United States District Court,
D. Delaware.

CORDIS CORPORATION,
Plaintiff.
v.
ADVANCED CARDIOVASCULAR SYSTEMS,
INC. and GUIDANT CORPORATION Defendants.

No. CIV. A. 97-635-SLR

Sept. 10, 1999.

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MEMORANDUM OPINION

ROBINSON**, District J.**

I. INTRODUCTION

Pending before the court is a motion for preliminary injunction filed by plaintiff Cordis Corporation ("Cordis") against defendants Advanced Cardiovascular Systems, Inc. and Guidant Corporation (hereinafter referred to collectively as "ACS"). (D.I.5) At issue is U.S. Patent No. 5,156,612 (the " '612 patent") and Cordis' charge that the ACS RX ROCKET Coronary Dilatation Catheter with its featured "XCELON ™ Nylon Balloon Material" infringes claim 12 of the '612 patent.

For the reasons that follow, Cordis' request for injunctive relief shall be denied.

II. FACTS

The parties to this litigation make and sell angioplasty products in the United States and abroad. The particular products at issue are balloon dilatation catheters for performing coronary angioplasty. More specifically, a procedure known as "percutaneous transluminal coronary angioplasty" ("PTCA") can be used

to widen a narrowing in a coronary artery without surgery. PTCA involves positioning a balloon catheter within the narrowed section of the coronary artery, using a guiding catheter and a guide wire. Inflation of the balloon causes it to expand the artery and compress the fatty buildup against the arterial wall. The balloon is then deflated and the catheter withdrawn to restore blood flow to the heart muscle.

Presently, two types of catheter systems are used: (1) "over-the-wire" ("OTW") catheters; and (2) "monorail" or "rapid exchange" ("RX") catheters. OTW balloon catheters are delivered to the diseased artery over a guidewire that is approximately 300 centimeters long. RX balloon catheters are delivered on a shorter (190 centimeters) guidewire. Cordis only markets OTW catheters. ACS markets both OTW and RX catheters. It is the "XCELON ^{TM} Nylon Balloon Material" of ACS' RX ROCKET Coronary Dilatation Catheter (the "RX ROCKET balloon") that allegedly infringes the '612 patent. (D.I.6, Ex. 2)

The '612 patent is directed to "balloons for medical devices and fabrication thereof." As described in the patent by way of background:

In the past, medical device balloon materials have included balloons having a wall thickness at which the material exhibits strength and flexibility that allow inflation to a working diameter or designated initial dilation diameter which, once achieved, is not surpassable to any significant degree without balloon breakage or substantially increasing the risk of balloon breakage. Balloons of these materials can be characterized as being substantially non-distensible balloons that are not stretchable, expandable or compliant to a substantial extent beyond this working diameter. Such substantially non-distensible balloons can be characterized as being somewhat in the nature of paper bags which, once inflated to generally remove folding wrinkles, do not further inflate to any significant degree. Polymeric materials of this substantially non-distensible type that are used or proposed for use as medical balloons include polyethylene terephthalates.

Other types of materials, such as polyvinyl chlorides and cross-linked polyethylenes can be characterized as being distensible in that they grow in volume or stretch with increasing pressure until they break. These materials are generally elastic and/or stretchable. When such extensible materials are used as medical balloons, the working diameter or designated dilation diameter of the balloon can be exceeded, based upon the stretchability of the material.

('612 patent, col. 1, lns. 49-68 to col. 2, lns. 1-7) Thus, the patent characterizes the prior art balloons as being either "substantially non-distensible" or "readily distensible." ('612 patent, col. 2, lns. 28-38) The former category (exemplified in the patent by polyethylene terephthalate or "PET") exhibits "especially high tensile strength," while the latter category (exemplified in the patent by polyvinyl chloride) "typically exhibit[s] a lower tensile strength." ('612 patent, col. 2, lns. 28-29, 45-47)

In their efforts to find a better balloon material, one with combined strength and compliance, the named inventors of the '612 patent utilized a computer program that constituted "a data base for searching materials based upon properties." (D.I. 55, Ex. 4 at 154, 172) The inventors input the desired engineering parameters-tensile strength and elongation at break-and the program provided a list of materials that met the parameters. (D.I. 55, Ex. 4 at 156-64; D.I. 57, Exs. 25, 26) Among the materials listed were nylons and polyamides. (D.I. 55, Ex. 4 at 166; D.I. 57, Exs. 25, 26) Based on several additional parameters, "including availability of medical grade versions ... [and] maximum tensile strength," the inventors ordered pellets of four or five materials, including "Rilson, which was Nylon 12." (D.I. 55, Ex. 4 at 173, 175-76) The '612 patent application was filed on October 4, 1988 and issued on October 20, 1992.

In this preliminary injunction proceeding, Cordis claims that the ACS "RX ROCKET balloon" infringes claim 12 of the '612 patent. Claim 12 reads as follows:

A balloon for a medical device, comprising:

a nylon material or a polyamide material tubing that had been radially expanded to a predetermined balloon diameter, wherein said nylon or polyamide material is Nylon 12;

said balloon has a collapsed profile at which the outer diameter of the balloon approximates the outer diameter of said medical device, said balloon further having a non-distended inflation diameter at which the balloon is inflated to its said predetermined balloon diameter, and said balloon also exhibits a distended inflation diameter at which the balloon is stretched to a profile having a diameter that is in excess of said predetermined balloon diameter; and

said balloon has a tensile strength greater than medical device balloons that are made of materials other than nylon or polyamide materials and that have an inflated profile exhibiting a distended size.

('612 patent, col. 16, lns. 28-46) (emphasis added). Also at issue is claim language found in, e.g., claim 1:

A balloon for a medical device, the balloon comprising:

a length of tubing made of Nylon 12, said length of tubing have been formed into the balloon during a balloon forming procedure including inflating at least a section thereof with a pressurized fluid in order to radially expand said length of tubing to at least double its outer diameter;

said balloon has a non-distended working profile having a predetermined size to which the balloon inflates without significant stretching thereof, and said balloon has an expansion profile having a maximum inflated size to which the balloon stretches without bursting during use, said maximum inflated size being greater than said predetermined size of the non-distended working profile; and

said expansion profile of the balloon had been tailored whereby said balloon has a maximum inflated size selected from a range of maximum inflated sizes that are a function of balloon processing conditions.

('612 patent, col. 14, lns. 46-66) (emphasis added). ACS denies infringement and contends that the '612 patent is invalid as obvious, pursuant to 35 U.S.C. s. 103, and unenforceable due to inequitable conduct.

III. STANDARD OF REVIEW

The framework for analyzing a request for injunctive relief at the preliminary stages of litigation rests upon two fundamental principles: a preliminary injunction constitutes extraordinary relief and the grant or denial of such relief is within the discretion of the court. *See generally,* Bell & Howell Document Management Prods. Co. v. Altek Sys., 132 F.3d 701, 704 (Fed.Cir.1997). These underpinnings are not absolute, however, and the court's discretion "must be measured against the standards governing the issuance of an injunction." Hybritech Inc. v. Abbot Labs., 849 F.2d 1446, 1451 (Fed.Cir.1988).

To obtain a preliminary injunction pursuant to 35 U.S.C. s. 283, a party must demonstrate that: (1) it has a

reasonable likelihood of success on the merits; (2) it would suffer irreparable harm if the injunction were not granted; 3) the balance of relative hardships tips in its favor; and 4) an injunction would not have a negative impact on the public interest. *See id*.

These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

Id.

IV. ANALYSIS

A. Likelihood of Success

It is Cordis' burden to demonstrate that, if this controversy were to be tried, Cordis would prevail in proving (by a preponderance of the evidence) that ACS is infringing the '612 patent and ACS would not successfully prove (by clear and convincing evidence) that the '612 patent is invalid. If Cordis "clearly establishe[s] a likelihood of success, it [is] entitled to a rebuttable presumption that it would be irreparably harmed if a preliminary injunction were not to issue." Bell & Howell, 132 F .3d at 705.

1. Literal Infringement

Literal infringement involves a two-step determination: the proper construction of the asserted claims and a determination whether the claims as properly construed read on the accused product or method. *See id.;* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370 (1996).

The principles of claim interpretation are well established in the law. The exercise begins always with the claim language, which defines the scope of the claim. *See* York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996). In analyzing claim language, the court must employ "normal rules of syntax," Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F .3d 1547, 1553 (Fed.Cir.1997), for "[a] claim must be read in accordance with the precepts of English grammar," In re Hyatt, 708 F.2d 712, 714 (Fed.Cir.1983). The court must ascribe to any technical term used in a claim "the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996).

In order to give context to the claim language, the court must review as well the specification.

The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication .... As we have repeatedly stated, "[c]laims must be read in view of the specification, of which they are a part." ... The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

The last source of intrinsic evidence relevant to claim interpretation is the prosecution history of the patent,

if it has been made part of the record.

This history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims.

The claims, specification, and file history ... constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention.

Id. at 1583. In order to further the "fair notice function of the requirement that the patentee distinctly claim the subject matter disclosed in the patent from which he can exclude others temporarily," Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed.Cir.1996), extrinsic evidence of claim interpretation, such as expert testimony, is not encouraged by the Federal Circuit. *See, e.g.,* Vitronics Corp., 90 F.3d at 1583.

a. Claim Construction

Consistent with the court's best understanding of the dispute, ACS maintains that it does not infringe the '612 patent because its RX ROCKET balloon does not meet either of the following limitations: (1) its expansion profile has not been "tailored"; and (2) its tensile strength is not "greater than medical device balloons that are made of materials other than nylon or polyamide materials and that have an inflated profile exhibiting a distended size." ('612 patent, claim 1 at col. 14, ln. 62 and claim 12 at col. 16, lns. 43-46)

1. "Tailored"

Cordis contends that the claim limitation requiring "[t]ailorability" means nothing more than "to fashion or adapt to a particular taste, purpose, need, etc." (D.I. 49, Ex. 9 at 1361) Cordis maintains that because ACS supplies balloons of different sizes for different needs, the tailoring limitation is met.

The court disagrees on the record presented. FN1 In introducing the concept of "tailoring," the specification describes the invention as including "utilizing a tailorable material such as a nylon material or a polyamide material that is formed into a balloon by appropriate axial elongation, radial expansion and heat treatment procedures." ('612 patent, col. 3, lns. 36-40) The specification goes on to state that "[t]ailorability that is achieved according to this invention is a function of the particular heat setting conditions." ('612 patent, col. 6, lns. 40-2) Consistent with the above, the specification provides that

[m]aterials according to this invention should be able to be tailored during balloon formation to possess the ability to be stretched a generally predetermined percentage beyond its non-distended or working diameter, the amount of this percentage depending upon conditions under which the parison was processed into the balloon.

('612 patent, col. 11, lns. 60-66) Finally, the specification explains that "balloon expansion tailorability is a function of heat setting conditions and of hoop expansion ratio for balloon materials according to the present invention." ('612 patent, col. 13, lns. 1-4) Illustrating this principle is

FIG[ure] 5 [which] gives four distention plots, tested at 37 (deg.) C for nylon balloons that are substantially identical except they were subjected to different heat set temperatures. In each case, the balloon was subjected to a 2 minute heat/cool cycle, with cooling being to room temperature. Each balloon was subsequently subjected to ethylene oxide sterilization. Curve F was subjected to a heat set temperature of 120 (deg.) C., curve G was at 130 (deg.) C., curve H was at 140 (deg.) C., and Curve I was at 150 (deg.) C. It will be noted that the curves illustrate different distention properties and the type of tailoring thus achieved.

('612 patent, col. 13, lns. 27-37)

The claim language in dispute is consistent with the quoted passages from the specification, that is, that the "expansion profile FN2 of the balloon ha [s] been tailored" so that the "maximum inflated size" of a balloon is "selected from a range of maximum inflated sizes that are a function of balloon processing conditions." ('612 patent, claim 1 at col. 14, lns. 62-66) (emphasis added). In other words, "tailoring" according to the patent is more than making different balloons for different needs. It involves the use of varying balloon processing conditions to vary a balloon's expansion profile. To hold otherwise would be to negate the significance of this aspect of the invention.

2. Materials that have an "inflated profile exhibiting a distended size"

Cordis maintains that the above-quoted language taken from claim 12 cannot apply to PET, because PET is generally described in the specification as a material associated with "substantially non-distensible balloons." ('612 patent, col. 1, lns. 49-66) ACS contends that, contrary to the general description contained in the specification, PET is a material that has an "inflated profile exhibiting a distended size." And indeed, the specification itself acknowledges that "[m]aterials such as polyethylene terephthalate (PET) inflate to their working size, but not therebeyond to an extent as great as others of the plotted curves" of Figure 4. ('612 patent, col. 12, lns. 43-45) (emphasis added). Thus, the fact that PET is only "substantially non-distensible" means, of course, that it is distensible to some extent, a property recognized in the Levy patent, U.S. Patent Re. 33,561. (D.I. 55, Ex. 7 at col. 2, lns. 63-7)

Cordis wishes the court to translate the claim language-"materials ... that have an inflated profile exhibiting a distended size"-to include the limitation that the materials must have "an inflated profile exhibiting a [significant or substantially] distended size." (*See, e.g.,* '612 patent, col. 1, lns. 49-54) Based on the record presented, the court declines to read such a limitation into the claim.

b. Infringement Analysis

At least for purposes of this preliminary injunction proceeding, the infringement analysis somewhat collapses into the claim construction. With respect to "tailoring," ACS contends that it does not

adjust balloon process conditions to create a balloon with a predetermined percentage increase in expansion diameter greater than its nominal inflated diameter. To the contrary, all of ACS's RX ROCKET balloons are made from the same basic fabrication process: a piece of tubing of appropriate size is blown at high pressure into a mold while heat is applied....

The result of this straightforward procedure is that, depending on the diameter of the tubing and mold used, a balloon is formed with a single nominal inflation diameter.... Due to the nature of the tubing material, it has been observed that ROCKET balloons can safely expand up to .25 mm beyond their nominal working

diameter ... Thus, in making balloons for the RX ROCKET, ACS does not adjust process parameters to create a balloon that can exhibit an expanded diameter of a predetermined percentage selected from a range of possible expanded diameters ... Instead, ACS makes a balloon of a certain nominal size, which so happens to be able to be stretched beyond that size by a fixed amount. That is not "tailoring" within the meaning of claim 1 and ACS's ROCKET balloons do not infringe that claim.

(D.I. 53 at 30-31, citing D.I. 57, Exs. 28, 30) Although ACS does not specifically aver that all of its balloons are subjected to exactly the same balloon processing conditions, especially the same heat set temperatures, the court understands that every balloon, regardless of size and regardless of processing conditions, has the same expansion profile (i.e., .25 mm beyond normal working diameter).

Cordis, for its part, maintains generally that "[t]he only way that you can get balloons across balloon sizes ... is to modify the processing techniques for the balloons." (D.I. 63 at 20) In support of this proposition, however, Cordis simply cites to two documents which are anything but self-explanatory. (D.I. 50 at 14, citing D.I. 49, Ex. 10 at 17993 and Ex. 11)

In sum, if this were a summary judgment proceeding, the court would conclude that there were genuine issues of material fact which preclude the entry of a summary judgment for either party. To the extent Cordis has the burden of demonstrating infringement, it has failed to carry that burden at the preliminary injunction stage.

With respect to the disputed limitation of claim 12, ACS maintains that its RX ROCKET balloon does not have a tensile strength greater than certain non-nylon balloons, particularly those made from the non-nylon material PET. Having concluded that neither the specification nor the language of the claim itself excludes PET as a material having an inflated profile exhibiting a distended size, the court further concludes that Cordis has not carried its burden of proof on this issue for purposes of these preliminary injunction proceedings.

2. Validity

ACS challenges the validity of the '612 patent under 35 U.S.C. s. 103, which provides in relevant part that "[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

The Supreme Court has stated that the obviousness determination

lends itself to several basic factual inquiries. Under s. 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this backdrop, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). Thus, the factual inquiries relevant to the obviousness inquiry include: (1) the level of skill in the pertinent art; (2) the scope and content of the prior art as viewed

through the eyes of the skilled artisan at the time of the invention; (3) the differences between the claimed invention and the prior art; and (4) relevant secondary considerations.

ACS maintains that the prior art's general references to "polymeric materials" include polyamides and nylons. (D.I. 63 at 62; D.I. 55 at col. 4, lns. 25-32) ACS contends as well that "nylon had been well known as a polymeric material used in the medical industry for 40 years. All of this technology, the properties of nylon, were well known. They were in computer and print databases." (D.I. 63 at 62)

And, indeed, apparently the inventors of the '612 patent resorted to using computer technology to match Cordis' marketing needs with a suitable material for its medical device balloons. The court, however, is not inclined at this juncture, on this preliminary record, to find the '612 patent invalid on this basis. Given the issues of fact attendant to the other prior art references relied upon by ACS,FN3 the court concludes that Cordis has carried its burden of proof on this issue, but not with "a clear showing" of validity. *See* Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 973 (Fed.Cir.1996).

B. Irreparable Harm

Given the above findings, Cordis has not clearly established a likelihood of success on the merits and, therefore, is not entitled to a rebuttable presumption that it will be irreparably harmed if an injunction does not issue. Nevertheless, the court is mindful of the presumption of validity that inheres to the '612 patent and the court's obligation to protect the integrity of the patent system against a business mentality which places more value on obtaining market share than on honoring a competitor's intellectual property.

Unlike perhaps a more typical case, the patented invention at bar is useful in more than one market. It is used by companies in the OTW catheter market, in which Cordis is a player. It is allegedly used as well by ACS in the RX catheter market, in which Cordis is not a player. Cordis maintains that ACS, by using its allegedly infringing RX ROCKET balloons with its RX catheter system, is taking sales away from Cordis, if not directly, at least indirectly, by taking sales away from the OTW market.FN4

ACS counters that the attraction of the RX catheter system is attributable to more than the balloons used and that there is no direct nexus between its allegedly infringing activities and Cordis' lost sales. ACS also argues that Cordis cannot claim irreparable harm when it has not sought injunctive relief in litigation against its major direct competitor, SciMed, and when it has licensed the use of the '612 technology to two other direct competitors, Medtronic and Schneider.

There is no question but that ACS' conduct will affect Cordis in this very competitive market setting. And once again, a product has been commercially launched into the medical community without any apparent prelaunch discussion, let alone determination, of intellectual property repercussions. Nevertheless, Cordis' posture, vis-a-vis its other competitors, does not present a very compelling case of irreparable harm. The fact that Cordis believed the litigation against SciMed to be more complicated than the litigation at bar (and, thus, Cordis may be less likely to succeed on the merits), does not change the fact that the harm suffered by Cordis at the hands of these two competitors is essentially the same. Similarly, the fact that the two licenses involve more than monetary compensation is less than compelling when the licensees substantially comprise the remainder of the OTW market.FN5

The court concludes that Cordis has not carried its burden of proof to demonstrate irreparable harm. Moreover, if an injunction does not issue and ACS is allowed to compete in the United States market, the

court finds that ACS will be able to redress the economic harms caused by such competition should Cordis ultimately prevail at trial. (D.I. 53 at 17; D.I. 55, Ex. 2 at 38-9)

C. Balance of Hardships

The court concludes that Cordis has demonstrated that it will be harmed more if an injunction does not issue than will ACS if an injunction does issue. Until November 1997, ACS had no income from its sale of the RX ROCKET Coronary Dilatation Catheter in the United States. To enjoin its activity is to reestablish the status quo circa November 7, 1997. Cordis, on the other hand, has sustained losses which may not be recouped, if at all, for months. Moreover, Cordis still stands in the position of the owner of a valid patent.

D. Public Interest

The parties have addressed the question of whether the public suffers more when efficacious medical devices FN6 are taken off the market (through, e.g., an injunction) or when efficacious medical devices never make it to the market in the first instance because the incentives offered by patent protection are no longer viable. As it has in the past, the court suspects that much of this tension is generated by money-driven business decisions and not the public interest. The court concludes under the circumstances at bar, however, that the public would be better served if an injunction did not issue.

V. CONCLUSION

It is the court's responsibility to weigh and measure each of the four factors deemed relevant to a preliminary injunction analysis against the other factors and against the form and magnitude of the relief requested. Having done so, the court concludes that the weight of the evidence does not support Cordis' request for injunctive relief. An appropriate order shall issue.

FN1. As is generally the case with preliminary injunction proceedings, matters of claim construction and determinations of infringement and validity are preliminary and subject to change after discovery and trial.

FN2. The word "tailored" in claim 1 modifies the phrase "expansion profile," not the word "balloon." The "expansion profile" is the "maximum inflated size to which the balloon stretches without bursting during use...." ('612 patent, claim 1 at col. 14, lns. 57-9)

FN3. Given the court's ultimate conclusion, the court declines as well to address in these proceedings the charge of inequitable conduct.

FN4. Cordis argues as well that ACS' alleged infringement was willful, thereby causing irreparable harm. (D.I. 50 at 29-32) Even if the court had found infringement, the fact that it was willful is not relevant to the question of irreparable harm. Indeed, willfulness is specifically deemed compensable by money (treble) damages.

FN5. Although the Federal Circuit in *Polymer Techs, Inc*. states that the presumption of irreparable harm may be rebutted by evidence that the "movants have engaged in a pattern of granting licenses under the

patent," 103 F.3d at 974 (emphasis added), the case cited for this proposition says the following:
There also is no indication in the record that HTMI needs an injunction to protect its right to refuse to exploit its invention commercially or to prevent others from doing so. To the contrary, the evidence shows that HTMI offered a license to New Image, so it is clear that HTMI is willing to forgo its patent rights for compensation. That evidence suggests that any injury suffered by HTMI would be compensable in damages assessed as part of the final judgment in the case. *See* T.J. Smith & Nephew Ltd. v. Consolidated Medical Equip., Inc., 821 F.2d 646, 648, 3 USPQ2d 1316, 1318 (Fed.Cir.1987) (licensing is "incompatible with the emphasis on the right to exclude that is the basis for the presumption in a proper case").

High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1557 (Fed.Cir.1995) (emphasis added). The granting of two licenses in a limited market is certainly more of a "pattern" than offering a single license, albeit to the defendant.
FN6. ACS provided some evidence of physician preference for its RX ROCKET Coronary Dilatation Catheter. (D.I. 53 at 35; D.I. 57, Exs. 33, 34)

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