

1                   (The following is an excerpt from the hearing of  
2                   04/11/14 before Chief Judge Sleet in Civil Action  
3                   No. 08-91 (GMS).

4                   THE COURT: All right.

5                   Following is the Court's ruling, which will be  
6                   followed up by a written opinion:

7                   Presently before the Court is Edwards' motion  
8                   for preliminary injunction. For the reasons that follow,  
9                   the Court will grant Edwards' motion in part and deny it in  
10                  part.

11                  To secure a preliminary injunction under Section  
12                  283, the movant must establish four factors: First, the  
13                  likelihood of success on the merits of the underlying  
14                  litigation; whether irreparable harm is likely if the  
15                  injunction is not granted; the balance of hardships as  
16                  between the litigants; and, finally, factors of interest to  
17                  the public.

18                  In order to establish a likelihood of success on  
19                  the merits, a patentee must show that it will likely prove  
20                  infringement of one or more claims of the patent in suit,  
21                  and that at least one of those claims will survive  
22                  challenges to its validity. Since Edwards has outright  
23                  prevailed in the litigation regarding the '552 patent and  
24                  the appeals process is over, the Court concludes that  
25                  Edwards has more than demonstrated a likelihood of success

1 on the merits. Medtronic's argument that since Edwards  
2 based its extension only on the Sapien as opposed to the  
3 Sapien XT Edwards' rights are limited to copies of the  
4 Sapien and do not cover the CoreValve Generation 3 is  
5 incorrect. Section 156(b)(1)(a) makes clear that it applies  
6 to uses of devices, not merely the actual devices and copies  
7 thereof.

#### 8 Irreparable Harm.

9 The Court also concludes that Edwards has  
10 demonstrated that it will suffer irreparable harm if not  
11 granted an injunction.

12 Despite Medtronic's vigorous arguments to the  
13 contrary, the Court is persuaded that Edwards will suffer a  
14 loss of sales and market share. First, Edwards is currently  
15 the only actor in the market and Medtronic will be Edwards'  
16 sole competitor in the United States should it enter the  
17 market. Thus, it is likely that at least some of the sales  
18 that Medtronic makes will be sales that Edwards could have  
19 made. Second, the declaration submitted by Rhonda Robb, the  
20 vice president and general manager of Catheter-Based  
21 Therapies at Medtronic, Inc., states clearly that "Medtronic  
22 will attempt to sell its product in some of the 284 sites in  
23 which Edwards sells its Sapien THV."

24 The Court is also convinced that Medtronic's  
25 entry into the market will cause price erosion. Medtronic

1 has a clear history of undercutting Edwards' prices in  
2 Europe, and Medtronic's statements regarding the price it  
3 will set for the CoreValve Generation 3 in the United States  
4 have been, at best, cryptic. Indeed, Medtronic does not  
5 state in its briefs what the price it will set for the  
6 CoreValve Generation 3 is. The Court will not take  
7 Medtronic's denial that it will undercut at face value in  
8 light of Medtronic's history of making dubious  
9 representations to the Court. For instance, the Court  
10 notes, as did the CAFC, that Medtronic claimed in July 2010  
11 that its facility in Mexico was fully equipped to take over  
12 manufacturing from the Irvine, California facility. Later,  
13 however, James Sparks, Medtronic's senior director of  
14 manufacturing, admitted during a deposition that Medtronic  
15 had misrepresented its Mexico operations.

16 In the end, the Court has no doubt that Edwards  
17 stands to be irreparably injured should Medtronic, a willful  
18 infringer that has flouted the jury verdict against it since  
19 2010, be allowed to commence commercial sales of the  
20 CoreValve Generation 3 in the United States.

21 The Balance of Hardships.

22 The Court concludes that the balance of  
23 hardships favors granting a preliminary injunction. Without  
24 a preliminary injunction, the core right protected by  
25 Edwards' patent - the right to exclude - would effectively

1 be rendered meaningless. Any harm to Medtronic is a result  
2 of its willful and ongoing infringement and, thus, cannot be  
3 counted in its favor.

4 The Public Interest.

5 Regarding the public interest factor, the Court  
6 is persuaded that there are patients who cannot be served by  
7 either the Sapien or Sapien XT and who need the CoreValve  
8 Generation 3. The Court is also convinced that the  
9 CoreValve Generation 3 is a safer device and that patients  
10 in whom it is implanted have better outcomes with a lower  
11 risk of death. At the same time, the Court cannot downplay  
12 the strong public interest favoring enforcement of patent  
13 rights. Thus, the Court finds that the public interest  
14 weighs in favor of granting Edwards a preliminary  
15 injunction, but that Medtronic must be allowed to sell its  
16 devices to those patients who cannot be helped by Edwards'  
17 devices.

18 It is toward that end that I will order, first,  
19 that Edwards' motion for a preliminary injunction is granted  
20 in part and denied in part; and that until the date on which  
21 the extended term of the '552 patent ends, Medtronic is  
22 enjoined from infringing Claim 1 of the '552 patent by  
23 selling and/or offering to sell in the United States the  
24 CoreValve Generation 3 Revalving System and any device not  
25 more than colorably different from it.

1           The parties are ordered to immediately enter  
2 upon discussions to determine if they can agree on a  
3 mechanism that will enable a sufficient number of CoreValve  
4 Generation 3 devices to be provided to hospitals and clinics  
5 currently trained on use of the Generation 3 device to  
6 enable physicians to make a clinical judgment as to whether  
7 to implant a Generation 3 or Edwards device without regard  
8 to whether sufficient numbers of the devices are available.

9           This matter shall be calendered for May 21st at  
10 10:00 a.m. to discuss the status of those discussions.

11           We are in recess.

12           MR. VAN NEST: Your Honor, excuse me. As I  
13 understand your order, the injunction is effective today?

14           THE COURT: Immediately.

15           MR. VAN NEST: So Medtronic would request a stay  
16 pending appeal of Your Honor's injunction.

17           THE COURT: I will not stay pending appeal.

18           MR. VAN NEST: In that event, Your Honor, in  
19 light of the public safety issues that were aired today,  
20 would the Court stay its order for a week to give us a  
21 chance, one, to seek immediately emergency relief in the  
22 Federal Circuit, and, two, at least give hospitals some  
23 notice of what has happened? Because, obviously -- maybe  
24 not obviously -- valves are not on the shelves at hospitals.

25           THE COURT: That is not obvious at all to me.

1 There has been no evidence to that extent. In fact, to the  
2 contrary, there has been evidence that there has been a  
3 stockpiling of devices.

4 MR. VAN NEST: Medtronic brings the valves to  
5 the procedures.

6 THE COURT: I am really not interested --

7 MR. VAN NEST: Fair enough.

8 THE COURT: But I will give you a week to notify  
9 hospitals.

10 What was the other purpose of the week?

11 MR. VAN NEST: To seek emergency relief in the  
12 Federal Circuit.

13 THE COURT: I will give you that week. Okay.  
14 Seven days. I will give you seven business days.

15 (Counsel respond "Thank you.")

16 (Court recessed at 5:01 p.m.)

17 - - -

18 Reporter: Kevin Maurer

19

20

21

22

23

24

25