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April 22, 2009

Mr. and Mrs. Wade S. Patrick
2147 W Comstock Dr
Chandler, AZ 85224

Re: *Sheri L. Patrick and Wade S. Patrick v. I-Flow Corporation*, USDC of Arizona Case
No. 2:09-cv-00723-LOA
Our File No.: 091704 and BA No.: 2008-000-09271

Dear Mr. and Mrs. Patrick:

I enclose a copy of the Complaint filed on your behalf in the United States District Court of Arizona.

Please call if you have any questions.

Very truly yours,



Brenda D. Steinle
Paralegal

:bds

Enclosure – as stated

Cc: Lee McIver of Beasley Allen Crow Methvin Portis & Miles, P.C. (via email only)

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7 Attorneys for Plaintiff

8 **IN THE UNITED STATES DISTRICT COURT**
9 **FOR THE DISTRICT OF ARIZONA**

10 **SHERI L. PATRICK and WADE S. PATRICK,**)

11 Plaintiffs,)

12 vs.)

13 **I-FLOW CORPORATION,** a)
14 Delaware Corporation,)

15 Defendant.)

NO. 2:09-cv-00723-LOA

COMPLAINT AND JURY DEMAND

Related to: *Lopez v. DJO, LLC, et al.*,
Case No. CIV 08-1063-PHX-SRB

16 Plaintiffs, by and through counsel, and for their complaint against defendant,

17 allege as follows:

18 **JURISDICTION AND PARTIES**

19
20 1. Plaintiffs Sheri L. Patrick and Wade S. Patrick were at all relevant times
21 residents and citizens of Maricopa County, Arizona.

22 2. Plaintiff Sheri L. Patrick underwent arthroscopic shoulder surgery on
23 September 2, 2004 at the Scottsdale Healthcare Shea-Piper Surgery Center in
24 Scottsdale, Arizona. At the end of surgery, an “On-Q PainBuster” pain pump
25 designed, manufactured, and marketed by defendant I-Flow Corporation was
26 implanted into her left shoulder by her orthopedic surgeon, Dr. David S. Bailie. The
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1 pain pump injected pain relief medication directly into plaintiff's shoulder joint on a
2 continuous basis, for up to 72 hours or more following the surgery.

3 3. Plaintiff Sheri L. Patrick underwent a second arthroscopic surgery on
4 January 16, 2007 at the Metro Surgery Center in Phoenix, Arizona. As before,
5 plaintiff's orthopedic surgeon implanted an "On-Q PainBuster" pain pump into her left
6 shoulder. The pain pump was designed, manufactured, and marketed by defendant I-
7 Flow Corporation. It injected pain relief medication directly into plaintiff's shoulder joint
8 on a continuous basis, for up to 72 hours or more following the surgery.
9

10 4. Defendant I-Flow Corporation ("I-Flow") is a Delaware corporation with
11 its principal place of business in California. Defendant I-Flow conducted regular and
12 sustained business in Arizona by selling and distributing its products in Arizona, as
13 described below.
14

15 5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332
16 because there is complete diversity of citizenship between the parties, and the amount
17 in controversy exceeds \$75,000.00, exclusive of interest and costs.
18

19 6. Venue in this district is appropriate under 28 U.S.C. § 1391 because a
20 substantial part of the events giving rise to this claim occurred in this district as
21 plaintiffs have at all times relevant resided in this judicial district, the pain pumps and
22 their medications were implanted and administered in this district, and plaintiffs
23 sustained injury in this district.
24

25 **FACTUAL BACKGROUND**

26 7. At all relevant times, defendant I-Flow designed, manufactured, and
27 distributed a product called a "pain pump," a medical device intended to deliver, via
28

1 catheter, continuous doses of pain relief medication directly into the shoulder joint
2 space. The pain pump delivers anesthetic pain medication directly into the operative
3 site for 72 hours or more immediately following shoulder surgery.

4 8. The pain pumps are designed and intended to be used with commonly
5 used anesthetics such as local anesthetics with or without epinephrine, in volumes of
6 250 cc's or more, over two days or more. The continuous injection of such
7 medications at such doses over time directly into the shoulder joint, however, can
8 cause serious and permanent damage to the cartilage of the shoulder joint. Plaintiff
9 Sheri L. Patrick had pain pumps inserted post-operatively, and received dangerous
10 doses of continuously injected medication in her left shoulder joint. Plaintiff, as a
11 result, suffered narrowing of the joint space and/or a condition called "chondrolysis,"
12 which is the complete or nearly complete loss of cartilage in the shoulder joint, an
13 irreversible, disabling, and extremely painful condition.

14 9. Plaintiff Sheri L. Patrick has already undergone additional surgeries,
15 including complete shoulder joint replacement, and will likely require additional surgery
16 as a result of the narrowing of the joint space and/or chondrolysis caused by the
17 dangerously defective pain pumps.

18 10. Defendant I-Flow did not warn plaintiff Sheri L. Patrick or her surgeon
19 about the unreasonable risks and dangers of using the pain pumps and anesthetic
20 medications in this manner. The surgeon used the pain pumps in the manner
21 instructed and directed by defendant.

**BEGAM
LEWIS &
MARKS**

A PROFESSIONAL
ASSOCIATION OF
LAWYERS

1 **FIRST CLAIM FOR RELIEF**

2 **(Strict Product Liability: Design Defect, Failure to Warn)**

3 11. Plaintiffs re-allege all previous paragraphs.

4 12. The pain pump devices were unreasonably and dangerously defective
5 beyond the extent contemplated by ordinary patients with ordinary knowledge
6 regarding the devices, in one or more of the following particulars:
7

8 A. The labeling failed to instruct or warn the U.S. medical community that
9 the safety of the device, and the anesthetic medications used in them,
10 had not been established for use in the shoulder joint space;

11 B. The labeling failed to disclose to the U.S. medical community that
12 continuous injection of commonly used anesthetics such as bupivacaine,
13 with or without epinephrine, in volumes of at least 250 cc's, for two or
14 more days, into the shoulder joint space, may cause serious and
15 permanent injury to the joint cartilage;

16 C. The labeling failed to include a precaution against placing the catheter of
17 the pain pump in the shoulder joint space;

18 D. The labeling failed to provide to the U.S. medical community adequate
19 instructions for the safe use of the device, failing specifically to identify
20 anesthetic medications that could be safely and effectively used in the
21 shoulder joint space;

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

13. The product defects alleged above were substantial contributing causes of the injuries suffered by plaintiff Sheri L. Patrick. Specifically, the pain pumps and local anesthetics used in them caused plaintiff to suffer the permanent loss of cartilage in her left shoulder, resulting in severe pain and discomfort of the shoulder, and loss of use and function of the shoulder and arm. The use of defendant I-Flow’s pain pump also rendered the therapeutic benefits of plaintiff’s shoulder surgery worthless. Plaintiff has undergone further surgery, including shoulder joint replacement surgery, and will also require future medical care, including additional shoulder surgeries, as she ages. In addition, plaintiff has suffered mental distress and anguish due to the permanent impairment of the use and function of her affected upper extremities.

SECOND CLAIM FOR RELIEF
(Negligence)

14. Plaintiffs re-allege all previous paragraphs.

1 15. At all relevant times, defendant I-Flow knew or reasonably should have
2 know that its pain pumps and the anesthetic medication used in them were
3 unreasonably dangerous and defective when used as directed and as designed. A
4 reasonably careful search and review of the scientific and medical literature, and other
5 information, should have indicated to defendant I-Flow that:
6

- 7 A. Commonly used anesthetics likely to be used in its pain pumps, such as
8 bupivacaine, with or without epinephrine, were harmful to human and
9 animal articular cartilage;
10 B. Use of the pain pumps in the joint space had not been approved by the
11 F.D.A., and in fact had been specifically rejected by the F.D.A.;
12 C. Continuous injection of 250 cc's or more of such medications, through a
13 catheter, directly into the shoulder joint, for two or more days, had not
14 been adequately tested for safety or effectiveness;
15 D. The risk of chondrolysis and other serious post-operative problems
16 associated with using the pain pumps as designed and instructed
17 outweighed the possible benefits of such use.
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20 16. Based on what it knew or reasonably should have known as described
21 above, defendant I-Flow was negligent in one or more of the following particulars:

- 22 A. Failing to instruct or warn the U.S. medical community that the safety of
23 the device had not been established for use in the shoulder joint space;
24 B. Failing to disclose to the U.S. medical community that continuous
25 injection of commonly used anesthetics such as bupivacaine, with or
26 without epinephrine, in volumes of at least 250 cc's, for two or more
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days, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

- C. Failing to include a precaution against placing the catheter of the pain pump in the shoulder joint space;
- D. Failing to provide to the U.S. medical community adequate instructions for the safe use of the device, specifically failing to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;
- E. Failing to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use in the shoulder joint space;
- F. Manufacturing a product designed to directly inject into the shoulder joint commonly used medications that were associated with damage to articular cartilage;
- G. Failing to conduct studies or otherwise investigate the potential harm to articular cartilage when exposed to the pain pumps and anesthetic medications in volumes of at least 250 cc's, for two or more days, into the shoulder joint space;
- H. Manufacturing a product designed to deliver, over time, dangerously high doses of medication directly into shoulder tissue; and
- I. Promoting the pain pumps for use in the joint space after the FDA had considered and rejected such an indication.

17. The negligent acts and omissions alleged above were substantial contributing causes of the injuries suffered by plaintiff Sheri L. Patrick. Specifically, the

1 pain pumps and local anesthetics used in them caused plaintiff to suffer the permanent
2 loss of cartilage in her shoulder, resulting in severe pain and discomfort of the
3 shoulder, and loss of use and function of the shoulder and arm. The use of defendant
4 I-Flow's pain pump also rendered the therapeutic benefits of plaintiff's shoulder
5 surgery worthless. Plaintiff has undergone further surgery, including shoulder
6 replacement surgery, and will also require future medical care, including additional
7 shoulder surgeries, as she ages. In addition, plaintiff has suffered mental distress and
8 anguish due to the permanent impairment of the use and function of her affected
9 upper extremities.
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12 18. The injuries suffered by plaintiff Sheri L. Patrick were the reasonably
13 foreseeable results of defendant's negligence.

14 **DAMAGES**

15 19. Plaintiffs re-allege all previous paragraphs.

16 20. As a result of her injuries as described above, plaintiff Sheri L. Patrick
17 has suffered economic and noneconomic damages in an amount in excess of \$75,000
18 as provided by law and to be supported by the evidence at trial.
19

20 **(Punitive Damages)**

21 21. Plaintiffs re-allege paragraphs 1-18 above.

22 22. Defendant I-Flow's actions, described above, were performed with
23 wanton disregard for the health and safety of plaintiff Sheri L. Patrick. Defendant's
24 actions, as described above, were performed with malice and in reckless disregard for
25 the rights of plaintiff Sheri L. Patrick, who used defendant's pain pumps. Defendant's
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1 failure to investigate the harms of its products has resulted in an excess of hundreds of
2 unnecessary injuries.

3 23. At a minimum, defendant I-Flow's acts and omissions, when viewed
4 objectively from the standpoint of defendant at the time of their occurrence, involved
5 an extreme degree of risk, considering the probability and magnitude of the potential
6 harm to others. Defendant had actual and subjective awareness of the risk involved
7 but nevertheless proceeded to market its pain pumps with conscious indifference to
8 the rights, safety or welfare of others, including plaintiff. Accordingly, plaintiff is entitled
9 to punitive damages against I-Flow.
10

11 **THIRD CLAIM FOR RELIEF**

12 **(Loss of Consortium)**

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14 24. For a third claim for relief against defendant I-Flow, plaintiff Wade S.
15 Patrick alleges as follows:

16 25. Plaintiff Wade S. Patrick re-alleges paragraphs 1-18 above.

17
18 26. As a direct, foreseeable and proximate result of the injuries to his
19 spouse, as stated above, plaintiff Wade S. Patrick has suffered the loss of love,
20 affection, protection, support, services, companionship, care, society and marital
21 relationship, all to his damage, in an amount to be determined by the jury.

22 **PRAYER FOR RELIEF**

23 Wherefore, plaintiffs demand judgment against defendant as follows:

24 1. Economic and non-economic damages to plaintiff Sheri L. Patrick in an
25 amount in excess of \$75,000 as provided by law and to be supported by the evidence
26 at trial;
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23 **BEGAM**
24 **LEWIS &**
25 **MARKS**

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