UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ETHICON ENDO-SURGERY, INC., et al., Plaintiffs and Counterclaim-Defendants, v. COVIDIEN LP, et al., Defendants and Counterclaim-Plaintiffs.	)	Civil No. 16-12556-LTS

ORDER ON MOTION FOR A PRELIMINARY INJUNCTION (DOC. NO. 38)

October 2, 2017

SOROKIN, J.

Defendants and counterclaim-plaintiffs Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, "Covidien") have moved for a preliminary injunction barring plaintiffs and counterclaim-defendants Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (collectively, "Ethicon") from marketing and selling the Enseal® X1 Large Jaw device ("the X1"). Doc. No. 38. Ethicon opposed the motion, which is fully briefed and was the subject of a hearing on September 18, 2017. For the following reasons, Covidien's motion is DENIED.

I. BACKGROUND

Ethicon and Covidien produce and sell competing lines of advanced energy vessel sealing instruments. Such instruments are used in surgical procedures involving dissection of blood vessels or tissue. The devices permit surgeons to grasp a vessel or tissue between two jaws at one end of the instrument, apply energy to the vessel or tissue to form a seal and stop the blood flow through it, then cut the sealed tissue using a knife that moves along the length of the jaws. Generally speaking, Ethicon has been the market leader in the category of these devices using

ultrasonic energy, and Covidien has been the market leader in the category using advanced bipolar (or radiofrequency) energy. The two companies are fierce, direct competitors, and this is not the first patent litigation between them. E.g., Covidien Sales LLC v. Ethicon Endo-Surgery, Inc., No. 3:14-cv-917, 2014 WL 5242872, at *1 (D. Conn. Oct. 15, 2014) (ruling on motion for preliminary injunction in patent infringement case by Covidien against Ethicon related to an advanced ultrasonic surgical device).

The Covidien product most relevant in this case is the LigaSure Impact, which has been on the market for about a decade. The Impact accounted for more than $150 million in sales in 2016 – more than 30% of Covidien's advanced bipolar product sales in the United States for that year. Covidien attributes the success of the Impact, and the entire LigaSure line of products, to its "ability to provide a consistent and reliable vessel seal." Doc. No. 39-1 at 10.[1] According to Covidien, the Impact's ability to deliver such a seal results from its incorporation of an invention protected by United States patent number 8,241,284 ("the '284 patent"). The '284 patent issued in August 2012, is assigned to Covidien, and is entitled "Vessel Sealer and Divider with Non-Conductive Stop Members." Doc. No. 42-1.

Only one claim of the '284 patent is at issue in Covidien's motion for a preliminary injunction.[2] That claim discloses:

> An endoscopic bipolar forceps, comprising:
>
> an elongated shaft having opposing jaw members at a distal end thereof, the jaw members including a length and a periphery and movable relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to

[1] Pincites in "Doc. No. ___" citations to documents appearing on ECF, the court's electronic docketing system, are to the page numbers assigned by ECF in the header appended to the top of each page upon filing.

[2] Five other patents are at issue in this lawsuit – one identified in the complaint and four more in the counter-claims – but Covidien does not tie its request for injunctive relief to any of them, so they need not be explored at this time.

> grasp tissue therebetween, the jaw members each including respective flat seal surfaces extending along a respective length thereof and adaptable to connect to a source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal;
>
> a *plurality* of *non-conductive stop members* disposed along the length of at least one of the seal surfaces of at least one of the jaw members such that the plurality of non-conductive stop members are disposed along the same plane on the seal surface with respect to one another, the non-conductive stop members *configured to maintain a uniform distance between the jaw members along the length thereof*;
>
> and a knife disposed in operative communication with at least one of the jaw members and translatable to sever tissue disposed between jaw members.

Id. at 23 (emphasis added). The critical limitations of the claim will be discussed in more depth below.

This lawsuit arises from Ethicon's development and release of the X1, which launched commercially in March 2017. The X1's predecessor, the Enseal® G2 Super Jaw device ("the G2"), had neither succeeded in meaningfully competing with the LigaSure line of products nor enabled Ethicon to gain ground in the advanced bipolar market. The parties disagree about the reasons for the G2's lack of commercial success, a point which will be explored further below. They agree, however, that the X1 was developed to remedy the G2's shortcomings, and that it succeeded in doing so. In the first several months following the X1's launch, a number of hospitals that previously had used LigaSure products began purchasing X1s instead. The X1's performance in that time period surpassed Ethicon's projections, totaling $7.8 million in revenue and adding 366 new accounts (i.e., customers that had not purchased G2s). Doc. No. 79-21 at 3.

The X1 and the G2 differ in several relevant ways. In place of the ridges or teeth running along the length of the G2's jaw, the X1 has six black bumps (three on each side of the knife channel) spaced along the bottom jaw, each rising .004 inches above the lower sealing surface. Instead of a single control causing the G2 to seal and cut in one action when activated by the surgeon, the X1 has separate sealing and cutting functions permitting surgeons to press one

button to seal, then press another button to activate the knife if and when they wish to do so. In addition, the shape and contour of the portion of the device held in the surgeon's hand was modified in an effort to achieve better ergonomics with the X1. One important feature was not changed: both the G2 and the X1 have a steel pin positioned at the far end of the lower jaw, which contacts the upper sealing surface when the jaws are in the closed position and sets the gap between the jaws (which, on the X1, is .008 inches).

The Impact has separate sealing and cutting functions, and has non-conductive spacers which set the gap between the upper and lower jaws. It has no steel pin.

Ethicon began exploring prototypes for a successor to the G2 at least as early as 2013. Doc. No. 60-36. In 2015, Ethicon petitioned the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office, seeking inter partes review and arguing that various claims in the '284 patent were invalid. Doc. No. 42-6 at 3. That petition was denied. Id. In spring of 2016, when it was beginning to plan for the X1's launch, Ethicon notified Covidien of the impending release in an effort to resolve any patent disputes before the launch. Covidien agreed to mediation later that year, after Ethicon received pre-market approval for the X1 from the Food and Drug Administration. When mediation failed, Ethicon filed this action seeking a declaratory judgment that the X1 does not infringe the '284 patent (and various others).

Covidien counter-sued for infringement of the '284 patent (and various others) and moved for a preliminary injunction. The issues raised by Covidien's motion were thoroughly explored by the parties in a series of well-written briefs, Doc. Nos. 39-1, 57-1, 78-1, 89-1, each of which was accompanied by exhibits including declarations, documents, and excerpted deposition testimony. Doc. Nos. 40-42, 58-65, 67, 79-85, 90-91 (including attached exhibits). Having carefully reviewed and considered this voluminous record, and in light of Covidien's

statement at the motion hearing that the Court could resolve the preliminary injunction question without an evidentiary hearing, the Court finds that no further briefing or hearings are necessary.

II. LEGAL STANDARD

With its motion, Covidien seeks "an extraordinary remedy that may only be awarded upon a clear showing that [it] is entitled to such relief." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008); accord LifeScan Scotland, Ltd. v. Shasta Techs., LLC, 734 F.3d 1361, 1366 (Fed. Cir. 2013). To make such a showing, Covidien "must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." Winter, 555 U.S. at 20. Covidien cannot prevail "unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001) (emphasis in original).[3]

To establish the first factor, Covidien "must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, *and* that [the same claim] will also likely withstand [any] validity challenges presented by" Ethicon. Id. at 1351 (emphasis added). Covidien "has not established that it is likely to succeed on the merits, and a preliminary injunction is not appropriate," if Ethicon raises "a substantial question concerning either infringement or validity." LifeScan, 734 F.3d at 1366 (quotation marks omitted).

"[I]n cases such as this – where the accused product includes many features of which only one (or a small minority) infringe – a finding that the patentee will be at risk of irreparable

[3] Although the preliminary injunction calculus "is not unique to patent law," the Court of Appeals for the Federal Circuit has "built a precedent applying" the usual standards "to a large number of factually variant patent cases." Trebro Mfg., Inc. v. Firefly Equip., LLC, 748 F.3d 1159, 1165 (Fed. Cir. 2014) (quotation marks omitted). As such, this Court looks for guidance primarily to the decisions of the Federal Circuit.

harm does not alone justify injunctive relief." Apple Inc. v. Samsung Elecs. Co., 695 F.3d 1370, 1374 (Fed. Cir. 2012). Rather, to establish the second factor, Covidien must prove "that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." Id. This nexus requirement "ensures that an injunction is not entered on account of irreparable harm caused by otherwise lawful competition." Apple Inc. v. Samsung Elecs. Co., 809 F.3d 633, 640 (Fed. Cir. 2015). If Covidien fails "to show that the patented features impact consumers' decisions to purchase" the X1, it has not shown the sort of irreparable harm that would warrant a preliminary injunction. Id. at 641.

III. DISCUSSION

Because Ethicon has raised a substantial question of non-infringement, and because Covidien has not established a connection between the harms it identifies and the allegedly infringing features of the X1, neither of the first two factors are satisfied here. The discussion that follows, therefore, focuses only on those two outcome-determinative issues, and does not reach questions of claim validity, the balance of equities, or the public interest.

A. Likelihood of Success on the Merits: Infringement

Covidien asserts that it "is likely to succeed on the merits because the Enseal X1 includes every limitation of claim 1 of the '284 patent." Doc. No. 39-1 at 17; see Stiftung v. Renishaw PLC, 945 F.2d 1173, 1178 (Fed. Cir. 1991) ("Infringement of a claim requires that the accused device meet every limitation of the claim . . . ."). Only certain limitations in claim 1 of the '284 patent are disputed here, and resolution of this component of the preliminary injunction analysis turns on a single disputed limitation. The relevant limitation specifies that the "plurality of non-conductive stop members" are "configured to maintain a uniform distance between the jaw members along the length thereof." Doc. No. 42-1 at 23.

The Court first must consider what the terms in this claim mean. See Nazomi Commc'ns, Inc. v. Nokia Corp., 739 F.3d 1339, 1343 (Fed. Cir. 2014) (stating infringement analysis begins with claim construction); Shuffle Master, Inc. v. VendingData Corp., 163 F. App'x 864, 864 (Fed. Cir. 2005) (explaining that if the parties dispute the meaning of a term that "is central to determining" likelihood of success on the merits, a court evaluating a preliminary injunction request must "provide some form of claim construction, even if abbreviated, preliminary, or tentative"). Both parties urge the Court to apply the "plain and ordinary meaning" of all terms. Doc. No. 57-1 at 22; Doc. No. 78-1 at 7-8. However, they disagree about what the "plain and ordinary meanings" of terms like "non-conductive" and "uniform" are. Compare Doc. No. 78-1 at 10 (proposing "uniform" should mean "the same within several thousandths of an inch"), and id. at 12 (proposing "non-conductive" should mean "does not allow current to pass directly between the seal surfaces"), with Doc. No. 57-1 at 16 (proposing "uniform" should mean "the same"), and id. at 18 (proposing "non-conductive" should mean "made of a material that is not capable of conducting electricity").

Having carefully considered the parties' submissions on these questions, the Court concludes that Ethicon's proposed meanings are at least sufficiently persuasive to raise a substantial question regarding the "plain and ordinary" meanings of the relevant terms. Experts and other witnesses for both sides agree steel is a material that can conduct electricity, and that the steel pin at the distal end of the X1's lower jaw actually does conduct electricity under certain circumstances when the instrument is in use. E.g., Doc. No. 63-1 at ¶¶ 17, 20 (Greg Trees, X1 designer); Doc. No. 65-2 at 10 (William Durfee, Covidien's infringement expert); Doc. No. 65-16 at 11-12, 16 (Jeffrey Unger, Rule 30(b)(6) designee for Covidien); Doc. No. 67-10 at ¶¶ 54-59 (Karl Leinsing, Ethicon's infringement expert); see also Doc. No. 42-1 at 18

(describing, in patent summary, non-conductive stop members as "made from an insulative material such as parylene, nylon and/or ceramic," and going on to list more than a dozen other materials, none of which are metals). The Court cannot conclude that a reasonable person of ordinary skill in the art would view the plain and ordinary meaning of "non-conductive" as encompassing the X1's steel pin. It undisputedly can and, sometimes, does conduct energy while the device is used as intended. Thus, Ethicon has raised a substantial question about whether the steel pin is a "non-conductive" stop member for purposes of the '284 patent.

The question, then, is whether the six black bumps on the X1's lower jaw – which are undisputedly "non-conductive" – are "stop members configured to maintain a uniform distance between the jaw members along the length thereof." Both parties agree that, in order to be "stop members" and to impact the distance between the jaws at all, the bumps would have to touch the upper jaw member when the jaws are closed. E.g., Doc. No. 65-2 at 32-33 (Durfee); Doc. No. 65-16 at 9 (Unger); Doc. No. 67-10 at ¶ 28 (Leinsing). And, Covidien does not dispute that the X1's manufacturing specifications require that the bumps *not* touch the upper jaw when the jaws are closed. See Doc. No. 63-1 at ¶¶ 9-13 (describing design specifications and inspection process which detects and eliminates as defective devices with bumps touching the upper jaw). Through its infringement expert, however, Covidien urges that: 1) one or more bumps could, and likely would, touch the upper jaw when the X1 is used during surgery; and 2) that the variation in distance between the jaws when that occurs (from .008 inches at the distal end where the steel pin controls the gap to .004 inches at the location of contact between a bump and the upper jaw) would not be so significant as to render the distance "non-uniform." See, e.g., Doc. No. 65-2 at 17-18 (describing how bumps "could during use of the instrument" contact upper surface, based on "bench testing" in which he "squeeze[ed] down in the middle of the jaws" and "caused the

jaws to deform enough" to create contact, while maintaining a "gap [that] was uniform enough to likely cause effective sealing"). Ethicon disputes both propositions.

Covidien has not shown a likelihood that use of the X1 in the manner intended would result in any black bump on the lower jaw coming into contact with the upper jaw. Even if the manufacturing tolerances of the steel pin and the black bumps theoretically would allow for a device with one or more bumps as tall as the pin, Doc. No. 79-15 at 10-11, 29-32, Ethicon would deem such a device defective, Doc. No. 63-1 at ¶¶ 9-13. There is no evidence before the Court establishing that the squeezing tests performed by Covidien's expert witness on two sample X1 devices bear any resemblance to the circumstances in which the devices are used by surgeons.[4] Absent non-speculative evidence relating the forces exerted on an X1 during surgery to those exerted by Covidien's experts in his tests, or suggesting that a person performing or witnessing

[4] Covidien has offered only general statements by its infringement expert, one surgeon, and one of its own employees that instruments like the X1 can experience various forces during use. Doc. No. 80 at ¶ 26 (describing forces such as pulling, and torqueing); Doc. No. 83 at ¶ 17 (same); Doc. No. 85 at ¶¶ 15-16 (describing forces from grabbing and squeezing thick tissue sufficient to "bend, twist and deflect" jaws); but see Doc. No. 90 at ¶¶ 11-14 (reflecting a surgeon's opinion that real-world settings would not subject the X1 to the amount of force necessary to cause contact between the bumps and the upper jaw). None of these statements, however, establishes that such forces are comparable to the manner in which Covidien's expert applied pressure during his "bench testing" of the device. See Doc. No. 80 at ¶¶ 20-25 (describing testing by squeezing the jaws together with fingers, using a digital force gauge to compress the jaws, and placing the end of the jaws into a slot while twisting the device); but see Doc. No. 91-9 at 54-57 (speculating that the device could be lodged between a bone and other tissue, or might "seesaw" against another instrument, and opining that forces in those circumstances would mimic the "equal and opposite" pressure applied in the tests). It also bears noting that the expert tested only two devices, and his own results reflect a material difference in the amount of force required to create contact in those two devices. See Doc. No. 80 at ¶ 24 (stating two pounds of force caused the bumps to touch on one tested device, and six pounds of force were required on the other).

such a surgery observed contact between a bump and the upper jaw, there exists a substantial question as to whether the X1's bumps are stop members within the meaning of the '284 patent.[5]

Furthermore, if distortion of the jaws is required to achieve contact between the upper jaw and the bumps, which are designed to be half as tall as the steel pin, it defies common sense and any concept of "plain and ordinary" to consider the gap beneath a bent or bowed upper jaw "uniform."[6] Cf. Doc. No. 42-6 at 9 (reflecting PTAB construed "uniform distance between the jaw members along the length thereof" as meaning "when tissue is held between the opposing jaw members . . . the distance between the jaw members is *the same* along the entire length thereof" (emphasis added)); compare Doc. No. 91-9 at 36-37 (reflecting opinion of Covidien's expert that change in gap from .001 inches to .005 inches, a 400% difference, could be considered uniform); with Doc. No. 67-6 at 16 (reflecting Covidien's position during prosecution

[5] Covidien relies on a "Jaw Assessment" by Ethicon which appears to show that tests done to measure the distance of the X1's gap before and after use revealed that one or more black bumps contacted the upper surface. Doc. No. 78-30. That test, however, was performed in 2015, when the X1 was still being developed. Id. The gap measurements reflect that the device being tested differed from the final version of the X1. Compare id. (reflecting that the gap between the closed jaws was approximately .005-.006 inches), with Doc. No. 41-10 at ¶ 45 (including table of measurements by Covidien's expert showing the gap on the X1s he tested was .007-.008 inches). The record contains no information explaining how the device was configured at the time of the test. However, another document reflects that changes were made to the target jaw gap, and to the height of the black bumps by 2017. Doc. No. 79-37. In addition, the Jaw Assessment notes that at least one black bump on each tested device touched the upper jaw *before* the test was performed, Doc. No. 79-30 – a fact which would cause the devices to be discarded as defective under the manufacturing specifications for the X1.

[6] During the motion hearing, Covidien's counsel conceded in response to a hypothetical question posed by the Court that if stop members touch the opposing jaw only when that jaw is bent or bowed, the device would not be practicing the limitations in claim 1 of the '284 patent. Covidien's argument regarding uniformity rests on the fact that manufacturing tolerances permit ranges of acceptable measurements above and below the stated targets, and that these ranges involve measurements comparable to the width of one or a few human hairs. Neither the Court nor Ethicon disputes these realities. However, the Court does not conclude from those facts that forcibly distorting the X1's jaws to eliminate an intentionally created space, under conditions not present in typical surgical use, maintains "uniformity" in the plain and ordinary sense of that word.

of a related patent that "'[s]ubstantially uniform' cannot be reasonably interpreted to include a 400% difference in distance"). Even if there were direct evidence showing the bumps were included in the design of the X1, in part, to ensure a *minimum* distance between the jaws at all times during use, including in the unlikely event that the jaws became distorted during use – and there is not – Ethicon has raised a substantial question as to whether they are configured to maintain a "*uniform*" distance between the jaws.

Accordingly, Covidien has not established it is likely to succeed in proving the X1 infringes claim 1 of the '284 patent and, thus, has failed to satisfy the first factor in the preliminary injunction test.

B. Likelihood of Irreparable Harm: Nexus

As to the second preliminary injunction factor, Covidien asserts "Ethicon's aggressive marketing and sales of the Enseal X1 device are *already* causing . . . irreparable harm to Covidien," Doc. No. 39-1 at 24, and that "[t]he nexus between Ethicon's infringement and the harm to Covidien is clear in this case," id. at 28. Because the record does not support the latter assertion – i.e., it is far from "clear" on the present record that there is any connection between Ethicon's alleged infringement and the harms Covidien cites – the Court need not consider whether those harms are, in fact, irreparable. Apple Inc., 809 F.3d at 641.

Covidien's nexus argument rests on two related assumptions: that the G2 failed commercially because it did not provide reliable vessel sealing; and that the X1 remedied the supposed sealing problem by incorporating stop members disclosed in the '284 patent.[7] Neither assumption is borne out by the record. First, the only evidence suggesting that the G2 was

[7] For purposes of this discussion, the Court assumes that the X1's black bumps are "stop members," and that they practice the relevant limitations of claim 1 of the '284 patent.

unable to provide reliable and effective vessel seals are unsupported opinions of Covidien's employees, e.g., Doc. No. 40-8 at ¶ 22 (reflecting belief of Covidien's Director of U.S. Marketing), and a general statement by one surgeon with limited experience using the G2, Doc. No. 84 at ¶ 14 (describing "inferior" performance by G2 "including its ability to provide consistent and reliable vessel seals" based on "approximately five" uses of the device a number of years ago).

These statements are contradicted – and substantially outweighed – by evidence that the G2 sealed as well as the Impact, see Doc. No. 60-15 (recounting tests by Ethicon showing the G2 "produced more uniform compression, stronger and more consistent vessel sealing, and reduced tissue sticking relative to LigaSure™"); cf. Doc. No. 79-29 at 7 (reflecting surgeon's assessment, when asked to compare "the seal and performance," that the X1 and G2 are "similar"); and that it failed to appeal to surgeons for other reasons, see Doc. No. 58-1 at ¶ 8 (reflecting surgeon's belief that the G2 had inferior ergonomics and "at times requires the use of two hands to operate"); Doc. No. 59-1 at ¶ 8 (reflecting surgeon's belief that the G2 "was a poor fit for [his] hands and the controls were difficult to operate"); Doc. No. 60-36 at 12-13, 19-21 (testing prototypes for G2 replacement and noting surgeon feedback showed separating the sealing and cutting functions was critical, with improved ergonomics important to many as well). Indeed, Covidien's own tests comparing the performance of the G2 and the Impact demonstrated that the devices provided comparably reliable and consistent vessel seals. See Doc. No. 60-27 at 7, 14 (showing both devices performed comparably in hemostasis test and surpassed threshold and bench test for burst pressure[8]).

[8] One Covidien employee stated burst pressures of "120 mmHg [are] typically sufficient to ensure that a vessel is properly sealed," and said Covidien also performs a bench test measuring "adequacy of vessel seals . . . by calculating whether there is a 95% probability of achieving a

Second, the record demonstrates that the major differences between the X1 and the G2 – and the reasons surgeons cite for preferring the X1 – have nothing to do with the steel pin, the black bumps, or stop members in general. See Doc. No. 58-1 at ¶ 7 (reflecting surgeon's preference for the X1 because it has "superior ergonomics, causes less thermal spread, and causes less surgical plume"); Doc. No. 59-1 at ¶¶ 8-9 (reflecting surgeon's preference for the X1 based on ergonomics, ease of use, and amount of heat generated during use); Doc. No. 60-36 at 4 (describing objective in creating the X1 as designing a device "that will enable surgeons to seal only / seal separately from cutting in contrast to" the G2 and other Ethicon devices); id. at 20 (stating ergonomics "was a major theme and the reason why so many LigaSure™ users indicated that they might switch"); Doc. No. 62-1 at ¶¶ 17-18 (identifying separate seal/cut functions and ergonomic design as demand drivers for the X1); Doc. No. 63-1 at ¶ 22 (calling separate seal/cut function a "significant difference"); Doc. No. 64-1 at ¶ 8 (stating the X1 "has superior ergonomics," and "is generally easier and more comfortable in the hand than" the Impact or the G2); Doc. No. 79-26 at 8 (reflecting surgeon's testimony that he tried the G2 but did not continue using it because he "didn't like the ergonomics"); Doc. No. 91-13 at 5-6 (reflecting surgeon's testimony that he believed the G2 sealed "cleaner" and left "less charred tissue" than the Impact, but that he used Impact more because it suited him better ergonomically).

To the extent Ethicon claims the X1 provides improved sealing, its claims are in comparison to the Impact (not the G2), and are tied specifically to sealing at the distal tip. See Doc. No. 42-3 at 2 (claiming in X1 marketing materials that the X1 "offers better sealing compared to LigaSure Impact™," and attributing "less bleeding in thick tissue" to "a larger distal

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burst pressure above 360 mmHg." Doc. No. 85 at ¶¶ 11, 13. The report of Covidien's test comparing the G2 and the Impact appears to show that both devices generally exceeded these markers. Doc. No. 60-27 at 7.

electrode surface area"); Doc. No. 60-13 (same, in press release announcing X1 launch); Doc. No. 60-37 (attributing "superior distal tip sealing" in X1 compared to Impact to "a complete/uninterrupted distal electrode surface area and larger electrode area beyond the end of the knife slot"); Doc. No. 63-1 at ¶¶ 23-26 (same, and stating that the X1's "non-conductive bumps . . . do not contribute to its superior sealing performance relative to the LigaSure Impact"); see also Doc. No. 59-1 at ¶ 7 (reflecting surgeon's opinion that the X1 seals better than the Impact in "thick" and "highly edematous tissue"); Doc. No. 61-1 at ¶¶ 7-10 (describing three procedures in which a surgeon believed the X1 sealed more effectively than the Impact); Doc. No. 64-1 at ¶ 7 (reflecting surgeon's preference for the X1 due to "better sealing performance at the distal tip").

And, to the extent hospitals or hospital groups, rather than doctors, are making purchasing decisions, price (not stop members) appears to drive those decisions. See Doc. No. 60-36 at 17 (noting "growing role of the economic provider in usage decisions, with pricing being key"); Doc. No. 60-39 (conveying sales representative's request that Covidien "consider Ligasure Impact price adjustment in near future" after hearing from customers that, due to economic factors, hospitals "were looking to save every dollar they can"); Doc. No. 65-18 at 5, 8 (reflecting Covidien's view that accounts were being lost to the X1 because hospital procurement teams were motivated to select less expensive options); cf. id. at 58 (agreeing that customers who purchase some items from Ethicon and others from Covidien, rather than seeking a single-source contract from one of them, are "not getting the most favorable pricing from either manufacturer").

In sum, the Court finds insufficient support for the assumptions upon which Covidien rests its nexus argument. The record simply does not establish that the G2 failed because it could

not seal effectively. Moreover, the weight of evidence before the Court suggests various factors besides the patented stop members are responsible for the X1's early success. Accordingly, Covidien has not shown irreparable harm *resulting from* the alleged infringement.

IV. CONCLUSION

Because Covidien has satisfied neither of the first two prongs of the preliminary injunction standard – and because either of those failures alone would doom its quest for the extraordinary remedy it seeks – the motion for a preliminary injunction (Doc. No. 38) is DENIED.

SO ORDERED.

/s/ Leo T. Sorokin
United States District Judge