IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. 14-878-LPS-CJB

FINAL JURY INSTRUCTIONS

TABLE OF CONTENTS

1. GENERAL INSTRUCTIONS

1.1. INTRODUCTION

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case. Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer.

I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating particular testimony and evidence.

Then I will explain the positions of the parties and the law you will apply in this case. And last, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

Please listen very carefully to everything I say.

You will have a written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

1.2. JURORS' DUTIES

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you will see and hear in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts.

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on any given issue. It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not guess or speculate, and do not let any bias, sympathy, or prejudice you may feel toward one side or the other influence your decision in any way.

1.3. EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath (including deposition transcript testimony that has been played by video or read to you), the exhibits that I allowed into evidence, and the stipulations to which the lawyers agreed.

Certain charts and graphics have been used to illustrate testimony from witnesses. Unless I have specifically admitted them into evidence, these charts and graphics are not themselves evidence, even if they refer to, identify, or summarize evidence, and you will not have these demonstratives in the jury room

Nothing else is evidence. The lawyers' statements and arguments are not evidence. The arguments of the lawyers are offered solely as an aid to help you in your determination of the facts. Their questions and objections are not evidence. My legal rulings are not evidence. You should not be influenced by a lawyer's objection or by my ruling on that objection. Any of my comments and questions are not evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And, sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. You must completely ignore all of these things. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way.

Make your decision based only on the evidence, as I have defined it here, and nothing else.

1.4. DIRECT AND CIRCUMSTANTIAL EVIDENCE

You may have heard the terms "direct evidence" and "circumstantial evidence."

Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believe him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

1.5. CONSIDERATION OF EVIDENCE

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

1.6. STATEMENTS OF COUNSEL

A further word about statements of counsel and arguments of counsel. The attorneys' statements and arguments are not evidence. Instead, their statements and arguments are intended to help you review the evidence presented.

If you remember the evidence differently from the way it was described by the attorneys, you should rely on your own recollection.

1.7. CREDIBILITY OF WITNESSES

You are the sole judges of each witness's credibility. You may believe everything a witness says, or part of it, or none of it. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witnesses' manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there is evidence tending to prove that the witness testified falsely about some important fact or whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial in person or by deposition testimony played by video or read to you. You have the right to distrust such witness's testimony and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was an innocent lapse of memory or an intentional falsehood, and that may depend upon whether it concerns an important fact or an unimportant detail.

1.8. NUMBER OF WITNESSES

One more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

1.9. EXPERT WITNESSES

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

1.10. DEPOSITION TESTIMONY

During the trial, certain testimony was presented to you by the reading of a deposition transcript or the playing of video excerpts from a deposition. If played by video, the deposition testimony may have been edited or cut to exclude irrelevant testimony. You should not attribute any significance to the fact that the deposition videos may appear to have been edited.

Deposition testimony is out of court testimony given under oath and is entitled to the same consideration you would give it had the witnesses personally appeared in court.

1.11. RULE 30(b)(6) DEPOSITION TESTIMONY

In this trial, there were certain witnesses identified as "Rule 30(b)(6) witnesses" for the parties. These Rule 30(b)(6) witnesses were designated to speak on certain topics on behalf of the entities which designated them as Rule 30(b)(6) witnesses. These witnesses include Jill Pastore, Jennifer King, and Jamie Berlanska (designated by Teva) and Charles Kinzig, Mary Ann Lukas, and Bart Murray (designated by GSK). Rule 30(b)(6) witnesses are required to testify about information known or reasonably available to the designating entity related to those particular topics. For answers within the designated topics, the entity is bound by the answers provided by its Rule 30(b)(6) witness.

If these witnesses also provided testimony outside of their designated topics based on their personal knowledge and/or provided their personal opinions in addition to testifying to factual information on behalf of the designating entities, the designating entities are not bound by answers that provide personal knowledge and/or personal opinions that are outside of the designated topics.

1.12. DEMONSTRATIVE EXHIBITS

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room for your deliberations. The remainder of the exhibits (including charts, PowerPoint presentations and animations) were offered to help illustrate the testimony of the various witnesses. These illustrative exhibits, called "demonstrative exhibits," have not been admitted, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.

In some instances, certain charts and summaries may have been received into evidence to illustrate information brought out in the trial. You may use these charts and summaries as evidence, even though the underlying documents and records are not here. You should give them only such weight as you think they deserve.

1.13. BURDENS OF PROOF

In any legal action, facts must be proven by a required standard of evidence, known as the "burden of proof." In a patent case such as this, there are two different burdens of proof that are used. The first is called "preponderance of the evidence." The second is called "clear and convincing evidence."

GSK contends both that Teva induced infringement of the '000 patent and that Teva induced infringement willfully. GSK also contends that it is entitled to damages related to the '000 patent. A party asserting patent infringement has the burden of proving infringement by a preponderance of the evidence. A preponderance of the evidence is evidence that, when considered in light of all of the facts, leads you to believe that what that party claims is more likely true than not. To put it differently, if you were to put the parties' evidence on opposite sides of a scale, the evidence supporting GSK's claims must make the scales tip somewhat toward its side. If the scale should remain equal or tip in favor of Teva you must find for Teva.

If you decide that Teva has induced infringement, you must go on and address the additional issue of whether or not this infringement was willful. GSK has the burden of proving that the infringement was willful by a preponderance of the evidence, meaning it is more likely true than not.

GSK also has the burden to establish the kind of money damages -- lost profits or reasonable royalties -- and amount of its money damages by a preponderance of the evidence. If GSK persuades you that Teva has infringed a valid patent, GSK is entitled to damages in an amount to compensate GSK for that infringement.

Teva denies that it has infringed, and denies that any such infringement was willful. Teva also contends that the '000 patent is invalid. A party challenging the validity of a patent has the burden of proving that the patent is invalid by clear and convincing evidence. Clear and

convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is, thus, a higher burden than proof by a preponderance of the evidence.

Some of you may have heard the phrase "proof beyond a reasonable doubt." That burden of proof applies only in criminal cases and has nothing to do with a civil case like this one. You should therefore not consider it in this case.

1.14. USE OF NOTES

You may use notes taken during trial to assist your memory. However, as I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency I think to attach undue importance to matters which one has written down. Some testimony which is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence, and are by no means a complete outline of the proceedings or a list of the highlights of the trial.

Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

2. THE PARTIES AND THEIR CONTENTIONS

2.1. THE PARTIES

I will now review for you the parties in this action, and the positions of the parties that you will have to consider in reaching your verdict.

As I have previously told you, the plaintiffs in this case are GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited. I will refer to the plaintiffs collectively as "GSK." The defendant in this case is Teva Pharmaceuticals USA, Inc., which I will refer to as "Teva."

2.2. THE PARTIES' CONTENTIONS

There is one patent at issue in this case: United States Patent No. RE40,000. Because these numbers are so long, patents are usually referred to by their last three digits. You heard the lawyers and witnesses in the case refer to GSK's patent as the '000 patent or the triple zero patent. A copy of the '000 patent has been given to you.

GSK contends that Teva induced infringement of the '000 patent and that the infringement was willful. GSK also contends that it is entitled to damages related to the '000 patent. Teva denies that it induced infringement of the '000 patent, and denies that any such infringement was willful. Teva also contends that the '000 patent is invalid for several independent reasons. Teva also denies that GSK is entitled to recover any damages related to the '000 patent.

2.3. SUMMARY OF THE PATENT ISSUES

I will now summarize the patent issues that you must decide and for which I will provide instructions to guide your deliberations. Here are the issues you must decide:

1. Whether GSK has proven by a preponderance of the evidence that Teva induced infringement of the '000 patent.

2. Whether GSK has proven by a preponderance of the evidence that Teva's infringement was willful.

3. Whether Teva has proven by clear and convincing evidence that one or more asserted claims of the '000 patent are invalid due to anticipation, obviousness, or lack of written description.

4. If you find that Teva is liable for infringement of one or more asserted claims of the '000 patent and you do not find the infringed claims invalid, then you must determine the amount of money damages to be awarded to GSK. GSK has the burden to establish the amount of its damages by a preponderance of the evidence.

I will provide more detailed instructions on each of the issues you must decide throughout elsewhere in these jury instructions.

3. THE PATENT CLAIMS

3.1. PATENT LAWS

At the beginning of the trial, I gave you some general information about patents and the patent system and a brief overview of the patent laws relevant to this case. I will now give you more detailed instruction about the patent laws that specifically relate to this case.

3.2. PATENT CLAIMS GENERALLY

Before you can decide many of the issues in this case, you will need to understand the role of patent "claims."

The patent claims are the numbered paragraphs at the end of each patent. The claims are important because it is the words of the claims that define what a patent covers.

The claims are intended to define, in words, the bounds of the invention. The figures and text in the rest of the patent provide a description and/or examples of the invention and provide a context for the claims, but it is the claims that define the breadth of the patent's coverage. Each of the asserted claims must be considered individually.

Each claim of a patent effectively acts as if it were a separate patent, and each claim may cover more or less than another claim. Therefore, what a patent covers depends, in turn, on what each of its claims covers.

You will first need to understand what each claim covers in order to decide whether or not there is infringement of the claim and to decide whether or not the claim is invalid.

3.3. CONSTRUCTION OF THE CLAIMS

It is the Court's duty under the law to define what the patent claims mean. As I instructed you at the beginning of the case, I have made my determinations, and I will now instruct you on the meaning of the claim terms. You must apply the meaning that I give in each patent claim to decide if the claim is infringed or invalid. You must accept my definitions of these words in the claims as being correct. You must ignore any different definitions used by the witnesses or the attorneys.

You are advised that the following definitions for the following terms must be applied:

Claim Term	Construction
"decreasing mortality caused by congestive heart failure" / "to decrease a risk of mortality caused by congestive heart failure"	"attempt[ing] to reduce the probability that a patient will die as a result of congestive heart failure."
"maintenance period"	"period of time over which the maintenance dose is taken into a patient's body"
"maintenance dosage"	"dosages in the therapeutic amount given during the maintenance period"
"administering"	"prescribing, dispensing, giving or taking (such that what is prescribed, dispensed, given or taken is actually taken into a patient's body)"
"have been shown to statistically decrease"	"have been shown to reduce mortality by a statistically significant amount"
"congestive heart failure"	"a condition that occurs as a result of impaired pumping capability of the heart and is associated with abnormal retention of water and sodium."

For any words in the claim for which I have not provided you with a definition, you should apply the plain and ordinary meaning to a person of ordinary skill in the art.

3.4. INDEPENDENT AND DEPENDENT CLAIMS

There are two different types of claims in the patent. The first type is called an "independent claim." An independent claim does not refer to any other claim of the patent. An independent claim is read separately to determine its scope. In this case, claim 1 of the '000 patent is an independent claim. You know this because it mentions no other claims. Accordingly, the words of claim 1 of the '000 patent are read by themselves in order to determine what claim 1 covers. The remaining claims of the '000 patent are dependent claims.

A "dependent claim" refers to and depends upon at least one other claim in the patent and thus incorporates all of the requirements of the claims to which it refers. Accordingly, to determine what a dependent claim covers, you must read both the dependent claim and the claim to which it refers. Here, for example, claim 2 of the '000 patent is a dependent claim. You know this because it refers to independent claim 1. Accordingly, the words of claims 1 and 2 are read together in order to determine what claim 2 of the '000 patent covers.

3.5. EFFECT OF REISSUE

When a patent owner submits a patent to the United States Patent Office for reissue, the surrender of the original patent takes effect at the moment when the reissue patent is granted. In other words, surrender and reissuance go hand-in-hand. Once the Patent Office grants the reissue patent, the original patent is no longer enforceable.

4. INFRINGEMENT

4.1. INFRINGEMENT GENERALLY

I will now instruct you how to decide whether GSK has proven by a preponderance of the evidence that Teva infringed the asserted claims of the '000 patent.

Recall that GSK must prove infringement by a preponderance of the evidence, i.e., that it is more likely than not that infringement has occurred.

You have heard evidence that both sides own other patents relating to carvedilol. As I stated earlier, there is only one patent at issue in this case: the '000 patent. Ownership of a patent is not a defense to patent infringement, nor is ownership of other patents evidence of infringement. Instead, for purposes of infringement, you must only consider the '000 patent

You must determine whether GSK has proven that Teva induced infringement for two time periods. The first time period is from January 8, 2008 through April 30, 2011. The parties have referred to this time period as the "Skinny Label Period" or "Partial Label Period." The second time period is from May 1, 2011 through June 7, 2015, when the '000 patent expired. The parties have referred to this time period as the "Amended Label Period" or "Full Label Period."

4.2 INDUCED INFRINGEMENT

GSK alleges that Teva is liable for infringement by actively inducing physicians to engage in acts that directly infringe the '000 patent. You must determine whether there has been active inducement on a claim-by-claim basis. Induced infringement may be shown by direct or circumstantial evidence. Teva is liable for active inducement of a claim only if GSK proves by a preponderance of the evidence each of the following:

1. that allegedly infringing acts are actually carried out by physicians that directly infringed one or more of the asserted claims of the '000 patent.
2. that Teva took some affirmative action, or that Teva continued to take an action that began before the '000 patent issued, after the '000 patent was issued on January 8, 2008, intending to cause the physicians to directly infringe by administering Teva's carvedilol product;
3. that Teva was aware of the '000 patent -- and that Teva knew that the infringing acts, if taken, would constitute direct infringement of the '000 patent by the physicians, or Teva believed that there was a high probability that the actions taken by others infringed the '000 patent and took deliberate steps to avoid learning of that infringement; and
4. that Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe.

I will now instruct you further as to the law for each of these elements.

4.2.1 DIRECT INFRINGEMENT

As I mentioned, a finding of induced infringement requires a showing that someone has directly infringed. However, a patentee is not required to present hard proof that any individual third-party direct infringer was actually persuaded to infringe, but may instead present evidence of inducement directed to an entire class of direct infringers.

GSK alleges that doctors as a class directly infringe the '000 patent. In order to prove direct infringement, GSK must prove by a preponderance of the evidence, i.e., that it is more likely than not, that doctors used Teva's carvedilol product in a manner that meets all of the requirements of a claim.

Deciding whether a claim has been directly infringed is a two-step process. The first step is to decide the meaning of the patent claim. I have already made this decision and I have already instructed you as to the meaning of some terms of the asserted patent claims. The second step is to decide whether any uses of Teva's generic carvedilol product are covered by an asserted claim.

To decide whether any uses of Teva's generic carvedilol product directly infringe an asserted claim, you must compare that use with the patent claim and determine whether every requirement of the claim is included in that use. If so, then that use of Teva's generic carvedilol product directly infringes that claim. If not, then the use does not directly infringe that claim.

You must determine, separately for each asserted claim, whether or not there is any infringement. There is one exception to this rule. If you find that an independent claim on which other claims depend is not infringed, there cannot be infringement of any dependent claim that refers to that independent claim. On the other hand, if you find that an independent claim has been infringed, you must still decide, separately, whether the use meets additional requirements of any claims that depend on the independent claim, and thus, whether those claims

have also been infringed. A dependent claim includes all the requirements of any of the claims to which it refers plus additional requirements of its own.

You may find direct infringement based on as little as one instance of the claimed use being performed. Proof of direct infringement may be based on circumstantial evidence.

4.2.2 AFFIRMATIVE ACTIONS INTENDED TO CAUSE INFRINGEMENT

GSK must prove by a preponderance of the evidence that Teva took actions after January 8, 2008 with the specific intent to cause physicians to engage in infringing acts. This can be shown through direct or circumstantial evidence.

In order to establish active inducement of infringement, it is not sufficient that physicians directly infringe the '000 patent. Nor is it sufficient that Teva was aware of acts by others that would directly infringe. Rather, in order to find inducement, you must find that Teva intended others to use its products in at least some ways that would infringe the asserted claims of the '000 patent, took affirmative acts to encourage direct infringement, and that those actions actually caused the direct infringement of the asserted claims of the '000 patent.

The parties do not dispute that a substantial percentage of the uses of carvedilol do not infringe the claims of the '000 patent. GSK must prove by a preponderance of the evidence that Teva took affirmative actions intending to induce infringement.

Among the evidence on which GSK has relied in attempting to show that Teva induced infringement of the '000 patent is evidence of statements in Teva's label for its generic carvedilol product. I remind you that there are two labels at issue in this case. The first is the so-called Skinny-Label or Partial Label from January 8, 2008 through April 30, 2011. The second label has been referred to as the Amended Label or Full Label, which was available from May 1, 2011 through the expiration of the '000 patent in June 7, 2015. You will need to consider each label separately.

GSK has also relied on the fact that Teva's generic product has an AB rating. The fact that Teva obtained an AB rating for its generic product is not by itself a sufficient basis to find that Teva had an intent to infringe.

4.2.3 KNOWLEDGE THAT THE ACTS, IF TAKEN, WOULD CONSTITUTE INFRINGEMENT

GSK must prove by a preponderance of the evidence that Teva was aware of the '000 patent. GSK must also prove by a preponderance of the evidence that Teva knew that the acts it induced physicians to take would, if taken, constitute infringement of the '000 patent, or that Teva believed that there was a high probability that the actions taken by physicians would infringe the '000 patent and took deliberate steps to avoid learning of that infringement.

Inducing infringement cannot occur unintentionally. It is not enough for the accused inducer to lead another to engage in conduct that happens to amount to infringement. Rather, to induce infringement, the accused inducer must persuade another to engage in conduct that the inducer knows – or believes with high probability, but deliberately avoided confirming – is infringement.

4.2.4 INDUCEMENT MUST CAUSE DIRECT INFRINGEMENT

Finally, GSK must prove that Teva's alleged inducement, as opposed to other factors, actually caused physicians to directly infringe the '000 patent. This means that Teva cannot be liable for induced infringement where GSK does not show that Teva successfully communicated with and induced a third-party direct infringer and that the communication was the cause of the direct infringement by the third-party infringer.

Like all other disputed issues in this case, this final element of induced infringement can be proven by circumstantial evidence. GSK is not required to present hard proof of any direct infringer physician stating, for example, that she read Teva's labels or other Teva materials and that these labels or other Teva materials caused her to prescribe Teva's generic carvedilol in an infringing manner. GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial – as opposed to direct – evidence.

4.3 WILLFUL INFRINGEMENT

If you have decided that Teva has induced infringement, you must go on and address the additional issue of whether or not this infringement was willful. To prove willful infringement, GSK must prove by a preponderance of the evidence that Teva had knowledge of '000 patent, and that Teva's conduct was reckless, willful, wanton, malicious, committed in bad faith, deliberate, consciously wrongful, flagrant, or as it may be described – "characteristic of a pirate." To determine whether Teva acted willfully, consider all of the facts.

If you do decide that there was willful infringement, that decision should not affect any damage award you give in this case.

5. INVALIDITY

5.1 INVALIDITY GENERALLY

The granting of a patent by the United States Patent and Trademark office carries with it the presumption that the patent is valid. The law presumes that the Patent and Trademark Office acted correctly in issuing the patent. Each of the asserted claims is presumed valid independently of the validity of each other claim. This presumption puts the burden on Teva of proving invalidity by clear and convincing evidence on a claim-by-claim basis; that is, you must be left with an abiding conviction that the asserted claims of the '000 patent are invalid. This burden may be more difficult to meet when the accused infringer attempts to rely on prior art that was before the patent examiner during prosecution.

Patent invalidity is a defense to patent infringement.

Even though the Patent Office examiner allowed the claims of a patent, you have the ultimate responsibility for deciding whether the claims of the patent are proven to be invalid. For a patent to be valid, the subject matter claimed in the individual claims of the patent must be new, non-obvious, and the specification of the patent must contain a sufficient written description of the claimed invention. A patent cannot take away from the right of anyone who wants to use what was already known or used by others, or what would have been obvious to those of skill in the art at the time the invention was made.

Teva alleges that the '000 patent is invalid because:

1. claims 1-3 and 6-9 are anticipated by David Kelly's 1993 article "Carvedilol in Heart Failure," which I will refer to as "Kelly 1993";
2. claims 1-3 and 6-9 are obvious in light of the prior art; and

3. claim 8 lacks an adequate written description because the specification does not suggest the inventors were in possession of methods for reducing mortality cause by CHF using carvedilol.

I will now instruct you in more detail why Teva alleges that the asserted claims of the '000 patent are invalid.

5.2 LEVEL OF ORDINARY SKILL

Patent invalidity defenses are evaluated from the perspective of a hypothetical "person of ordinary skill in the art" The hypothetical person of ordinary skill in the art is presumed to be aware of all the prior art at the time of the invention. You are to determine the level of ordinary skill in the art to which the claimed invention pertains at the time the claimed invention was made. In deciding what the level of ordinary skill in the relevant field is, you should consider all the evidence introduced at trial, including but not limited to: the levels of education and experience of other persons actively working in the field.

5.3 ANTICIPATION

In order for someone to be entitled to a patent, the invention must actually be new. In general, inventions are new when the identical invention as claimed has not been used or disclosed before. If the claim is not new, we say that it was "anticipated" by prior art. Prior art is the general body of knowledge in the public domain, such as articles or other patents before the claim was made. A claim that is "anticipated" by the prior art is not entitled to patent protection.

Anticipation must be proved on a claim-by-claim basis. In this case, Teva alleges that claims 1-3 and 6-9 of the '000 patent are anticipated by the Kelly reference. Teva must convince you of this by clear and convincing evidence, i.e., that the evidence leaves you with an abiding conviction that it is highly probable that the claims are invalid. To anticipate a claim, each and every element in the claim must be present in a single item of prior art, and arranged or combined in the same way as recited in the claim. You may not combine two or more items of prior art to find anticipation.

To anticipate the invention, the disclosure in the prior art reference does not have to use the same words as the claim, but all of the requirements of the claim must be there, either stated expressly or inherently, so that someone of ordinary skill in the art to which the claimed invention pertains, looking at that one reference, could make and use the claimed invention. Thus, for purposes of anticipation, you should consider that which is expressly stated or present in the item of prior art, and also that which is inherently present.

A party claiming inherent anticipation must prove by clear and convincing evidence that the allegedly inherent element necessarily is present. Occasional results are not inherent. A claim is inherently anticipated when the claimed invention inherently (necessarily) results from

practice of what is disclosed in the written reference, even if the inherent disclosure was unrecognized or unappreciated by one of ordinary skill at the time of the reference.

In assessing Teva's anticipation defense, you must decide whether Teva has proven by clear and convincing evidence that Kelly expressly or inherently discloses to a person of ordinary skill in the art all the physical steps of the claimed treatment method. Thus, you must compare the physical steps of the patent with the physical steps of the prior art method and assess whether there is a manipulative difference between them. One example of a manipulative difference would be if the patented method and the prior art method are directed to treatment of two different patient populations. If there is no difference between the steps of the prior art and patented method, then the result is inherent and the claim is anticipated.

Prior art that discloses a generic use can anticipate a claim applying a more specific use that falls within the generic use. The question is whether one of ordinary skill in the art is able to "at once envisage" the more specific use provided in the asserted claim based on the more generic use provided in the prior art.

In addition, in order for a prior art reference to anticipate a claim, it must enable a person of ordinary skill in the art to make and use the invention without undue experimentation. The prior art reference must be sufficiently described to place the public in possession of the invention such that persons of skill would know how to practice or carry out the claimed method in light of the reference. For purposes of anticipation, a prior art printed publication, such as Kelly, is presumed to be enabling. GSK bears the burden of proving non-enablement of Kelly by a preponderance of the evidence. With respect to non-enablement of Kelly, the sole question for you to decide is whether Kelly is too theoretical to be enabled. Teva bears the ultimate burden to show anticipation by clear and convincing evidence.

When considering the question of enablement of the prior art, you may consider other prior art references. Anticipation does not require actual performance of suggestions in a disclosure. Proof of efficacy is not required for a prior art reference to be enabling. You must make your decision whether or not the degree of experimentation required is undue based upon all of the evidence presented to you. You should determine whether or not, in the context of the Kelly publication and the state of the art at the time of GSK's patent application, a person having ordinary skill would need to experiment unduly to make and use the full scope of the printed publication.

Some factors you may consider in determining whether it would take undue experimentation to practice the claimed method include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance required; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Finally, in considering Teva's anticipation defense, you must take into account the following rulings that I have made:

1. Kelly discloses administering carvedilol with an ACE inhibitor as required by claim 1 of the '000 patent.
2. Kelly discloses administering a "therapeutically acceptable amount" of carvedilol in "daily maintenance dosages" as required by claim 1 of the '000 patent.
3. The inherency arguments advanced by applicants to the Patent Office during prosecution are not the same inherency arguments now being advanced by Teva in this case.

5.4 OBVIOUSNESS--GENERALLY

Even though an invention may not have been identically disclosed or described before it was made by an inventor, in order to be patentable, an invention must not have been obvious to a person of ordinary skill in the art at the time the invention was made.

Teva contends that the asserted claims of the '000 patent are invalid for obviousness. Teva bears the burden of proving obviousness by clear and convincing evidence. To establish that a patent claim is invalid for obviousness, Teva must show, by clear and convincing evidence, that the claimed invention would have been obvious to a person having ordinary skill in the art at the time the invention was made. In determining whether the claimed invention was obvious, you must consider each claim separately. You should not use hindsight, such as by using the '000 patent as a roadmap to select from the prior art and retrace the path of the inventors. In other words, you should only consider what was known prior to the invention date, without the benefit of the later '000 patent and what that patent teaches.

In order to be patentable, an invention must not have been obvious to a person of ordinary skill in the art at the time the invention was made. The issue is not whether the claimed invention would be obvious today to you, as a layperson, to me as a judge, or to a genius in the art, but whether it would have been obvious to one of ordinary skill in the art at the time it was made. The existence of each and every element of the claimed invention in the prior art does not necessarily prove obviousness. Most, if not all, inventions rely on building blocks of prior art. To show obviousness, the law does not require that the prior art provide proof, to a statistical certainty, that the claimed result would work. In the context of obviousness, only a reasonable expectation of success is required, not conclusive proof or absolute predictability.

You must put yourself in the place of a person of ordinary skill in the art at the time of invention. In addition, you may consider whether there was a reason to combine or modify the

prior art references in the fashion claimed by the patent at issue. To find that the prior art rendered a claimed invention obvious, you must find that a person having ordinary skill in the art would have had a reasonable expectation of successfully accomplishing the claimed method.

In determining obviousness or non-obviousness of the subject matter of each of the asserted claims, you should take the following steps:

1. Determine the scope and content of the prior art;

2. Identify the differences, if any, between each asserted claim and the prior art;

3. Determine the level of ordinary skill in the pertinent art at the time the invention of the patent was made; and

4. Consider objective factors of non-obviousness

Against this background, you will then decide whether the subject matter of each asserted claim would have been obvious or nonobvious to a person of ordinary skill in the pertinent art.

5.4.1 SCOPE AND CONTENT OF THE PRIOR ART

As I just instructed you, in deciding whether or not the claimed invention is obvious to one of ordinary skill in the art, you must first determine the scope and content of the prior art. This means that you must determine what prior art is reasonably pertinent to the particular problem with which the inventor was faced. Prior art is reasonably pertinent if it is in the same field as the claimed invention or is from another field that a person of ordinary skill would look to in trying to solve the problem the named inventor was trying to solve.

5.4.2 DIFFERENCES BETWEEN THE CLAIMED INVENTION AND PRIOR ART

You should analyze whether there are any relevant differences between the prior art taken as a whole and the asserted claims of the '000 patent from the view of a person of ordinary skill in the art as of February 8, 1995. Your analysis must determine the impact, if any, of such differences on the obviousness or nonobviousness of the invention as a whole, and not merely some portion of it. Keep in mind that a claim is not proved obvious merely by demonstrating that each of the elements existed in the prior art. Most, if not all, inventions rely on building blocks of prior art. Therefore, you should consider the prior art as a whole and determine whether a reason existed at the time of the invention that would have prompted a person of ordinary skill in the art in the relevant field to combine the known elements in the way the claimed invention does.

The reason could come from the prior art, the background knowledge of one of ordinary skill in the art, the nature of the problem to be solved, market demand, or common sense. You may also consider whether the problem or need was known, the possible approaches to solving the problem or addressing the need were known and finite, and the solution was predictable through use of a known option. Accordingly, you may evaluate whether there was some teaching, suggestion, or motivation to arrive at the claimed invention before the time of the claimed invention although proof of this is not a requirement to prove obviousness. Teachings, suggestions, and motivations may be found in written references including the prior art itself. However, teachings, suggestions, and motivations may also be found within the knowledge of a person with ordinary skill in the art including inferences and creative steps that a person of ordinary skill in the art would employ. Additionally, teachings, suggestions, and motivations

may be found in the nature of the problem solved by the claimed invention, or any need or problem known in the field of the invention at the time of and addressed by the invention.

In analyzing the relevance of the differences between a claimed invention and the prior art, you do not need to look for precise teaching in the prior art directed to the subject matter of the claimed invention. On the other hand, if the combination of known elements yielded unexpected or unpredictable results, or if the prior art teaches away from combining the known elements, then this evidence would make it more likely that the claim that successfully combined those elements was not obvious.

5.4.3 LEVEL OF ORDINARY SKILL

I have already given you instructions about how to determine the level of ordinary skill at Instruction 5.2.

5.4.4 OBJECTIVE EVIDENCE OF NONOBVIOUSNESS

You must also take into account any objective evidence (sometimes called "objective indicia" or "secondary considerations") that may shed light on whether the claims were obvious. "Objective indicia" or "secondary considerations" must be considered before a conclusion on obviousness is reached.

"Objective indicia" or "secondary considerations" can include:

(A) Whether the invention was commercially successful at least in part as a result of the merits of the claimed invention (rather than the result of design needs or market-pressure advertising or similar activities);

(B) Whether the invention satisfied a long-felt need;

(C) Whether others copied the invention;

(D) Whether the invention achieved unexpected results compared to the closest prior art; evidence of unexpected results may be used to rebut a case of obviousness even if that evidence was obtained after the patent's filing or issue date; there is no requirement that an invention's properties and advantages were fully known before the patent application was filed, or that the patent application contains all of the work done in studying the invention;

(E) Whether others tried and failed to make the invention;

(F) Whether others in the field praised the invention;

(G) Whether persons having ordinary skill in the art of the invention expressed surprise or disbelief regarding the invention;

(H) Whether the inventor proceeded contrary to accepted wisdom in the field; and

(I) Whether others invented the invention at roughly the same time.

GSK has the burden to show evidence of "objective indicia" or "secondary considerations" and to show that there is a connection, sometimes called a "nexus," between the

evidence showing any of these factors and the claimed invention, if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue. However, Teva always maintains the ultimate burden to show obviousness by clear and convincing evidence, taking into account any objective indicia that you may find.

5.5 WRITTEN DESCRIPTION

Teva contends that the asserted claims of the '000 patent are invalid for lack of an adequate written description. Teva has the burden of proving lack of adequate written description for each asserted claim by clear and convincing evidence.

The law requires that a patent application contain an adequate written description of the invention to ensure that the inventor was in possession of the invention at the time the patent application was filed.

The written description requirement is satisfied if a person having ordinary skill reading the patent application would have recognized that the application describes the full scope of the claimed invention as it is finally claimed in the issued patent and that the inventor actually possessed that full scope by the filing date of the relevant application.

In the patent application process, the applicant may keep the originally filed claims, or expand, narrow or change the claims between the time the patent application is first filed and the time a patent is issued. An applicant may amend the claims or add new claims. The written description requirement ensures that the issued claims correspond to the scope of the written description that was provided in an application.

In deciding whether a specification satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent when the application was filed. The written description requirement may be satisfied by any combination of words, structures, figures, diagrams, formulas, experiments, data, etc., contained in the patent application.

6 PATENT DAMAGES

6.1 DAMAGES INTRODUCTION

If you find that Teva induced infringement of any valid claim of the '000 patent, you must then consider what amount of damages to award to GSK. I will now instruct you about the measure of damages. By instructing you on damages, I am not suggesting which party should win this case, on any issue. If you find that each of the asserted claims is either invalid or not infringed, then you need not address damages in your deliberations.

The damages you award must be adequate to compensate GSK for the infringement. They are not meant to punish an infringer. Your damages award, if you reach this issue, should put GSK in approximately the same financial position that it would have been in had the infringement not occurred.

GSK has the burden to establish the amount of its damages by a preponderance of the evidence. In other words, you should award only those damages that GSK establishes that it more likely than not suffered. GSK must prove the amount of damages with reasonable certainty, but need not prove the amount of damages with mathematical precision. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

There are different types of damages that GSK may be entitled to recover. In this case, GSK seeks lost profits. Lost profits consist of any actual reduction in business profits GSK suffered as a result of Teva's infringement. Teva contends that lost profits are not available to GSK, and a reasonable royalty is the proper measure of damages. A reasonable royalty is defined as the money amount GSK and Teva would have agreed upon as a fee for use of the invention at the time prior to when infringement began.

I will now give you more detailed instructions regarding damages.

6.2 DATE DAMAGES BEGIN AND END

GSK filed this lawsuit on July 3, 2014. GSK may seek damages for up to six years before this lawsuit was filed. The '000 patent expired on June 7, 2015. Therefore, the maximum period over which GSK may recover damages is from July 3, 2008 through June 7, 2015.

In determining damages, you must determine when the damages began. There are two potential damages starting dates in this case. The first date is July 3, 2008, which is when Teva was selling its generic carvedilol with the Skinny or Partial Label, and which under the law is the maximum time period for which GSK may collect damages against Teva for infringement of the '000 patent. The second date is May 1, 2011, which is the date that Teva amended to its "full" label. You must decide which of these damages starting dates to apply based on the facts.

6.3 LOST PROFITS

GSK is seeking lost profits damages in this case. To prove lost profits, GSK must show a causal relationship between Teva's induced infringement and GSK's loss of profit. GSK must show that, but for Teva's infringement, GSK would have made additional profits through the sale of all or a portion of the sales of carvedilol made by Teva. GSK must prove this by a preponderance of the evidence, more likely than not. Part of your job is to determine what the customers who purchased carvedilol from Teva would have done if the alleged infringement had not occurred. It is important to remember that the profits I have been referring to are the profits allegedly lost by GSK, not the profits, if any, made by Teva on the allegedly infringing sales.

6.3.1 LOST PROFITS—THE PANDUIT FACTORS

GSK has proven its lost profits if you find that, with respect to sales of Teva's product that were used to infringe the '000 patent and for which the infringement was caused by Teva's inducement, GSK has proven each of the following factors by the more likely than not standard:

(1) There was a demand for the patented method;

(2) GSK would have captured infringing sales made by Teva, despite the availability of other acceptable noninfringing substitutes;

(3) That GSK had the manufacturing and marketing ability to make the sales of Teva's carvedilol actually made by Teva and for which GSK seeks an award of lost profits—in other words, that GSK was capable of satisfying the demand; and

(4) The amount of profit that GSK would have made if Teva had not infringed.

I will now explain each of these factors.

6.3.2 LOST PROFITS—DEMAND

The first factor asks whether there was demand for the patented method in the relevant market. GSK can prove demand for the patented invention by showing significant sales of GSK's Coreg® for accomplishing a claimed method or significant sales of Teva's carvedilol for accomplishing a claimed method but not for sales of these products for purposes of accomplishing a use that is not claimed in the '000 patent.

6.3.3 LOST PROFITS—ACCEPTABLE NONINFRINGING SUBSTITUTES

The second factor asks whether there were non-infringing, acceptable substitutes for the patented products in the marketplace and the impact of such substitute products on the marketplace absent the sale of Teva's carvedilol. If the realities of the marketplace are that competitors other than GSK would likely have captured some or all of the sales made by Teva, even despite a difference in the products, then GSK is only entitled to lost profits on those sales that it would have captured, not those sales that would have been captured by others.

To be an acceptable substitute, the products must have had one or more of the advantages of the patented invention that were important to the actual buyers of the infringing products, not the public in general. The use of the acceptable substitutes also must not infringe the patent because they did not include all the features required by the patent. For example, the use of generic carvedilol supplied by companies other than Teva was not an acceptable non-infringing substitute. The acceptable substitutes, in addition, must have been available during the damages period. An acceptable non-infringing substitute is available if, during the damages period, a competitor or Teva had all the necessary equipment, materials, know-how, and experience to design and manufacture the acceptable non-infringing substitute. The substitute need not have actually been sold at that time. If you determine that some of Teva's customers would just as likely have purchased a non-infringing acceptable product, then GSK has not shown it lost those sales but for Teva's sales.

6.3.4 LOST PROFITS—CAPACITY

The third factor asks whether GSK had the manufacturing and marketing ability to actually make the sales it allegedly lost due to Teva's infringement. GSK must prove that it could have supplied the Coreg® needed to make the sales GSK said it lost. GSK must also prove that it is more likely than not it had the ability to market and sell the additional Coreg®.

6.3.5 LOST PROFITS—AMOUNT OF PROFIT

A patent holder may calculate its lost profits on lost sales by computing the lost revenue for sales it claims it would have made but for the infringement, and subtracting from that figure the amount of additional costs or expenses it would have incurred in making those lost sales, such as cost of goods, sales costs, packaging costs, and shipping costs. Certain fixed costs that do not vary with increases in production or scale, such as taxes, insurance, rent, and administrative overhead, should not be subtracted from a patent holder's lost revenue.

GSK is not entitled to lost profits based on any infringement of the '000 patent that was not caused by Teva's inducement. GSK has the burden of proving the amount of any direct infringement that was caused by Teva's inducement with reasonable certainty. However, GSK need not provide direct evidence that Teva induced any specific use of Teva's carvedilol according to the patented method to obtain lost profits damages. In other words, GSK need not demonstrate a one-to-one correspondence between Teva's sales of carvedilol and directly infringing physicians. GSK may introduce circumstantial evidence of direct infringement by the entire class of physicians prescribing Teva's generic carvedilol for the patented method.

6.4 REASONABLE ROYALTY—GENERALLY

A reasonable royalty is the royalty that would have resulted from a hypothetical negotiation between the patent owner and the alleged infringer just before the infringement began. In considering this hypothetical negotiation, you should focus on what the expectations of the patent holder and the infringer would have been if they had entered into an agreement at that time, and if they had acted reasonably in the negotiations. You should assume that both parties to the hypothetical negotiation believed the patent to be valid and infringed and that both parties are willing to enter into a license. You should also assume that the patent holder and the infringer would have acted reasonably and would have entered into a license agreement.

Having that in mind, you may consider any relevant fact in determining the reasonable royalty for the use of a patented invention, including the opinion testimony of experts. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

A reasonable royalty is typically made up of (1) a base and (2) a rate (or percentage) that is applied to that base. The ultimate combination of royalty base and royalty rate must reflect the value attributable to the infringing features of the product, and no more.

7 DELIBERATION AND VERDICT

7.1 INTRODUCTION

I have concluded the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

7.2 UNANIMOUS VERDICT

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges – judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A form of verdict has been prepared for you. I will review it with you in a moment. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. You will then return to the courtroom and my deputy will read aloud your verdict.

It is proper to add the caution that nothing said in these instructions, and nothing in the form of a verdict, is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is your sole and exclusive duty and responsibility.

7.3 DUTY TO DELIBERATE

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that – your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

7.4 SOCIAL MEDIA

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, a cell phone, smartphone, iPhone, blackberry, tablet or computer, the Internet, any Internet service, any text or instant messaging service, any Internet chat room, blog or website such as Facebook, LinkedIn, YouTube, Instagram, Snapchat or Twitter to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

7.5 COURT HAS NO OPINION

Let me finish by repeating something I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.