

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

COOLSYSTEMS, INC.,)	
)	
Plaintiff,)	
)	C.A. No. _____
v.)	
)	JURY TRIAL DEMANDED
NICE RECOVERY SYSTEMS LLC,)	
)	
Defendant.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff CoolSystems, Inc. (“Plaintiff” or “CoolSystems”), by and through its undersigned counsel, alleges as follows:

NATURE OF ACTION

1. This action seeks to redress defendant NICE Recovery Systems LLC’s (“Defendant” or “NICE”) infringement of CoolSystems’ U.S. Patent No. 7,896,910 (“the ’910 Patent”). As pled below, NICE has infringed and continues infringing the ’910 Patent through its Nice1 Cold/Compression Therapy System (“Nice1”).

THE PARTIES

2. CoolSystems manufactures medical devices for injury treatment and post-operative recovery applications. It is a California corporation with a principle place of business at 1800 Sutter Street, Suite 500, Concord, California 94520, and is registered to do business in the State of Delaware.

3. NICE is a limited liability company organized and existing under the laws of the State of Delaware with a principle place of business at 1382 Kalmia Ave, Boulder, Colorado 80304. NICE’s registered agent for service is United States Corporation Agents, Inc. at 300 Delaware Ave., Suite 210-A, Wilmington, Delaware 19801.

JURISDICTION AND VENUE

4. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

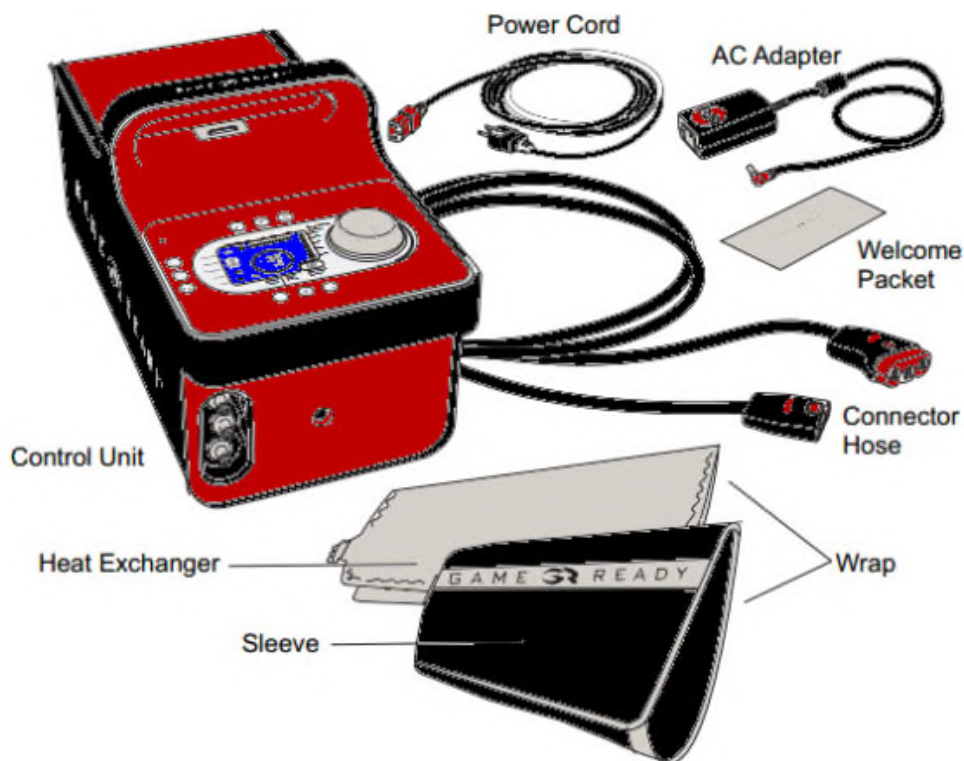
5. As a Delaware limited liability company, NICE is subject to the Court's general personal jurisdiction.

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400 because NICE is incorporated and subject to personal jurisdiction in this District, and because it has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in this District.

BACKGROUND

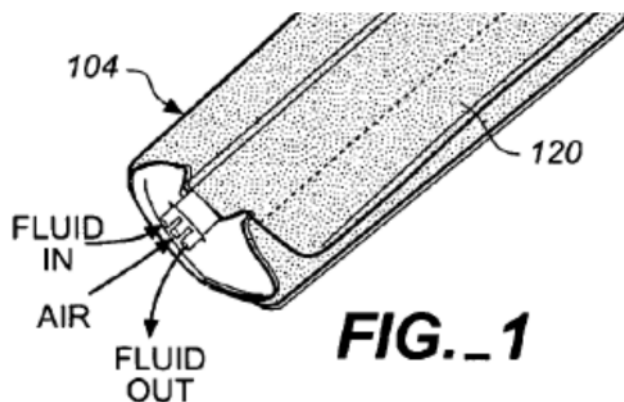
7. CoolSystems, doing business as Game Ready, is a leader in active compression and cold therapy technology for injury treatment and post-operative recovery. Its products are best-in-class and the rehabilitation products of choice for orthopedic surgeons, clinics, and physical therapy centers.

8. CoolSystems has developed a popular line of products that enable the simultaneous circulation of cold water and air, integrating compression and cold therapies that reduce swelling and pain from injuries. A representative system is shown in the diagram below. It includes a control unit that holds cold water and pumps both water and air; a wrap including a heat exchanger and a compression sleeve with a three-port connector; a connector hose (also having a three-port connector) to attach the wrap to the control unit, and certain accessories.



9. CoolSystems' three-port connector allows a patient to quickly and easily attach the wrap to the control unit when he or she is ready to receive therapy.

10. The CoolSystems' products are covered by the '910 patent. The three-port connector on the wrap is shown in Figure 1 of the '910 patent:



11. CoolSystems filed its application for the '910 Patent on May 17, 2004. On May 1, 2011, after fully examining the application, the United States Patent and Trademark

Office (“USPTO”) duly issued the ’910 Patent, entitled “Modular Apparatus for Therapy of an Animate Body.” A true and correct copy of the ’910 Patent is attached as **Exhibit A**.

12. CoolSystems is the record assignee and owner of all rights, title, and interest in the ’910 Patent, including the rights to sue, recover damages and obtain equitable relief for the patent’s infringement.

13. The facts detailed below show that NICE makes, uses, sells, and offers to sell in the U.S. products that infringe the ’910 Patent. NICE’s infringing product is the Nice1, shown here:



14. The Nice1 Operations Manual (a true and correct copy of which is attached as **Exhibit B**) states that NICE designed its Nice1 to provide “cold and compression therapy” to “aid recovery and reduce pain associated with soft tissue injuries. The device works by circulating cooled water and air through a therapy wrap that is placed on the injured body part.

The cooled water circulates through the therapy wrap and provides cold therapy; the air inflates the therapy wrap causing it to compress around the injured body part.”

15. The Nice1 includes a three-port connector, shown as follows:



16. Medical devices must receive FDA approval before they are marketed in this country. If a medical device is substantially equivalent to an earlier device that the FDA has already approved, the manufacturer of the new device may avail itself of the less stringent approval process under Section 510(k) of the Food, Drug and Cosmetic Act. According to the FDA, that section

requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification – also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories.¹

On December 8, 2014, NICE submitted to the FDA a Section 510(k) premarket notification of intent to market (“PMN”) its Nice1 (a true and correct copy of which is attached as **Exhibit C**).

¹ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/> (last accessed on Apr. 10, 2016).

NICE's Section 510(k) PMN stated that the Nice1 is substantially identical to CoolSystems' Game Ready System:

Substantial Equivalence	The Nice1 is substantially equivalent to the Game Ready System, CoolSystems Inc., K071050, Product Code ILO/IRP for cooling and compression based on intended use, design, energy delivered, performance, safety and bench testing.
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NICE's PMN then detailed the bases for its conclusion that the Nice1 is substantially identical to CoolSystems' Game Ready System. *See* Exhibit C at 5-6.

17. On the basis of NICE's PMN – with its averment of substantial equivalence to CoolSystems' Game Ready System – the FDA granted NICE approval to begin marketing the Nice1 on December 23, 2014.

18. NICE currently offers for sale, sells, and/or uses Nice1 throughout the United States, including in this District, either directly or through its distributors, such as The MedCom Group, Limited.

19. CoolSystems advised NICE in February 2016, by detailed letter, that its Nice1 infringed the '910 Patent. Consequently, NICE has known since at least then that it is infringing the '910 Patent by making, using, selling, or offering to sell the Nice1.

20. Despite its actual knowledge of the '910 Patent, NICE continues its infringement. Its actions belie any intention of ceasing its infringement of the '910 Patent from CoolSystems.

CLAIM FOR RELIEF

Infringement Of The '910 Patent [35 U.S.C. § 271(a)]

21. CoolSystems re-alleges each and every allegation set forth in the preceding paragraphs.

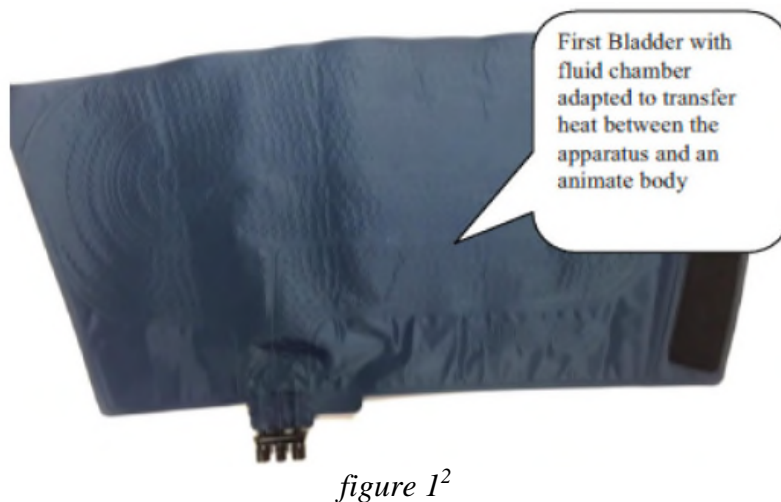
22. As detailed in the following paragraphs, NICE has infringed and continues its infringement under 35 U.S.C. § 271(a) of at least claims 7 and 8 of the '910 Patent (the

“Asserted Claims”), either literally or under the doctrine of equivalents, by making, using, selling, or offering to sell the Nice1 in the United States without license or authority.

NICE Infringes Claim 7

23. The Nice1 meets the limitations of and thus infringes claim 7 because it is a wrap that circulates cooled water and air through two bladders, for purposes of heat transfer, where:

- a. The first bladder has a chamber for fluid that transfers heat between an apparatus, which is the source of the cooled water, and an animate body, the patient or user, by circulating the cooled water through that chamber, as shown in figure 1;



- b. The first bladder has an inlet port and tube that brings the fluid into the fluid chamber as shown in figure 2;
- c. The first bladder has an outlet port and tube that removes the fluid from the fluid chamber back into the apparatus that is the source of the cooled water as also shown in figure 2;

² This figure and the following figures contain photographs of the components of an actual NICE1 system.

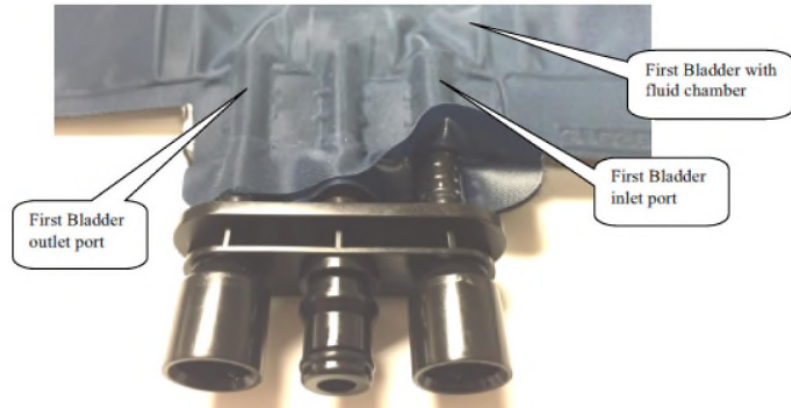


figure 2

- d. The second bladder has an inflatable chamber as shown in figure 3;



figure 3

- e. The second bladder also has an inflation port and tube to allow air into and out of the inflation chamber, as shown in figure 3;
- f. The inflation tube is placed between the input tube and the output tube, all three of which combine to form a three-port manifold as is apparent from the picture above, as also shown in figure 3, and
- g. The inflation tube is above the inlet and outlet tubes because it seals the second bladder containing the inflation chamber and the second bladder is

on the opposite side of the first bladder containing the fluid chamber,³ as shown in figure 4. In other words, the inflation tube is separated from the input and output tubes by the top of the first bladder and by the bottom of the second bladder, placing it above the input and output tubes, as figure 4 shows.

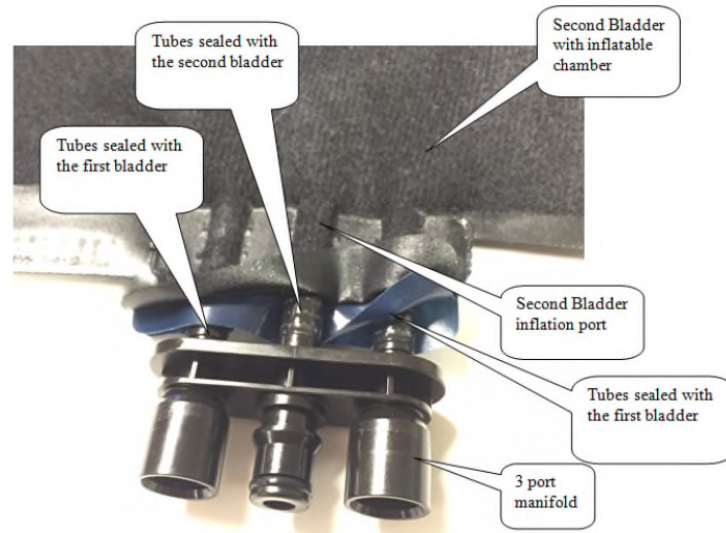


figure 4

NICE Infringes Claim 8

24. The Nice1 also meets the limitations of and thus infringes claim 8 because it is a wrap that circulates cooled water and air by having two bladders, for purposes of heat transfer, where:

- a. The first bladder has a chamber for fluid that transfers heat between an apparatus, which is the source of the cooled water, and an animate body,

³ The first bladder comes into contact with the person wearing the wrap, so it is the first bladder that would be considered the bottom and the second bladder would be considered the top.

the patient or user, by circulating the cooled water through that chamber, as shown in figure 1 above;

- b. The first bladder has an inlet port and tube that brings the fluid into the fluid chamber, as shown in figure 2 above;
- c. The first bladder has an outlet port and tube that removes the fluid from the fluid chamber back into the apparatus that is the source of the cooled water, as shown in figure 2 above;
- d. The second bladder has an inflatable chamber, as shown in figure 3 above;
- e. The second bladder also has an inflation port and tube to allow air into and out of the inflation chamber, as shown in figure 3 above; and
- f. The inlet port, outlet port, and inflation port combine to form a three-port manifold, and the tubes form a fluid-tight seal with the respective bladders, as shown in figure 4 above.

25. NICE has infringed and continues to infringe these claims by making, using, selling, and offering to sell its Nice1 system in the U.S.

NICE's Infringement is Willful and Continues to Harm CoolSystems

26. Because the Nice1 meets each limitation of the Asserted Claims in the manner alleged above, and because NICE has had actual knowledge of the '910 Patent since at least February 2016, NICE's infringement has been willful since then, if not before.

27. NICE's infringement of the '910 Patent has damaged CoolSystems, both by violating CoolSystems' right to exclude others from making, using, selling or offering to sell Nice1 in the U.S., but also because CoolSystems and NICE compete head-to-head in the U.S.

Nice1 and CoolSystems dual-action wraps compete for the same consumers and NICE's acts of infringement are causing CoolSystems to lose customers and market share.

28. For the reasons set forth in the preceding paragraphs, NICE's continuing infringement of the '910 Patent irreparably harms CoolSystems. CoolSystems will continue to suffer irreparable harm absent entry of a permanent injunction enjoining NICE and its agents, servants, employees, representatives, affiliates, and all others acting with them, from infringing the '910 Patent by making, using, selling, and offering to sell its Nice1 system, any substantially equivalent devices, in the U.S.

PRAYER FOR RELIEF

WHEREFORE, CoolSystems respectfully requests that the Court enter judgment in favor of CoolSystems and against NICE as follows:

- A. Finding that NICE is and has been infringing the '910 Patent;
- B. Permanently enjoining NICE and its affiliates, employees, agents, officers, directors, attorneys, successors, and assigns, and all those acting on behalf of or in active concert or participation with any of them, from infringing the '910 Patent;
- C. Requiring that NICE render a full and complete accounting to CoolSystems for NICE's profits, gains, advantages or the value of business opportunities received from its acts of infringement;
- D. Requiring that NICE pay CoolSystems damages, together with interest and costs as fixed by the court, to compensate CoolSystems for NICE's infringement of the '910 Patent;
- E. Enhancing by three-fold the damages that NICE must pay CoolSystems pursuant to 35 U.S.C. § 284;

F. Finding the case exceptional under 35 U.S.C. § 285 and requiring that NICE pay to CoolSystems all of its attorneys' fees and costs and expenses in this action;

G. Awarding CoolSystems prejudgment interest, post-judgment interest, and costs; and

H. Such other and further relief as the Court may deem appropriate.

JURY DEMAND

CoolSystems, Inc. respectfully demands a trial by jury on all issues raised in this Complaint that are properly triable by a jury.

Respectfully submitted,

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