. The infusion of pain
12 medication via the pain pump continued over the course of at least two days following surgery.

13 12.

14 Following the surgery in April 2004, plaintiff experienced ongoing pain, immobility and
15 lack of function in his shoulder. In March 2008, plaintiff underwent a second surgery on the
16 same shoulder, and during that procedure it was discovered that plaintiff had experienced
17 extensive Grade IV chondromalacia, which is the nearly total loss of all of the articular cartilage
18 in his shoulder joint.

19 13.

20 In approximately March 2009, as a result of the chondrolysis caused by use of a pain
21 pump following his April 2004 surgery, plaintiff had yet another surgery—the total replacement
22 of his shoulder joint. It is likely that plaintiff will require additional medical care and treatment,
23 including additional surgeries, and another shoulder replacement.

24 14.

25 Plaintiff's shoulder injury is permanent, disabling, it limits his movement, function, his
26 ability to work, and his ability to perform the tasks of daily living. His permanent, disabling
27 injury causes chronic and acute pain, and will be painful for the rest of his life.

1 15.

2 None of the defendants warned the plaintiff or his treating surgeons about the
3 unreasonable risks and dangers of using the pain pumps and anesthetic medications in this
4 manner. Plaintiff's surgeon used the pain pumps in the manner instructed and directed by the
5 defendants.

6 **FIRST CLAIM FOR RELIEF**

7 **(Strict Products Liability: Design Defect, Failure to Warn)**

8 16.

9 Plaintiff re-alleges all previous paragraphs.

10 17.

11 The pain pump devices, and the anesthetic medications used in them, were unreasonably
12 and dangerously defective beyond the extent contemplated by ordinary patients with ordinary
13 knowledge regarding the device, in one or more of the following particulars:

- 14 A. The labeling failed to instruct or warn the U.S. medical community that the safety
15 of the device and its medications had not been established for use in the shoulder
16 joint space;
- 17 B. The labeling failed to disclose to the U.S. medical community that continuous
18 injection of commonly used anesthetics such as lidocaine or marcaine, with or
19 without epinephrine, in volumes of at least 250 cc's, for two or more days, into
20 the shoulder joint space, may cause serious and permanent injury to the joint
21 cartilage;
- 22 C. The labeling failed to include a precaution against placing the catheter of the pain
23 pump in the shoulder joint space;
- 24 D. The labeling failed to provide to the U.S. medical community adequate
25 instructions for the safe use of the device, failing specifically to identify
26 anesthetic medications that could be safely and effectively used in the shoulder
27 joint space;

- 1 E. The labeling failed to disclose to the U.S. medical community that the
2 effectiveness of the device was uncertain for use in the shoulder joint space;
- 3 F. The labeling failed to disclose to the U.S. medical community that the FDA had
4 considered the defendants' request to put this indication in the pain pump label,
5 and then had rejected this precise indication for the pain pumps' use, to deliver
6 the pain medicine directly into the joint space.
- 7 G. The products were designed to inject commonly used medications associated with
8 damage to articular cartilage directly into the shoulder joint; and
- 9 H. When used as designed, the pain pumps delivered, over time, dangerously high
10 doses of medication directly into shoulder tissue.

11 18.

12 The medications manufactured by the Doe defendants used in the pain pump devices
13 following plaintiff's shoulder surgery, were defective in design and unreasonably dangerous for
14 the following reasons:

- 15 A. Marcaine can kill the chondrocytes in the shoulder joint space and lead to
16 chondrolysis, a disabling, painful and untreatable condition;
- 17 B. These medications as used in the pain pump devices caused plaintiff to develop
18 chondrolysis;
- 19 C. The instructions and labeling for Marcaine failed to disclose the risks as
20 enumerated in subparagraphs A through H of the preceding paragraph.

21 19.

22 The product defects alleged above were substantial contributing causes of the injuries
23 suffered by this plaintiff. Specifically, the pain pumps and the anesthetic medication used in
24 them caused plaintiff to suffer the permanent loss of cartilage in his shoulder, resulting in severe
25 pain and discomfort of the shoulder, loss of use and function of the shoulder and arm, and
26 requiring multiple surgeries. The use of the pain pumps and the anesthetic medication used in
27 them also rendered the therapeutic benefits of his initial shoulder surgery worthless. Plaintiff

1 will also require future medical care, including additional shoulder surgeries, as he ages,
2 including but not limited to, shoulder replacement. In addition, he has suffered mental distress
3 and anguish and has suffered permanent impairment of the use and function of his affected arm.

4 **SECOND CLAIM FOR RELIEF**

5 (Negligence)

6 20.

7 Plaintiff re-alleges all previous paragraphs.

8 21.

9 At all relevant times, each of the defendants knew or reasonably should have known that
10 their pain pumps and the anesthetic medication used in them were unreasonably dangerous and
11 defective when used as directed and as designed. A reasonably careful search and review of the
12 scientific and medical literature, and other information, should have indicated to the defendants
13 that:

- 14 A. Commonly used anesthetics likely to be used in their pain pumps, such as
15 lidocaine and marcaine, with or without epinephrine, were harmful to human and
16 animal articular cartilage;
- 17 B. Use of the pain pumps in a joint space had not been approved by the F.D.A., and
18 in fact had been specifically rejected by the F.D.A.;
- 19 C. Continuous injection of 250 cc's or more of such medications, through a catheter,
20 directly into the shoulder joint, for two days or more, had not been adequately
21 tested for safety or effectiveness;
- 22 D. The risk of chondrolysis and other serious post-operative problems associated
23 with using the pain pumps and their medications as designed and instructed
24 outweighed the possible benefits of such use.

25 22.

26 Based on what they knew or reasonably should have known as described above,
27 defendants DJO, Curlin, McKinley and Moog were each negligent in one or more of the

1 following particulars:

- 2 A. In failing to instruct or warn the U.S. medical community that the safety of the
3 device had not been established for use in the shoulder joint space;
- 4 B. In failing to disclose to the U.S. medical community that continuous injection of
5 commonly used anesthetics such as lidocaine or marcaine, with or without
6 epinephrine, in volumes of at least 250 cc's, for two or more days, into the
7 shoulder joint space, may cause serious and permanent injury to the joint
8 cartilage;
- 9 C. In failing to include a precaution against placing the catheter of the pain pump in
10 the shoulder joint space;
- 11 D. In failing to provide to the U.S. medical community adequate instructions for the
12 safe use of the device, specifically failing to identify anesthetic medications that
13 could be safely and effectively used in the shoulder joint space;
- 14 E. In failing to disclose to the U.S. medical community that the effectiveness of the
15 device with these medications was uncertain for use in the shoulder joint space;
- 16 F. Manufacturing a product designed to directly inject into the shoulder joint
17 commonly used medications associated with damage to articular cartilage;
- 18 G. Manufacturing a product designed to deliver, over time, dangerously high doses
19 of medication directly into shoulder tissue; and
- 20 H. Promoting the pain pumps for use in the joint space after the FDA had considered
21 and rejected such an indication.

22 23.

23 Based on what they knew or reasonably should have known as described above in
24 paragraph 20, the Doe defendants had a duty to warn physicians of the dangers of using their
25 bupivacaine drugs for long periods of time in joint spaces but failed to do so. The Doe
26 defendants also had a duty to test and investigate the use of their local anesthetic drugs in
27 arthroscopic surgery, but failed to do so. As a result, the Doe defendants breached their duties in

1 the following particulars:

- 2 A. In failing to test and investigate the use of their marcaine/bupivacaine drugs in
3 arthroscopic surgery;
- 4 B. In failing to instruct or warn the U.S. medical community that the safety of their
5 marcaine/bupivacaine drugs had not been established for use with pain pumps in
6 the shoulder joint space;
- 7 C. In failing to disclose to the U.S. medical community that continuous injection of
8 commonly used anesthetics such Marcaine and Sensorcaine, in volumes of at least
9 250 cc's, for two or more days, into the shoulder joint space, may cause serious
10 and permanent injury to the joint cartilage;
- 11 D. In failing to instruct or otherwise include a precaution against placing the catheter
12 of the pain pump with Marcaine or Sensorcaine in the shoulder joint space;
- 13 E. In failing to provide to the U.S. medical community adequate instructions for the
14 safe use of Marcaine and Sensorcaine and failing to warn physicians to use only
15 those medications that could be safely and effectively used in the shoulder joint
16 space;
- 17 F. In failing to disclose to the U.S. medical community that the effectiveness of
18 Marcaine and Sensorcaine was uncertain for use with pain pumps in the shoulder
19 joint space;
- 20 G. Manufacturing Marcaine and Sensorcaine with the knowledge that these drugs
21 were being marketed by defendants DonJoy, McKinley, Curlin and Moog for use
22 with pain pumps in the shoulder joint space and at dangerously high doses, and
23 knowing that use of these drugs in such a manner was associated with damage to
24 articular cartilage;
- 25 H. Promoting Marcaine and Sensorcaine for use in pain pumps, and specifically for
26 use at high doses in the shoulder joint space without FDA approval for such
27 indications; and

1 I. Failing to warn pain pump manufacturers and sellers not to promote the use of
2 Marcaine and Sensorcaine with pain pumps for infusion directly into the shoulder
3 joint space.

4 24.

5 The negligent acts and omissions alleged above were substantial contributing causes of
6 the injuries suffered by plaintiff. Specifically, the pain pumps caused plaintiff to suffer the
7 permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the
8 shoulder, loss of use and function of the shoulder and arm, and requiring multiple surgeries. The
9 use of the pain pumps also rendered the therapeutic benefits of the initial shoulder surgery
10 worthless. Plaintiff will also require future medical care, including additional shoulder surgeries,
11 as he ages, including but not limited to, shoulder replacement. In addition, he has suffered
12 mental distress and anguish and has suffered permanent impairment of the use and function of
13 his affected arm and shoulder.

14 25.

15 The injury suffered by plaintiff was the reasonably foreseeable result of defendants'
16 negligence.

17 **DAMAGES**

18 26.

19 Plaintiff realleges, as if fully set forth at length, paragraphs 1-27, inclusive, above.

20 27.

21 As a result of their injuries described above, plaintiff Martin Jaramillo has suffered
22 noneconomic damages in the sum of FOUR MILLION, FIVE HUNDRED THOUSAND
23 DOLLARS (\$4,500,000.00); economic damages for past medical expenses in the sum of TWO
24 HUNDRED THOUSAND DOLLARS (\$200,000.00); will more likely than not incur reasonably
25 necessary medical care in the future, to his future economic damages of THREE HUNDRED
26 FIFTY THOUSAND DOLLARS (\$350,000.00); and past and future impairment of earning
27

1 capacity in the sum of TWO HUNDRED FIFTY THOUSAND DOLLARS (\$250,000.00).
2 Plaintiff prays for leave to modify his economic damages prior to trial based upon the
3 information then known.

4 **JURY DEMAND**

5 28.

6 Pursuant to Fed.R.Civ.P. 38(c), plaintiff requests a trial by jury

7 **PRAYER FOR RELIEF**


8 Wherefore, plaintiff demands judgment against defendants as follows:

9 1. On the First and Second Claims for Relief, plaintiff prays for judgment against
10 each of the defendants for the sum of FOUR MILLION, FIVE HUNDRED THOUSAND
11 DOLLARS (\$4,500,000.00) noneconomic damages, together with economic damages for past
12 medical expenses in the sum of TWO HUNDRED THOUSAND DOLLARS (\$200,000.00), and
13 future medical expenses in the sum of THREE HUNDRED FIFTY THOUSAND DOLLARS
14 (\$350,000.00), for past and future impairment of earning capacity in the sum of TWO
15 HUNDRED FIFTY THOUSAND DOLLARS (\$250,000.00), and for plaintiff's reasonable costs
16 and disbursements incurred herein, not including the attorney fees he incurs in prosecuting this
17 action.

18 2. Plaintiff prays for such other and further relief as justice requires.

19 DATED this 21st day of September, 2009.

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