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Judge Dyk (00:00:00):

Pleasure of moving the admission of my four law clerks who wish to become members of the bar of this court. So could you please stand? And Judge Moore will preside for purposes of these motions. First, I move the admission of David Bender, who is a member of the bar and is good standing of the highest court of New York. I have knowledge of his credentials. I'm satisfied that he possesses the necessary qualifications. And next I move the admission of Stanley Chin, who's a member of the bar and is in good standing with the highest court of California. I have knowledge of his credentials and am satisfied that he possesses the necessary qualifications. Next, I moved the admission of Andrew W. Rob who's a member of the bar and is in good standing with the highest court of California. I have knowledge of his credentials and then satisfied that he possesses the necessary qualifications.

Judge Dyk (00:01:02):

And then finally, I move the admission of Alyssa van Toobagan, who is a member of the bar, and is in good standing with the highest court of Illinois. And I have knowledge of her credentials and I'm satisfied that she possesses the necessary qualifications. And I'd like to say, with respect to all four of you, that not only do you have the necessary qualifications, which is sort of a minimum standard, that you are, have been exceptional law clerks each and every one of you. And it has been an immense pleasure to have you. And I'm proud to have you as members of the bar here and look forward to your appearing before us. And I'm sure you will do as excellent a job when you appear before us as you have as law clerks. So thank you. So.

Judge Moore (00:01:46):

Any objection, Evan?

Judge Wallach (00:01:47):

I have no doubt based on Judge Dyk's recommendation that they're imminently qualified.

Judge Moore (00:01:53):

This is one—I'd say apart from marrying each of you someday—this is the most fun day—

Judge Dyk (00:02:00):

Some of them are married already.

Judge Moore (00:02:02):

Okay!

Court (00:02:02):

<Laughs>

Judge Moore (00:02:04):

You better not be married. This is one of the nicest and most joyous things that we judges get to do for our clerks. So I welcome each of you to our bar and please turn face the Admiral who will administer the oath.

Admiral (00:02:21):

Do each of you solemnly swear [**inaudible**] truth of court, yourselves as attorneys and counselors of this court, uprightly and according to law and that you will support the Constitution of the United States of America.

Clerks (00:02:32):

I do.

Admiral (00:02:32):

Congratulations. Welcome to the bar.

Judge Dyk (00:02:32):

Congratulations. All right. We'll turn to our two cases this morning. The first of these is number 141274 Momenta Pharmaceuticals, Inc. versus Teva Pharmaceuticals. Ms. Maynard.

Deanne Maynard (00:02:56):

Thank you, Your Honor. Just as preliminary matter to the court grant to the motion to consolidate the arguments of the two cases. And so we will be arguing—I'll be arguing both the first two cases, my opening position, and then I believe my colleagues [**inaudible**] are going to take their turns.

Judge Dyk (00:03:09):

That's fine. Fine.

Deanne Maynard (00:03:11):

Thank you, Your Honor. May it please the court. Deanne Maynard for appellant Sandoz and Momenta—

Judge Dyk (00:03:19):

Could I understand what your position is at this point? I've read the briefs carefully. Do I understand correctly that you're saying that the running of the process itself is protected by the Safe Harbor, but that the use of it for commercial sale is not protected and that there's an infringement under 271G as a result. Is that, is that a fair statement of the position?

Deanne Maynard (00:03:47):

No, Your Honor. That's partly correct. Our position is that the plain text of both section 271E and 271G makes the—both the use, the use is not protected under 271E and the sales are infringing. Under—

Judge Dyk (00:04:07):

So your position is that the running of the test itself is not protected by the Safe Harbor?

Deanne Maynard (00:04:11):

That's correct, Your Honor, the Amphastar and Teva manufacturer are using Momenta's patented methods who make each commercial batch of enoxaparin for sale. That commercial exploitation of the patented invention is not covered by the plain text of section 271E.

Judge Dyk (00:04:31):

Look, could I—if I understand you brief correctly, what you're saying is that the running of the test has a dual purpose that it's run to ensure FDA compliance and that it also, quite apart from that, has a commercial purpose. Is that—am I understanding that correctly?

Deanne Maynard (00:04:49):

Yes and no, Your Honor, if I may. So, just a step back. When the Safe Harbor covers activities that one do to develop information for submission to the FDA for regulatory approval, that could be pre-marketing approval or post-marketing approval, but it would still have to be for developing information that one's going to provide to the FDA for some type of regulatory approval. That's how the Supreme Court has consistently interpreted the 271E and that's consistent with its purpose, but once one moves past—

Judge Moore (00:05:17):

So why—what in 271E says anything about approval. It says under a fed—development and submission of information under a federal law, why are you infusing the word approval? No doubt, Merck and Lilly talked about approval because they were approval cases. But I don't see where approval gets morphed into either one.

Deanne Maynard (00:05:41):

Because it has to be the development and submission of information under a federal law. Here, the federal law is the FTCA. That refers the court to the FTCA. When the FTCA talks about submissions, it repeatedly talks about submissions in the context of presenting something to the FDA for some sort of approval to do something: file an NDA, to do a new drug file, an IND, file an ANDA.

Judge Dyk (00:06:05):

We, we dealt with that in the original opinion. And let's assume for the moment that we're not going to change that aspect of the, of the original opinion that the, the keeping of the information, which is available to the FDA falls within the Safe Harbor. Let's just assume that for a moment, my understanding is that you are arguing that even if that is so, that the testing here has a commercial purpose that is unrelated to the FDA compliance, is that correct?

Deanne Maynard (00:06:37):

That's correct. Your Honor. So I, I would like to fight hard the premise that your first opinion should be binding. I think under Supreme Court law it isn't all you decided was likelihood success. But taking that—

Judge Moore (00:06:46):

Okay. I'm sorry. Go ahead—

Deanne Maynard (00:06:48):

Taking that premise, you are correct that they are not using the test solely to develop and submit information for under the FDCA. They are using the test in their commercial manufacturing to, to decide which batches go into the final product and which batches do not. That—

Judge Dyk (00:07:09):

Okay now that's where I'm a little confused because I've read the briefs and I've looked at the references in the fact, what is it, what is the evidence that we have at this point that it has that commercial purpose, unrelated to FDA compliance?

Deanne Maynard (00:07:32):

So in the, in the Amphastar record, there's a declaration from Mr. Crawford.

Judge Dyk (00:07:38):

Who's Mr. Crawford?

Deanne Maynard (00:07:39):

He is a former pharmaceutical executive with lots of experience in the pharmaceutical industry.

Judge Dyk (00:07:46):

Okay.

Deanne Maynard (00:07:47):

And he describes the purpose it's at, in the Amphastar JA, Your Honor. It is at JA 12432.

Judge Dyk (00:07:54):

Is that in the first volume?

Deanne Maynard (00:07:57):

Yes, it is. Your Honor. The very back.

Judge Moore (00:08:02):

Is your argument that the word solely means that if you are doing it in order to comply with an FDA requirement, but also doing it for commercial purposes and wouldn't qualify under the Safe Harbor, because isn't everything you do in part for commercial purposes at some point?

Deanne Maynard (00:08:23):

Well, I think first, Your Honor, this, this would be, you know, fighting the premise of Judge Dyk's question, but the, there is, there is nothing about required by the FDA, in the text of the Safe Harbor, either. The fact that the FDA requires manufacturers to retain these records applies to every drug for both branded and generic that's manufacturing in the United States. If that is enough to fall within the Safe Harbor, then—

Judge Moore (00:08:51):

Well wait. Okay. So, but now you're arguing maintenance versus submission, I guess. I, so, so there's, there's, there's two.

Judge Moore (00:08:58):

I mean, you would say there are three statutory interpretation arguments here. I wouldn't agree with you on one of them, but the other two where I'm open-minded is the word solely and the word submission. I'm an all-out on the table kind of gal causes a lot of issues in this case. So I want to help you focus on what you might actually prevail on. So solely and submission, tell me how I should construe solely, which is the heart of Judge Dyk's question. And that was also what I was getting at with you, but you then morphed your answer into submission versus maintenance. So I would like you, if you could, to keep those as separate and discreet.

Deanne Maynard (00:09:32):

Thank—

Judge Moore (00:09:34):
Does that help?

Deanne Maynard (00:09:35):
Yes. Thank you. Honor. I'll focus on solely, but I would like to address the submission—

Judge Moore (00:09:37):
Go ahead. Well, if you really want to get to it, go to it.

Deanne Maynard (00:09:37):
Because I would like convince Your Honor.

Judge Moore (00:09:40):
I want to hear both.

Deanne Maynard (00:09:41):
No, I—

Judge Dyk (00:09:42):
Why don't we do that later? Let's stick with one thing at a time. Okay.

Deanne Maynard (00:09:45):
Thank you.

Judge Dyk (00:09:46):
So you have, you have this declaration, what does this declaration say about the commercial purpose of the testing that's non-FDA related?

Deanne Maynard (00:09:55):
The declaration, both the Crawford declaration and the Amphastar record and the Lou supplemental declaration in it, PVA record establish that they're doing it for quality control purposes in order to sort which batches are the drug they're trying to make and which batches are not the drug they're trying to make.

Judge Dyk (00:10:12):
Okay. So where, where do I find that in this declaration? Where, where does he say this?

Deanne Maynard (00:10:16):
So if you look at JA 12432,

Judge Dyk (00:10:22):
Okay.

Judge Dyk (00:10:24):
That's the—

Deanne Maynard (00:10:25):

That's the beginning. I'm sorry. So paragraph 24 on 12439.

Judge Dyk (00:10:31):

Okay.

Deanne Maynard (00:10:32):

And that paragraph not all of which I think I can out loud, but essentially it establishes that they use the process on intermediate drug substance to decide which batches of intermediate drug substance conform to what they're trying to make and which do not.

Judge Moore (00:10:48):

This is the 15 to 25%. Is that what I'm not supposed to say out loud? No, I'm allowed to say that that's in the end. That's right.

Deanne Maynard (00:10:55):

I think that's fine, Your Honor.

Judge Moore (00:10:57):

Okay.

Deanne Maynard (00:10:57):

So but what they're trying to do. Then they take, they test their batches that are going, so it's going along the assembly line as a manufacturing company for quality control purposes, they want to make sure that's what they sell is what they're intending to sell. They're checking it with our test. And that is a crucial step in their manufacturing process to decide what goes on and becomes in the syringe that they sell and what doesn't. Then if it passes the test, it gets joined together with other batches of conforming substance and ultimately continues along into the final product that is the syringe. They're doing the test for quality control purposes.

Judge Dyk (00:11:31):

Yeah, but the question is, are they doing the test for FDA purposes or independently for commercial quality control firms?

Judge Wallach (00:11:40):

Is the FDA requiring them to do that quality control?

Deanne Maynard (00:11:44):

The FDA requires drug manufacturers yes, to do everything that they've promised to do in their ANDA or their NDA. But once you move into routine commercial exploitation of a patented intervention, which is what this is, they're just using our process as part of making their enoxaparin. And they don't have to use our process. That's a crucial factual difference between the record now—

Judge Dyk (00:12:08):

Well what you're saying that they would be doing this anyway. Even if there weren't an FDA requirement?

Deanne Maynard (00:12:12):

As a drug manufacturer, responsible drug manufacturer, they would definitely be doing something to make

sure that what they're going to sell in their syringe is actually what they're purporting it to be. And that they're selling it for yes, Your Honor. Otherwise there's all kinds of consequences to drug manufacturers if they don't do that.

Judge Dyk (00:12:26):

Well is this a disputed issue as to whether this is done for non-FDA purposes?

Deanne Maynard (00:12:33):

Well, we've asserted in declarations with the Lu declaration and the Crawford declaration that these are done for quality control purposes. I do think that there, that this is not done solely—

Judge Dyk (00:12:44):

No, no. I understand what you think.

Deanne Maynard (00:12:46):

Right.

Judge Dyk (00:12:46):

What I'm asking you is this a matter that's disputed between the parties that there is this non-FDA purpose?

Deanne Maynard (00:12:54):

I believe it is disputed. I expect they will tell you they're doing it solely to comply with the FDA's requirement, but I think they would be doing something to ensure that their product is—

Judge Moore (00:13:02):

Would that then make it a question of fact, that's inappropriate for resolution on summary judgment?

Deanne Maynard (00:13:07):

That at a minimum would require reversal, that summary judgment was granted in their favor on this record. The, but I would like to switch if I may, to the submission versus—

Judge Wallach (00:13:16):

Before you do.

Deanne Maynard (00:13:16):

Yes, Your Honor.

Judge Wallach (00:13:17):

Let me switch you a little bit on focus on this question. You argue that even if the Safe Harbor exempts commercial use of, of the method Tevas' sales activity, isn't exempted has the patent on enoxaparin active ingredient expired?

Deanne Maynard (00:13:40):

Yes, that's my understanding, or it was held invalid. It's not in play anymore.

Judge Wallach (00:13:45):

Are there any patents on the actual chemical synthesis of the drug?

Deanne Maynard (00:13:53):

I do not know whether anyone claims a patent on a manufacturing method that would.

Judge Wallach (00:13:58):

Okay. What precedent or alleged history supports the view that a patent covering neither the active ingredient nor the actual chemical synthesis should prevent sales of enoxaparin, as opposed to preventing use of the method?

Deanne Maynard (00:14:16):

Because the whole purpose of the legislation was to prevent people from using patented processes by others, in order to make products that they were going to sell. And so it, what Teva has done is they're using—they've effectively done exactly what the principal purpose of the legislation was to stop, which is moved abroad or using our patent to process abroad as an essential step to making the final product that they're selling, which is the drug in the syringe to try to avoid liability. And when they bring that product—

Judge Dyk (00:14:51):

You're saying that a quality control process is a process by which the product is made. Is that the idea?

Deanne Maynard (00:14:57):

The test for whether the product is made by something is whether it's an essential step to the end product.

Judge Dyk (00:15:04):

So you're your content that the answer is yes.

Deanne Maynard (00:15:06):

In this situation. I don't think you have to hold as broadly as every quality control test Judge Dyk.

Judge Moore (00:15:11):

For example. Let me give you an example, Ms. Maynard. Suppose that there's a quality control test at the very end, because I only want to sell the best of my batches. I want to really be known for just the purest form of something and the very best. And so at the end, I've got 20 things that could arguably be sold, but I want to sell only the top three. And I do a quality control to see which one is the best, the purest, the whatever. And then I sell it. You would agree that that doesn't feel like made by language, right?

Deanne Maynard (00:15:38):

That would definitely be a harder case, but that's not what we have here. What we have here is the raw material is on one end of the process. It moves along the manufacturing to the syringe that sold that would be more like testing the syringe.

Deanne Maynard (00:15:48):

That would be more like the Philip Adams case. This isn't that. This is in the middle of the process where as the places I point to in the Crawford affidavit, Your Honor, and then in the Lou supplemental decoration for Teva is JA5162 to 69. This is testing of intermediate drug substance to decide what goes on and what doesn't almost like can—

Judge Moore (00:16:07):

Let me make it simple so I can understand. I'm baking a cake. I got two bowls of white powder in front of me. One is sugar, one salt. I don't know which ones which; recipe calls for a cup of sugar and a piece in the salt up. That's the salt boom, is that part of the process, my finger sticking in the salt to figure out which

one is salt. So I make the recipe properly part of making the cake.

Deanne Maynard (00:16:32):

I would argue it could be Your Honor. This is a much more complicated situation here. What the whole premise of their 271E argument is that this is a necessary step to determining whether what they're allowing to become in their final product is the enoxaparin sodium that they are allowed to sell.

Judge Dyk (00:16:49):

But what happens when they're testing the intermediate? It supposed suppose the intermediate flunks the test, is it discarded?

Deanne Maynard (00:16:55):

Yes, Your Honor. It's discarded. And that's what the batch records show and the records in here show, show that the—if one looks at the batch records in both of the JAs, one can see, and I can walk you through it. If you want to take the time to do that, that the lots are multiple batches are tested. If they pass a test, they're then joined together in one lot and then go along the process and are later formulated into the product that is the syringe. And under 2671G it is the product that is the syringe is the infringing sale. That's the sale. And so this is testing. It's an essential step in the words of, of Bayer V Houser and biotechnology. It's an essential step along the process.

Judge Moore (00:17:40):

And we have to decide this question regardless of what we conclude on 271E, isn't that correct?

Deanne Maynard (00:17:45):

That's true for two reasons, Your Honor, both in Teva, that's the basis of the liability. And in the Amphastar case, it's the basis of the liability for Octavus and Watson who are selling only. So, but to your point, judge Wallach, the biotechnology case is closer to what we have here. It is a case about a plasmid the patented method there makes the plasmid. The plasmid then makes another thing that makes the thing that is ultimately sold. So this is just like that. It's an essential step in the process from going with the starting heparin material to the syringe. And if you don't do it, you won't end up with the right thing in the syringe.

Judge Moore (00:18:22):

So Ms. Maynard, can I move you now to solely in submission, you really wanted to reach him before and nobody would let you, but I'd love for you to.

Deanne Maynard (00:18:28):

I, sorry.

Judge Moore (00:18:29):

So first, before you actually tell me your arguments on the merit, I'd like you to tell me why it isn't either law of the case, or some sort of binding precedent...

Judge Moore (00:18:40):

When some overly eager judge decides to write an opinion that addresses those issues, a statutory interpretation, even though they weren't raised free for argue by anybody at any point below or on appeal. So tell me why our court and or this case isn't governed by that prior decision of that overly side, the judge.

Deanne Maynard (00:18:57):

What the court was deciding before was whether or Momenta was likely to succeed. That was the limit of

your holding. The court stated that multiple times in its opinion—

Judge Moore (00:19:08):

And wasn't it true that only preapproval post approval was argued to us, but not solely, or the submission maintenance question?

Deanne Maynard (00:19:14):

That's correct, Your Honor, which is precisely why—

Judge Moore (00:19:16):

Wouldn't argue below and wasn't argued to us last time.

Deanne Maynard (00:19:18):

That's exactly right, Your Honor, which is precisely why the Supreme Court has said preliminary injunction opinions are only about what they've decided, which is who's likely to succeed, that there are two key aspects, but one of the ones you have focused on Your Honor is exactly right, which is neither submission nor maintenance or the distinction that the FTCA draws between those two terms was brief before this court. And it's very significant to the ultimate outcome on the merits here. It's now in this record, the FTCA treats those two terms differently. It—

Judge Dyk (00:19:48):

Wouldn't it be fair to say that the first time around this issue of 271G infringement and the, and the question of whether this testing has a non FDA purpose was not argued, right?

Deanne Maynard (00:20:00):

That's true too, Your Honor. So the, and also in addition, the test that we sought to leave to amend the district court, which is district court swept in under 271E were not before the court before. And we think the district court has done an overly generous view of 271E to keep us from amending those and that that was an error of law, and that we should be allowed to add those tests as well. But to Judge Moore's point, the submission point is clear from the text of the statute that submitting and maintaining are two distinct activities.

Judge Moore (00:20:31):

Well, it's clear the text of the FTCA statute. It's not clear from the text of the hatch Waxman act. I can't find the word maintaining anywhere else in the relevant statute that we're actually enforcing here.

Judge Moore (00:20:41):

I mean, do you agree?

Deanne Maynard (00:20:42):

Yes, but that's helpful to us, Your Honor, because it's only the development and submission of information that falls within the Safe Harbor, the maintenance of information doesn't fall within the Safe Harbor, but also to your point, if the development and submission of information under a federal law, and as you know, the FTCA is one of those federal laws. So it makes sense to look to that law, to see what the submission and that law makes clear. It repeatedly uses submission. Sometimes it's supposed to marketing for, but its submission submitting a change to use the drug for new use, submitting a change to your label, but just the ordinary routine maintenance of commercial records is not called the submission—

Judge Moore (00:21:18):

Because you have to maintain everything. Labeling shipping documents, basically any piece of paper that is produced in the course of manufacturing, things, selling or anything, a jug is required to be maintained.

Deanne Maynard (00:21:29):

Exactly under the same batch—

Judge Moore (00:21:31):

Talk about solely cause your time's going to run out.

Judge Dyk (00:21:32):

But wait, well, before we get to solely, one more question on that. It seems to me, there's a difference here between the maintenance of all the manufacturing records to show that you're complying with your own manufacturing procedures and maintaining records that are designed to show that you are complying with FDA requirements, this falls into the latter category. Doesn't it?

Deanne Maynard (00:21:56):

All records though, Your Honor, there are so many FDA requirements you're required by the FDA to do everything that's in your NDA and in your ANDA. And then you're required by these batch regulations that the court relied on one to keep records of all of it. So, basically, what you would be able to do under the logic of men. One is here propose Sanofi's method of manufacturing in your answer—

Judge Dyk (00:22:18):

I think you're not addressing my question, which—

Deanne Maynard (00:22:20):

I beg your pardon.

Judge Dyk (00:22:20):

Which is whether there's a difference between keeping records, which show that you're complying with FDA requirement and everybody agrees there's an FDA requirement here and keeping records, which are designed to show your manufacturing process. So if there is an issue later on as to your manufacturing process, that can, that can be looked at for that purpose. In other words, not all of the records that you're talking about are designed to document compliance with FDA requirements. No, or my mistaken?

Deanne Maynard (00:22:51):

Yeah. I'm not sure. I'd like to address that when I get back up, I'm not sure there's a distinction that you're trying to draw, Your Honor, all the records are required by the FDA. You're required to keep all of these records on—

Judge Moore (00:23:00):

Like labeling.

Deanne Maynard (00:23:01):

Everything that you do.

Judge Moore (00:23:02):

[**inaudible**] You've got a label.

Judge Wallach (00:23:03):

It's a Venn diagram in effect, the FDA requires to you to keep all the records used, say, you're going to keep as well as everything else we tell you to keep. Is that fair to say?

Deanne Maynard (00:23:13):

I can give it a more precise answer when I stand up Your Honor, but Judge Dyk, I just don't think there's a distinction and it wouldn't matter here. It would still make the Safe Harbor, a safe ocean. You would still be able to tell the FDA that you are going to use someone else's patented method to make your product. And as long as ANDA was approved and the FDA doesn't look to see whether or not it has, it is not approving ANDAs and NDAs based on any patent-based tests. It doesn't look to see whether you're violating somebody's patent, nothing in the Safe Harbor suggests that the FDA was given compulsory licensing authority by requiring or the—

Judge Dyk (00:23:48):

But that to show bio equivalency to the NDA product, right?

Deanne Maynard (00:23:51):

No, Your Honor. No, Your Honor. So just to clarify, just step back. So bio equivalency is something you show during the regulatory approval process in order to be allowed to make a generic drug.

Judge Dyk (00:24:00):

Right.

Deanne Maynard (00:24:00):

Bio equivalency is that your drug will have the same effect on the human body as the brand of drug. Once you get marketing approval, then you simply have to comply with the manufacturing processes that you told the FDA you were going to do. That's what every drug manufacturer does. That's what these batch calculations are for. They could have; we have not charged with infringement. Any activity that occurred for the purposes of showing bio equivalency to get approved.

Judge Dyk (00:24:28):

No, no, I understand that. But I thought there was, I thought the purpose of these tests was to show that the continued manufacturer of the product was the same as what was proposed in the first place.

Deanne Maynard (00:24:38):

No, Your Honor, the purposes of these batch regulations, and this is in our reply brief, like on pages, the very introduction of the gray brief to the Amphastar case is to show that you are complying with the manufacturing procedures that you told the FDA you would comply with. There's not this continuing approval that Amphastar argued in the first case you are approved, then you must keep doing it. Every drug manufacturer must keep doing what they told will be FDA. They were going to do branded and generic. And so the upshot of the rationale would be if you told the FDA. So in that sense everything's required, everything that you tell the FDA you're going to do is required.

Judge Dyk (00:25:18):

Okay. I understand what was the other question about submission?

Judge Moore (00:25:21):

Solely?

Judge Dyk (00:25:21):

Oh.

Judge Moore (00:25:21):

No, I really wanted you to address solely because Justice Scalia, quite frankly, just dropped it out of Merck. I mean, he quoted the, I'm trying to figure out what solely means.

Deanne Maynard (00:25:31):

Right.

Judge Moore (00:25:32):

Um so, and, and he just dropped it out of the quote as though it weren't actually part of the statute, which is really not the way I generally view him on statutory interpretation. And so I don't know that it was meaningful. It wasn't argued in that case and everything. And I'm trying to figure out what solely modifies.

Deanne Maynard (00:25:48):

Mm-hmm <affirmative>.

Judge Moore (00:25:49):

Does it mean that when you are doing it, you really have to be doing it for FDA approval or for an FDA submission of some sort, but you can then clearly you can then later use the information that resulted from those tests for publicity, for raising capital, whatever, but what does solely model solely for uses reasonably related to development and submission information? What do I do with solely?

Deanne Maynard (00:26:15):

Well I, two things, one, I think you're right. It solely has to be given some meaning because it's there. I think it modifies for uses. It has to be solely for uses reasonably related to the development submission of information here. The use to which they are putting our patented method is commercial manufacturing. It's a commercial manufacturing method in the patent—

Judge Dyk (00:26:41):

Well but that's true in the very beginning of the approval process when you're developing an alternative drug and you're doing it obviously with an eye to ultimate commercial exploitations is not an abstract approval by the FDA. It's an approval so that you can commercialize it. Correct?

Deanne Maynard (00:26:57):

But that's very different context, Judge Dyk. So when you're doing it to get approval, you are doing it to prove to the FDA that I am able to make the drug, I am trying to get approval to make.

Judge Dyk (00:27:08):

So solely in that context doesn't mean solely for FDA purpose.

Deanne Maynard (00:27:12):

Well, there you are doing it. You're doing it solely to develop information, to give to the FDA, to try to get approval—

Judge Dyk (00:27:21):

No, you're doing it also to develop a commercial product, right?

Deanne Maynard (00:27:25):

Well if that were true, then there would be nothing within the Safe Harbor, right? So, because it solely in that you're doing it then to get approval, there's no dispute that they're doing it now to make sure their product that continues along the manufacturing line and goes into the—

Judge Dyk (00:27:42):

I don't understand the distinction. I mean, in the first place, when you're developing the product, you, your idea is I'm doing this to develop a commercial product, and you are also developing information in the course of that for the FDA. So it isn't, the information is not solely for the FDA. It's also even at that stage for commercial purposes. No?

Deanne Maynard (00:28:05):

It is ultimately down the road, incidentally, going to set you up to commercially market. That's the purpose of the Safe Harbor. I mean, that's the whole legislative history shows that it's to allow the generics to get ready to market so that there won't be an undue extension on the branded patent, you know, after, because it takes a while to get regulatory approval, but you're allowed this. I think if you go back to the reason the legislation was passed and the Roche Ebola case that it was meant to overturn there, they, this court held—the opinion of this court said that even though they were using the patent invention solely to try to apply to the FDA to get approval, there was infringement. And that was the impetus part of the impetus for the legislation in made in that it looked at in that was like Judge Dyk.

Deanne Maynard (00:28:45):

I think you can say that we are doing it to develop information which develop information is more than just record regularly ordinary commercial activity. It has a different connotation to develop information, to submit for potential regulatory approval, which is exactly the Merck and Eli Lilly talk about the purposes. Then it is solely for that purpose, but here it's not solely for that purpose. Even if it's also incidentally to maintain records, to show that they're complying with their, they're doing it to manufacture each commercial batch for sale. And that's just totally different than the batches, when they were making them to try to show the FDA, they could get regulatory approval. That's the kind of development and submission that the FDCA where it talks about submission. So I think you have to look at the word solely for uses reasonably related to development submission altogether as a package in context. Can I make one more point, Judge Dyk about commercial?

Judge Dyk (00:29:36):

Just hold on one second.

Deanne Maynard (00:29:36):

Yeah. One frequent—

Judge Dyk (00:29:40):

Quickly.

Deanne Maynard (00:29:40):

In context, too, if you look at the broader hatch wax scheme, like in the E provisions E two, when you bring a suit, the E four remedies talk about stopping commercial sales, which is distinct from the uses under E one for approval. Thank you, Your Honor.

Judge Dyk (00:29:55):

Okay. We'll, we'll give you four minutes for rebuttal.

Deanne Maynard (00:29:58):

Thank you very much Judge Dyk.

Judge Dyk (00:30:01):

And the other parties will get some additional time also.

Henry Dinger (00:30:04):

May it please the court Henry Dinger, I'm arguing for Teva pharmaceuticals. And in the case against Teva, you don't have to deal with the interpretation of E one, even though I'm prepared to argue that you already did so in the earlier Momenta v Amphastar case.

Judge Wallach (00:30:23):

Mr. Dinger.

Henry Dinger (00:30:25):

Yeah.

Judge Wallach (00:30:25):

Is there a business or legal reason Teva has to use Momenta's patented process if it wants to sell an enoxaparin?

Henry Dinger (00:30:35):

The answer is, I don't know, I don't think there's anything in the record that that addresses that because this court in Momenta One said that it didn't matter, even if there were alternatives, the statute doesn't require—

Judge Wallach (00:30:48):

Well you indicate in your brief, in the red brief, that the FDA requires manufacturers to comply with the USP monograph for an enoxaparin.

Henry Dinger (00:31:00):

They—

Judge Wallach (00:31:02):

It requires release test.

Henry Dinger (00:31:03):

The FDA requires that the generic enoxaparin that is sold have certain chemical characteristics and the test that Teva uses, and Teva has only received FDA approval to sell enoxaparin that has those chemical characteristics. The test in question is intended to establish that the batch that is sample has those characteristics. That is why it is reasonably related to the submission of the development of submission of information under federal pharmaceutical law.

Judge Wallach (00:31:40):

Does the USP monograph still recite the release test that was performed when an enoxaparin was first approved in 1993?

Henry Dinger (00:31:51):

I don't know the answer to that. And I'm not sure that's in the record, Your Honor. That wasn't the basis on which the case, the summary judgment was argued or the district court decided it.

Judge Dyk (00:32:02):

Does the testing here have a purpose other than FDA?

Henry Dinger (00:32:08):

I mean, if, if the question is, would it be done, had not the FDA required it I, the, the answer is we don't know the fact is it is done in order to demonstrate that the enoxaparin that's being produced conforms to the drug that was approved when the FDA approved.

Judge Dyk (00:32:28):

Let's – I understand there seems to be a lack of facts in the record about some of these issues, which may have to be developed later, but let's assume that there, that there was proof and that it were established, that the testing would've been done for commercial purposes anyway, quite apart from any FDA requirements, would we then be within the Safe Harbor or not?

Henry Dinger (00:32:54):

I would say no, Your Honor, because the cases of this court have made it clear, whatever solely means you've explained what it doesn't mean. And what it doesn't mean is that you can't use inform– if you use a patented process that is otherwise within the Safe Harbor and the use of that patent generates information. This court has made clear that you can use the information generated.

Judge Dyk (00:33:18):

That seems to be a bit different from my hypothetical in the sense that there, the FDA information is generated and the FDA information is used for other purposes, or as in my hypothetical, the initial processing or testing has a dual purpose, one for the FDA and also for commercial purposes. And that it would've been done for commercial purposes. Even if there hadn't been an FDA requirement.

Henry Dinger (00:33:44):

I don't believe that issue was developed at all below, but I suggest that it is both under this court's interpretation of 271E one. And, and under 271G it is not relevant at least in the Teva case, because to the extent we use this process and that's disputed, but you can assume that we do for purposes of this appeal. It our product is not made by this process.

Judge Moore (00:34:12):

Before you move on to that, though. Can I ask you, when you file your submission to the FDA and you get approved to manufacture a drug, aren't you approved to manufacture it only precisely as you submitted and were approved?

Henry Dinger (00:34:32):

It must conform to the specification set forth in the abbreviated new drug application—yes, you required to do that.

Judge Moore (00:34:39):

So then isn't, I mean, the natural extension of your argument, it seems to me would be that every step in the manufacturing process, every single step is required by the FDA, because you are required to submit to the FDA exactly what steps you will undertake, and you, then you are not allowed to deviate from, I

mean—

Henry Dinger (00:35:00):

Two thin—

Judge Moore (00:35:00):

Problem, I have. The problem is.

Henry Dinger (00:35:01):

I—

Judge Moore (00:35:02):

Simply FDA requirements is necessary. Then there's nothing left in from Harbor under your argument, because you have to submit to the FDA precisely what you will do, and then you have to follow it. And if you deviate from it, you're not following FDA requirements.

Henry Dinger (00:35:17):

Yes. To the extent that you have, to the extent that the manufacturing process is identified in the, in the end, you have to follow it. Here, of course—

Judge Moore (00:35:26):

And you would be violating FDA requirements if you failed to do so, correct?

Henry Dinger (00:35:31):

Yes. You, you would, although this information goes to the very definition of the drug that's approved, the enoxaparin and this goes to, to establish the FDA has defined the characteristics that established bio equivalency.

Judge Dyk (00:35:45):

Well, it seems to me to follow up on Judge Moore's cause got a hard road to hoe, if the contention is that you've selected a manufacturing process and told the FDA about it and therefore it comes within the Safe Harbor in E. And that, that seems to me a hard argument. You don't have to, you have to be I would think saying that the testing here is designed to show FDA compliance for an independent FDA requirement, rather than a requirement of your own manufacturing process that you've chosen for your own reasons. Is that clear enough?

Henry Dinger (00:36:26):

I understand the question, Your Honor. But I think this court has already said it doesn't matter whether you pick whether there are non-infringing alternatives. I think the court squarely held that—

Judge Dyk (00:36:37):

That's fine, but, but the fact that there're non-infringing alternatives is probably true in initially developing information for initial FDA approval and maybe different ways of doing it. And yet it doesn't make any difference that you've chosen a patented method that you still get the benefit of the Safe Harbor. This question, it seems to me as all little bit different, and it looks like bootstrapping, if you say, oh, well we chose a manufacturing method. We told the FDA how we were going to manufacture the drug. And therefore the process is a process that's required by the FDA that doesn't feel right.

Henry Dinger (00:37:19):

I think it is the same issue, Your Honor, but I really would like to get to the made by argument because the answer to your question doesn't matter in the Teva case, because the only basis for liability directed at Teva is 271G, which requires that the product that we sell in the United States be made by the patented process overseas.

Judge Dyk (00:37:42):

No, that's not true. I mean, and neither side has bothered to look at the Senate report at the time this legislation was passed, which says specifically that it applies both the products made in the United States and, and made abroad. And the reason for that is that before 271G was enacted under Supreme Court and circuit authority and our predecessor courts authority 271A was not infringed by the making of a product according to a patent and processes. So the Senate report, if you look at the Senate report, you will see explicit statement that this is covering both the products made abroad and those made in the United States.

Henry Dinger (00:38:28):

But the fact remains in order to, in order for 271G to apply the product that is imported or so must be made by the patented process. The only patent here is a patent process. There are no product patents at issue in this case. And so it must be shown that Teva's—these enoxaparin products for Teva cells in the United States are made by a process. And it wasn't because of the nature of the patent in suit. This is a patent that is solely designed to generate information, data about a product.

Judge Moore (00:39:06):

Well, no data about a product. So you can decide which piece is which batches to move forward with for further manufacturing.

Judge Wallach (00:39:14):

Is it made by if you are not permit to sell it otherwise?

Henry Dinger (00:39:21):

No, I don't think so. Your Honor. I mean, and your opinion in the Philip and Adams case supports that, in that case the plaintiff alleged that the certificate the patent allegedly infringed by the certification process that was challenged was integrated into the manufacturing process. And this court said, no, all it does is develop information about the product that it conforms to a particular standard just as the patent is alleged to be used in this case. And this court repeatedly said, "that's not good enough. It is not a step in manufacture. It is not a step in synthesis." That is how this court in the Bay case, distinguished biotechnology group, in that case, the patented process was used to synthesize something to create a mid-material object here. The only purpose of the patent is to develop information. And even if the information is used in a manufacturing process that does not change the analysis, it is not a patent to make anything that is sold. My time is up. I'm happy to. You may have additional questions.

Judge Dyk (00:40:43):

Okay. Thank you,

Judge Dyk (00:40:53):

Mr. Hay. I'm sorry. Shah. Mr. Shah.

Pratik Shah (00:41:02):

Thank you, Your Honor. May it please the court. Pratik Shah for the Amphastar appellees. Let me start with

the solely limitation. Since that's gotten some attention today. It is true that this patent, the 886 patent, to the extent that it's infringe at all is used for the purpose of complying with the FDA requirements. That is what the Safe Harbor requires. There is no dispute that Amphastar is using this patent to comply with the FDA requirements. Now, what the other side is saying, well, they're also using this as part of their manufacturing process. I would submit that is not true. There's nothing in the evidence that would nothing in the record that would suggest that Amphastar would use this method, this patented, allegedly patented method to use this without the FDA requirement. But putting that aside, even assuming there was some other commercial purpose at use here of which there is no evidence.

Pratik Shah (00:41:52):

I think this court's decision and it's twice foreclosed one, by this opinion in Momenta, this court's opinion Momenta One. But before that, by this court's opinion, in the AB talk case, here's what AB talk case specifically says about the solely limitation. And I'm quoting from page 1030 of the AB talk decision. The statute therefore does not look to the underlying purposes or attendant consequences of the activity. As long as the use is reasonably related to FDA approval. In other words, the statutory language allows the company to use its data from the test for more than FDA approval. And here's the sentence, a few sentences down in that same paragraph, quote, as long as the activity is reasonably related to obtaining FDA approval, Jacob's intent, the company's intent or alternative uses are irrelevant to its qualification to invoke the 271E one shield that is precisely the situation.

Judge Dyk (00:42:49):

If that's the case, and the other cases on which you rely are cases in, in which the information would've developed for been developed for the FDA only the purpose of the original development of the information was only for FDA purposes. And then once the information was available, it was then used for these other purposes.

Pratik Shah (00:43:08):

Your Honor, that's not, if I may respectfully respond, that's not true in AbTox. The whole premise of AbTox litigation is the other side argued. They're not doing this for FDA approval. They're just doing this so that they can promote their product. They're developing this information to promote the product. They never had any intent to submit it to the FDA. That is the fact situation in AbTox. Here, we're on stronger ground than AbTox because everyone agrees they're at least doing this to comply with the FDA requirement. They couldn't sell this drug without using it to comply with the FDA process. Now, Momenta is arguing well, they're also using it for this commercial objective. And if one thing is clear in AbTox—

Judge Moore (00:43:49):

Can you, maybe, you're kind of yelling at us.

Pratik Shah (00:43:51):

Oh, I'm sorry.

Judge Moore (00:43:52):

So try to tone the decibels down a little bit.

Pratik Shah (00:43:54):

Sure.

Judge Moore (00:43:55):

So and— slow down a little bit too, you're going really fast. So when it comes to solely though I understand your argument about what AbTox stands for, and it's not a bad argument. Judge Dyk pointed out that there

may be some differences but importantly, how does it give meaning to the word solely? What you tell me how I mean, because I can't read the word out of the statute and if I read AbTox the way you're suggesting, I should read that prior case of ours, I may be bound by it. And if I am, I'll live with that, but.

Pratik Shah (00:44:28):

Sure.

Judge Moore (00:44:29):

How does the word solely still have any meaning at all in the statute under your interpretation?

Pratik Shah (00:44:34):

Sure, Your Honor. So I think solely does still have content under our reading of the statute. And I think the SGS brief, the solicitor General's brief in the Classon case, which was also addressing the—

Judge Moore (00:44:44):

Yes, trust me I've read it.

Pratik Shah (00:44:46):

Yes. If I could—they, I think, proffer the work that solely is doing in the statute and here's what they say. A particular use may be in, on page 17 of the SGS brief does a particular use, may be reasonably related to the development and submission of information and therefore may fall within the Safe Harbor, even if it serves other purposes as well, and also advances other commercial objectives. It cites AbTox. Then it says by contrast, and here's where it gives work to solely to answer your question by contrast, if a defendant makes multiple uses of a patented invention e.g. by selling a patented drug commercially while simultaneously administering it to research subjects during a controlled study, one use may provide a basis of in for arrangement liability, even though the other use falls within the Safe Harbor.

Pratik Shah (00:45:35):

So what solely the work is doing, let's say a company is using the patent invention in two wholly distinct subset of its activities. One is using it as part of a clinical research study. The other it's selling the drug. What the SGS brief does, it gives content too solely. It says, well, yes, the clinical study that's certainly protected, but just simply selling a drug for commercial purposes. That's not. And so that's what solely does, it doesn't give a blanket use to the company to use the patented product for whatever purposes it, for whatever uses it wants to, if it's using it for multiple different things, it has to be one of those and not the other.

Judge Moore (00:46:11):

But you stop short of the page 18 paragraph.

Pratik Shah (00:46:14):

Sure.

Judge Moore (00:46:16):

Which further elaborates on what they mean. And I'm not sure that the government is really arguing what yes, the argued what you said, which is that they say in, in post approval context that inquiry may be substantially more difficult because the drug maker simultaneous engage in ordinary commercial manufacturing sale, the product in question, in such circumstances, the more nuanced analysis is required. A drug maker's use of a patented invention and routine commercial activity is not immunized from infringement liability merely because for example, the company may periodically report adverse reactions

to the FDA. Why doesn't that feel a lot, like this case, you are maintaining these documents just in case the FDA wants to come and inspect them the state, by the way, don't do very often, but they do randomly and occasionally. So, and then even then they come by and inspect them. I'm not sure that meets submitted. They can, if they so choose to ask you to copy them and they'll take them away with them, maybe that meets the submitted language maybe, but you see, I kind of feel as though the maintenance of records in this scenario feels a lot like keeping records to report adverse reaction to the FDA.

Pratik Shah (00:47:29):

Well. No, Your Honor. So if, if we're going to move to the submit versus maintenance argument—

Judge Moore (00:47:34):

Well what if this is, also in solely.

Pratik Shah (00:47:35):

Sure.

Judge Moore (00:47:35):

I mean, you were telling me the SG supported your view of solely. And I actually think it doesn't. I think the subsequent sentences indicate that they think that when you're doing something for mass production and commercial manufacturing it doesn't at all.

Pratik Shah (00:47:47):

Here—no, I would disagree with you. I think that really does support our example. If you read a couple sentences after the sentences, you read it, then repeats the example that I gave of when a use wouldn't be solely, likewise, that it directs it to a clinical trial as opposed to, as opposed to routine commercial sales, that would be protected under the plain terms of the statute. But here's the point I would make. I don't, there's slippery slope argument that this will open it up to everything in [**inaudible**]. This will license a wholesale infringement of manufacturing processes or the, or to the extent the SG briefs, purely commercial manufacturing processes. That is not what this case is. And the—

Judge Dyk (00:48:28):

Okay. Two. So stop there. That seems to be a critical point. What I referred to as bootstrapping.

Pratik Shah (00:48:34):

Yes.

Judge Dyk (00:48:34):

Where you use the process in the course of the manufacturing, you have to keep the records to show that you, that you used the process that you told the FDA that you were going to use. It can't be that by choosing a process and then telling the FDA about it, keeping records to show that you did it brings about the Safe Harbor. It has to be something more than that. No?

Pratik Shah (00:48:58):

Yes, it does have to be something more than that. Let me tell you the two things that's more than that. One is this is an FDA prescribed test to meet the USP standard. The USP standard has to be 15 to 25%. The USP also has a companion test, which it makes the official test. That's the language it uses. I'm not saying it's the only test and the [**inaudible**]. Even if there are alternatives, that's not dispositive—

Judge Moore (00:49:19):

But you keep talking about all that. And so it matters, first off, it doesn't matter to his client at all, right? Because at best its law is the case and his client's not sucked into law of your case. So, and if at worst under the Supreme Court jurisprudence, it's not binding because it was a tentative finding, made it a preliminary stage of the analysis, which wasn't made briefed or argued before anybody. So it kind of feels an awful lot like it fits right in that Supreme Court sweet spot on why it isn't given law of the case status.

Pratik Shah (00:49:49):

Well, Your Honor, even if you want to depart from your prior opinion, which I submit was completely correct on the non-infringing—

Judge Moore (00:49:56):

Well thank you, I appreciate the validation. Why, nonetheless.

Pratik Shah (00:49:58):

But if I can explain why it's correct, because the non-infringing alternative solely as this court pointed out does not modify the patented invention. It modifies, it uses reasonably related to there's nothing in the Safe Harbor that suggests it has to be the solely available use in order to qualify it. But here is why Judge Dyk getting your question, why it doesn't encompass everything in there. I think there's a sharp distinction to be drawn between the type of testing method here to comply with the USP standard to show it's within the 15 to 25% range. That it's the same product and any number of wholesale manufacturing processes that would be used to do it. The limitation comes from the text of the Safe Harbor itself.

Judge Moore (00:50:38):

But wait. But the FDA doesn't require you to use their patented process. This record is clear. It was not, this was not the record before the court previously at the preliminary in junction stage where everybody accepted that let's assume for purposes of P.I., this is the only way of doing it. But the record now is clear that this is not the only way of doing it. There are non-infringing processes you can use to determine whether your batch falls in the 15 to 25% range. So how can you say their patented process is required for you to use, to comply with FDA requirements?

Pratik Shah (00:51:15):

Well, Your Honor, again, I would disagree with you. It wasn't presented in the first case. Momenta made that argument—

Judge Moore (00:51:21):

I want to know how you can respond to the argument on the merit– why you are required by the FDA to use patented process. When there are non-infringing methods you could use to obtain the identical information?

Pratik Shah (00:51:33):

Your Honor, because the word solely does not modify the patent invention. There is nothing in the Safe Harbor that says you must—

Judge Moore (00:51:39):

No, that has nothing to with solely. You stood here and argued in response to Judge Dyk's question that you are required to perform this process by FDA no else you are not. I want to clear yes or no. Are you required to form the patented process by the FDA or are you simply required? I guess can't ask this. Yes or no. So I'm giving alternatives.

Pratik Shah (00:51:56):

Okay.

Judge Moore (00:51:57):

Are you required to form the patented process by the FDA or are you required to determine whether or not its 15 to 25% compliance?

Pratik Shah (00:52:03):

It is the latter and the way that Amphastar satisfies the ladder is by doing the, US–, the official USP test.

Judge Dyk (00:52:11):

And in terms of initial approval, there's no requirement in the statute that the test be the only way of doing it. As long as you run the test to submit to the FDA nobody's ever contended, that that wouldn't be covered by the Safe Harbor simply because there was no alternative test in that context.

Pratik Shah (00:52:29):

That's right. Yes, Your Honor. And it's the same text that applies pre-approval and post-approval so I don't know where you read in that limitation in the post-approval category that suddenly says the non-infringing alternatives, which are okay in the pre-approval test are no longer okay. In the post-approval test.

Judge Moore (00:52:48):

But let me go back to my one more time.

Pratik Shah (00:52:50):

Mm-Hmm <affirmative>.

Judge Moore (00:52:50):

Are you required to perform the patented process by the FDA?

Pratik Shah (00:52:55):

No, Your Honor. We perform that to satisfy the FDA requirement that's it. It satisfies the 15 to 25% requirement.

Judge Moore (00:53:04):

You choose, to be clear, you choose to use the patented process to satisfy an FDA requirement, but you don't, you are not required to use that process. Correct?

Pratik Shah (00:53:12):

Well, when Your Honor, when you say choose, I'm not sure how to answer that with a yes or no, because the FDA, when it has the USP 15 to 25% standard, that comes with an official companion test. And if you use that official companion test, which, which Amphastar uses, then you've met all the efficacy, reliability requirements. You can certainly go out and innovate on your own and come up with another test that may be more effective or more reliable—

Judge Moore (00:53:39):

But doesn't this record reflect the fact that there are already known non-infringing processes that could absolutely give you the same compliance information?

Pratik Shah (00:53:46):

Your Honor, they contest they use another test that is not infringing, but that they made that same contention in Momenta One. This court said Momenta makes this argument, but the fact that there are non-infringing alternatives does not affect the analysis for the reasons that I've stated. I don't want to repeat myself, but that's, that's what that is. Now, if I can address, just briefly, the policy argument or the scenario that you are drawing that well, does this sweep into all the manufacturing methods that might be in [**inaudible**]? And I think the text—

Judge Dyk (00:54:16):

The idea is you choose the manufacturing method. You're required to inform the FDA about that. And you're required to make maintain records to show that you've kept within the parameters of your own manufacturing process. That's correct. Right. That you do have to keep those records?

Pratik Shah (00:54:33):

Yes, Your Honor. But here's the distinction in this case, this has nothing to do with the chosen manufacturing method. There's no patents over the manufacturing method. There's nothing about Amphastar's chosen manufacturing methods that are issued here. The question is the same as requirement is this the same product that they produce at the end of their process that they said they would produce in their [**inaudible**]. And the patent here is a testing patent. It is specifically designed to develop information. And that is what the Safe Harbor requires development of reasonably related to it, not like a manufacturing patent. And when you use a manufacturing patent or process, you're using it to make the product. Now that may incidentally generate records that you have to keep under the maintenance record requirements. But that is not the main purpose. That is not the main use. It is much more directly related and therefore much more reasonably related to the development of information to use a testing patent like Momenta's, then it would be a wholesale manufacturing process, which incidentally generates the records. And I—

Judge Dyk (00:55:39):

But that argument, it seems to me, gets into the question of what the purpose of the test is to distinguish the hypothetical, the bootstrapping hypothetical I gave to you on the ground that, in that situation, the primary purpose of the test is commercial rather than for the FDA. So why don't, if purpose matters, don't we have to get into purpose. Here is the purpose of this test to generate records to show FDA compliance, or is the purpose of the test to ensure compliance with commercial processes? I mean, it seems to me that the purpose of the test, as you're explaining it, is pertinent.

Pratik Shah (00:56:27):

Your Honor, I don't think you have to get into purpose because there can't be any dispute on this record from an objective standpoint that at least Amphastar is doing this, that that's reasonably related to complying with the FDA requirement that they show that it's within the 15 to 25% standard. The fact that it may also be serving some other commercial ends does not disqualify it from the Safe Harbor that would add. So that's how I think I would deal with the purpose inquiry. And if I could just point you to the JA 102, which is the actual text of the patent claims, there are 886 patent claims. It makes clear this is not some broad scale-manufacturing patent or manufacturing process. The terms of the claims itself claim one in claim six, it claims quote a method for analyzing an enoxaparin sample for the presence of a sugar quote that results from a method of making an enoxaparin.

Pratik Shah (00:57:20):

And the last line of that claim, of both claims, is to thereby analyze the enoxaparin sample. This isn't about making manufacturing, enoxaparin some wholesale sweeping decision in Momenta One. This is about testing the product to develop information, to generate the data, to show the FDA that they're making the

same thing that they said they would make. And to take Judge Moore your baking cake hypothetical. I think it's a good one. I think our case is even stronger because at least in your baking cake hypothetical, you're using the salt in the actual cake. Here, you're simply taking a sample out of a batch, running the test and throwing out the sample. There is nothing from the patented process—

Judge Moore (00:58:03):

No, but you, but then you're using the other samples. I mean—

Pratik Shah (00:58:06):

Your Honor—

Judge Moore (00:58:06):

[**inaudible**] threw out the sugar, but kept the salt.

Pratik Shah (00:58:08):

Well the—

Judge Moore (00:58:08):

I mean, using the ones that are compliant and throwing out the ones—

Pratik Shah (00:58:11):

I respectfully disagree, Your Honor, the default method is if momentum didn't—it uses all of its batches.

Pratik Shah (00:58:17):

The only thing that's going on here is if it runs a test, which it has to run to comply with the FDA requirement, it could not sell this stuff without running the test. If that test comes out and says, this does not comply with the FDA requirement, then they discard that batch. There is nothing in the 886 patent that says that does covers anything related to the processing, the manufacturing—the making of that. It's like if you have a food processing plant and the health inspector comes in, takes a test of the product and says, "this doesn't meet the standards, throw out that batch." You would not say that that was part of the making of that food product. That's exactly what's going on here. They are doing the tests per FDA requirements, and they throw out the sample that's what's happening. It's a testing by the terms of their own patent.

Pratik Shah (00:59:05):

It is a testing patent to analyze a sample. It does nothing more. This is not a case about broad manufacturing methods, and you haven't seen a single case in the two and a half years since Momenta One has been in the books that has come up on the slippery slope that they suggest you do not have a single Amicus before this court for any patent holder manufacturing methods holder saying that this pose a problem. And we think that's because the limitations of the Safe Harbor is this court construed it in Momenta One provide more than adequate protection from the slippery slope arguments that they make.

Judge Wallach (00:59:38):

Mr. Shah. I want to ask you about the dog that barked in the night. You'll recall that Watson says, well, Holmes, the dog didn't bark and, and Holmes says precisely. So in Plaza, the SGS brief doesn't say some stuff. It says the Momenta court additionally held for purses of 27181 information may be deemed submitted to the FDA if it is preserved in records that FDA regulations require a manufacturer make approval for inspection on FDA request, we express no view on the correctness of that conclusion or the court's ultimate conclusion.

Pratik Shah (01:00:24):

Yes.

Judge Wallach (01:00:25):

So, what does that silence mean?

Pratik Shah (01:00:28):

Well, I think we take the SG at its word. It didn't take a position of its view on this court's interpretation of submission, but on submission I would submit, even if you use—

Judge Moore (01:00:38):

Do you think we should ask the government first its use since like they have some?

Pratik Shah (01:00:43):

Well, they said they don't take a position. So I don't think they have views, but I don't think it's necessary because I think this—

Judge Wallach (01:00:49):

You don't take views on whether we were correct or not?

Judge Moore (01:00:50):

Yes!

Pratik Shah (01:00:50):

Right.

Judge Moore (01:00:50):

And in fact, they went to great pains to say, we don't take views on whether you're correct on your statutory interpretation or whether you got the outcome of the case correct.

Pratik Shah (01:00:58):

Well, here, Your Honor is why I don't think you need to revisit submission. And if you do revisit, you should come to the same outcome that you came to. And that's because even if you apply the plain meaning of submission, that Momenta offers on page 40 of its brief, that is to present something to somebody for approval or study, that's quoting their brief page 40 that's their plain meaning definition—

Judge Moore (01:01:20):

You argue to me that the SGS brief who really supports your view of solely. I mean, you're giving me a great idea here. Why don't we ask him and find out?

Pratik Shah (01:01:29):

Well, Your Honor, I, you obviously can do whatever you think is fit. I think this court's decision in Momenta One, the arguments here provide ample ground to affirm and come to the same conclusion that it came onto its interpretation of the Safe Harbor, and then reach the 271G argument. What I would say about submission again is we meet the plain meaning of submission that they, that they present, present something to somebody for approval or study. That is what it, the fact that they do that on site to FDA inspectors rather than mailing in the records should not be a distinction on which it turns. And again, even if there was some ambiguity as to whether, this activity falls within the scope of submission, the language

of the statute is not that they must do it for submission. It must be reasonably related to a submission. And I would think we're okay on submission alone.

Pratik Shah (01:02:19):

But certainly if you add the gloss of whether keeping records that the FDA can come inspect it, photocopy it and take it with them is at least reasonably related to making those records available for approval or study.

Judge Dyk (01:02:30):

Okay. Thank you, Mr. Shah.

Pratik Shah (01:02:32):

Thank you. Your Honors.

Judge Dyk (01:02:34):

Ms. Maynard, you have four minutes here.

Deanne Maynard (01:02:37):

Thank you, Your Honors. I'd like to start with the patent. So this is a manufacturing patent, and if I can draw your attention to A84 which is the patent in the back of the blue brief, in the Amphastar case, in particular at line—in the detailed description column 28 line 31, this information can be used to standardize the production of low molecular weight heparin composition.

Judge Moore (01:03:07):

Wait, hold on. You said.

Deanne Maynard (01:03:09):

I beg your pardon.

Judge Moore (01:03:09):

84.

Deanne Maynard (01:03:10):

I'm on page A84. I'm in column 28.

Judge Moore (01:03:11):

Column 28.

Deanne Maynard (01:03:14):

This is only one of several places in the patent.

Judge Moore (01:03:16):

I thought you said line 31 there.

Deanne Maynard (01:03:18):

I beg your pardon? I'm in column 28. I'm in line—yeah, line 31. It starts with the word further, Judge Moore.

Judge Moore (01:03:23):

Yeah.

Deanne Maynard (01:03:23):

Further, this information can be used to standardize the production of LMWH compositions, thus resulting in LM, WH with less batch to batch variability, and improved ratios of desirable and undesirable activities.

Deanne Maynard (01:03:38):

We pull out in the Crawford affidavit, which is in the AMFSA J at page 12436, paragraph 19. Multiple places in the patent that talk about manufacturing and reducing batch to batch variability, and then significantly, the last step of claim 53 is selecting a batch for further processing. That is on page, A105, the line—column 70, starting around line 24, selecting a batch of enoxaparin based upon a comparison of the determination of the test of the presence of the structural signature associated with the non-actually curing sugar associated with peak nine, figure one to the reference standard for enoxaparin.

Judge Dyk (01:04:27):

Well—but that's all that shows is you could use it for those purposes. It doesn't show that the appellees here are using it for that purpose. That's the question that we were asking.

Deanne Maynard (01:04:38):

Well, that that's precisely what we've accused them of in the complaint, Judge Dyk.

Judge Dyk (01:04:42):

Well, I'm not sure about that. I mean, the complaint seems to focus more on their doing this for FDA purposes, but I understand you're— they haven't objected to this contention being within the scope of the case. But the fact is, it seems to me—we don't—we can't tell from this record, whether this is solely for FDA purposes or whether it has a commercial purpose.

Deanne Maynard (01:05:07):

Well, two points to address the complaint point. The complaint references the requirements of the USP to establish our reasonable belief that they were probably infringing our patent, but what they're alleged were doing in the complaint, and then the on this record, the uncontested affidavits of Lou in both the Teva record and the Amphastar record detail, a great length, how they are infringing each step of the claims, including the step of claim 53, to your point about the solely Judge Dyk, what they are using—

Judge Dyk (01:05:37):

So we don't know whether you're right or whether they're right, right?

Deanne Maynard (01:05:39):

Well, this was resolved on the Safe Harbor grounds, Your Honor, on a summary judgment against us. Obviously, there's more—

Judge Dyk (01:05:49):

So you're saying there's a fact issue? If this is a determinative, if the commercial purpose of this is determinative, we have a fact issue, right?

Deanne Maynard (01:05:59):

No one disputes that they are—

Judge Dyk (01:06:00):

Yes, no.

Deanne Maynard (01:06:02):

Yes. If there's a fact dispute, there would have to be a reversal, but I think it's important to step back and look at the statute as a whole. It says solely for uses reasonably related to the development and submission of information under the FDCA. And when you look at the situations in which information is submitted, they all involve approval, FDA approval, what they are doing here. And what we've accused them of doing here is simply using it in the ordinary commercial exploitation routine commercial manufacturer. It's just like the SGS brief. I think the SGS brief supports our position, not their position with respect to sole the—

Judge Moore (01:06:38):

I guess we'll figure that out at some point, is my guess. But apart from that question, I don't understand how either of the two passages you read to me support your notion that this is a manufacturing process.

Judge Moore (01:06:48):

When you look at claim 52, right after the section you read, it says selecting a batch very next line is to thereby analyze the sample. So I don't see how that says, you know, selecting a batch for further manufacturing, like you alluded to. It's to analyze a batch, to analyze.

Deanne Maynard (01:07:06):

Two points, Your Honor. One, it's my understanding that in claim-ease, speak, this is the way you write a claim like this, where you start out the preamble and you close it with to analyze. But importantly, in the claim construction—

Judge Moore (01:07:16):

That's how you write a claim that is meant to be a claim that analyzes things as a claim, as opposed to a claim that manufactures things I've never seen in, what did you call it? Claim-y?

Deanne Maynard (01:07:28):

Claim-y. <Laughs>

Judge Moore (01:07:28):

You used that word for her, a—

Deanne Maynard (01:07:30):

I beg your pardon.

Judge Moore (01:07:30):

We have never seen a manufacturing claim that starts and ends with analysis.

Deanne Maynard (01:07:35):

If I may draw your attention to the claim construction order in the court below it is it's in the [**inaudible**] at A2345, it interpreted the selecting a batch of an enoxaparin limitation to mean selecting a quantity of enoxaparin that was produced in a single process for further testing or processing. And I think if you look at the passages in the Crawford affidavit, that detailed more parts of the patents, Your Honor, that you'll see that this patent is about using the analysis to reduce batch-to-batch variability in manufacturing. That's exactly the use to which they're putting it here.

Judge Moore (01:08:09):

What does that have to do with the manufacturing. Figuring out using information you gain from manufacturing always helps you improve or stay the course for manufacturing. That doesn't morph that information or the test that you perform to get it into a manufacturing test.

Deanne Maynard (01:08:27):

Here, they're using it though, Your Honor, to decide what they're using it just like on a—you would a mechanical sort along a conveyor belt to decide which—

Judge Wallach (01:08:36):

Quality control.

Deanne Maynard (01:08:36):

No, even more than that, Judge Wallach. They're using it to decide whether interim drug substance goes in or out along the, the manufacturing line. And it gets—if it fails the test, it's like it's rejected by the mechanical sorter. And if it passes a test, it goes on and it's joined together with other batches that pass and sold in the syringe.

Judge Wallach (01:09:01):

Okay. Thank you, Ms. Maynard. We're out of time. Thank all counsel.

Deanne Maynard (01:09:04):

Thank you, Your Honor.

Judge Wallach (01:09:05):

The two cases are submitted and that concludes our session for today.

Bailiff (01:09:08):

All rise.