No.

IN THE
Supreme Court of the United States

CLASSEN IMMUNOTHERAPIES, INC.,
A MARYLAND CORPORATION, PETITIONER

v.

ELAN PHARMACEUTICALS, INC.,
A DELAWARE CORPORATION

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION(S) PRESENTED

The Supreme Court decision in *Merck v. Integra*, 125 S.Ct. 2372 (2005) left uncertainty as to the enforceability of research tools under 35 U.S.C. §271(e)1 . The Supreme Court commented in Footnote 7 on p. 2382 , "We therefore need not and do not-express a view about whether, or to what extent, 35 U.S.C. §271(e)1 exempts from infringement the use of "research tools" in the development of information for the regulatory process." The CAFC has come to different conclusions on research tools used after marketing approval. Two CAFC panels arrived at opposite rulings (*Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) , (*Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.*, 809 F.3d 610, 620 (Fed. Cir. 2015. In the current case the two separate CAFC panels came to a different opinion on the applicability of *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–24 (Fed.Cir. 1992) to a research tool.

In the current case, in contrast to Momenta, the court ruled use of the research tool was "non-routine" and raises different questions than Momenta:

1.The CAFC has developed a litmus test to determine when 35 U.S.C. §271(e)1 applies to research tools used after marketing approval. The litmus test was introduce in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) "The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained. *Id at 1070* ." In subsequent cases including the current case the CAFC has struggled with defining what constitutes "non-routinely" reported and thus protected

by the safe harbor. The litmus test classifies something as "routine" if it is FDA required for ongoing FDA approval but "non-routine" if the post marketing use is not required by the FDA. Is the CAFC's litmus test for research tools consistent with the law?

2. In this case, as opposed to Momenta's case, the court granted safe harbor because Elan's submissions to the FDA were deemed "non-routine" because they were necessary to update the Skelaxin product label and to change the FDA-approval process for generic versions of Skelaxin (Appx. 42a) . What if the FDA recommends but does not require its use, is use still "routine"? Is this arbitrary?

3. As written and intended by Congress the safe harbor of 35 U.S.C. §271(e)1 is applied when (the whole) "invention" is used to for submission of data to the FDA. Is the CAFC's decision in this case to extend the safe harbor under 35 U.S.C. §271(e)1, to inventions where one or more but not all steps of an invention creates or uses data submitted to the FDA, consistent with the law?

4. Is the CAFC's decision to extend the safe harbor in this case to sale of product, where the product is claimed by process claims and where the process may utilize data submitted to the FDA, consistent with the law?

Rule 29.6

Classen Immunotherapies is a privately owned supchapter S corporation formed in the State of Maryland.

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JURISDICTION

The judgment of the Court of Appeals was entered on October 17, 2017. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS INVOLVED

35 U.S.C. §271(e)1.

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of

drugs or veterinary biological products.

STATEMENT

This is a case about enforceability 35 U.S.C. §271(e)1 on research tools used in post marketing activity at a time when the user is generating profit from sale of its product. The CAFC has developed a litmus test for when the safe harbor is applied in research tools post marketing. The litmus test discriminates depending on whether the use is for "routine" filing with the FDA versus "non routine" filing with the FDA. The current suit pertains to patents on research tools for screening pharmaceutical adverse events information and commercializing the data as well patents pertaining to products created using these methods. In this case use of the research tool, as opposed to Momenta's tool, was classified as "non routine" by the court and the safe harbor was applied.

The US Supreme Court has made one recent pivotal decision regarding enforceability of patents in 35 U.S.C. §271(e)1, *Merck kGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193 at 202 (2005). In that decision the US Supreme Court left open the enforceability of research tools. The Supreme Court commented in Footnote 7 on p. 2382 , "We therefore need not and do not-express a view about whether, or to what extent, 35 U.S.C. §271(e)1 exempts from infringement the use of "research tools" in the development of information for the regulatory process." Since that time the current moving party filed cert with the USSC regarding 35 U.S.C. §271(e)1 in another case *Classen Immunotherapies, Inc. v. Biogen Idec*, 130 S.

Ct. 3541 (2010). Cert was granted and the cases was remanded back to CAFC where Classen ultimately prevailed *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) . The CAFC has made several other recent opinions pertaining to 35 U.S.C. §271(e)1 *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) and *Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.*, 809 F.3d 610, 620 (Fed. Cir. 2015) besides the current case.

The CAFC has now solidified a new litmus test for 35 U.S.C. §271(e)1 pertaining to research tools used after market approval of a drug. The litmus test was introduce in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) "The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained. *Id at 1070* ." The current case solidifies the litmus test and further defines what is "routinely" reported or "not routinely" reported . The current case also extends the safe harbor of 35 U.S.C. §271(e)1 to individual steps of an invention as well as sales of products made using a research tool.

In the Momenta case, the CAFC ruled twice with different results each time. In the current case the case went before the CAFC twice and got different opinions each time. A large part of the problem is the litmus test the Circuit Court is now trying to employ during post market approval use is arbitrary and is not supported by the law. The court applies the safe harbor to use of a research tool employed for "non routine" submissions to the FDA but does not apply the safe harbor to uses of the research tool that are deemed

"routine" submission to the FDA. In the Momenta case, use of Momenta's patented research tool was initially ruled to be "non routine" (covered by a safe harbor) and then later ruled to be "routine" (not covered by the safe harbor). The fact that the FDA required batch testing of the product made the use of Momenta's patented invention "routine".

The current case in contrast to Momenta involves use of a research tool that the court eventually ruled is "non-routine" for the submission to the FDA. According to the recent decisions, performing safety research on one's product after market approval and updating the label is "non-routine" thus protected under the safe harbor of 35 U.S.C. §271(e)1 . Elan's submissions to the FDA were deemed "non-routine" because they were necessary to update the Skelaxin product label and to change the FDA-approval process for generic versions of Skelaxin (Appendix 42a). However a different CAFC panel ruled on submission of vaccine safety data to the FDA and came to a different conclusion in a separate set of patents belonging to Classen. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) "The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained. *Id at 1070* ." The later ruling favored Classen after the USSC granted Classen's cert on the case (*Classen Immunotherapies, Inc. v. Biogen Idec*, 130 S. Ct. 3541 (2010)) . In the current case the two separate CAFC panels came to a different opinion on the applicability of *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–24 (Fed.Cir. 1992) to a research tool.

According the current rulings use of a patented research tool can "non- routine" in 2018 but required by the FDA and thus "routine" in 2019 (or vice versa if the FDA discontinues requiring its use after 2018). In this scenario the identical use can be infringement in 2019 but not in 2018 (or vice versa). If the FDA indicates it is planning on making use mandatory after January 1st, 2019, would use in 2018 still be "routine" ? In other situations the FDA could recommend use of a tool but not absolutely require it, or allow one of several methods to be used. The case law does not clarify what would be "routine" in these scenarios. Thus the definition of whether a specific use is "routine" can very from day to day and is very arbitrary.

The safe harbor of 35 U.S.C. §271(e)1 was written to support pre marketing development of generic products. The discrimination on applying safe harbor was use for pre-market approval development versus post marketing sales. The CAFC's new litmus test for use in post market approval activity, "routine" versus "non routine" submission to the FDA, is not supported by the law and is arbitrary.

A. Factual Background

Dr. Classen discovered that common vaccines are causing an epidemic of diabetes and other autoimmune diseases. On realizing that companies have little financial incentives to find adverse events or admit their products cause harm, Classen developed research tools to incentivize companies to look for adverse events associated with their already marked products and warn consumers of the adverse events. The research tool is particularly valuable for older

products that may even have gone off patent and for which pharmaceutical companies invest little.

Dr. Classen's research lead him to invent, a novel "System for creating and managing proprietary product data." Dr. Classen's efforts were then, and continue to be directed toward awareness that not only are vaccines causing an massive epidemic of diabetes and autoimmune diseases but many other pharmaceuticals are causing severe unrecognized adverse events. Classen patented research tools are not directed to finding adverse events per se but are directed to screen adverse event information to find adverse events that are patentable and can lead to increased profits by inhibiting generic competition. As such Classen 's patented research tool creates a strong positive financial incentive for companies to look for new adverse events and disclose these adverse events even in older products that have gone generic.

This civil action for patent infringement was brought by Plaintiff-Appellant, Classen Immunotherapies, Inc., the owner by assignment from Dr. John Barthelow Classen, of United States Letters Patent Numbers: ***6,219,674*** and ***6,584,472***. The remaining defendants is: Elan. Each of the patents at issue are based upon the research of Dr. John Barthelow Classen, M.D. Each patent claims priority to the Classen patent application Serial Number 09/449,178 filed on November 24, 1999. The ***6,219,674*** patent was invalidated in re-exam as well as 107 of the 137 of the originally issued claims of the ***6,584,472*** patent. Of the remaining claims, only claims 36, 42, 48–50, 59, 73–76, 84, 131, and 135 were asserted against Elan.

A Markman hearing has never been held, however the remaining patents in suit can be summarized as following:

Claim 36 (which depends on claim 33) of the '472 Patent can be summarized as the following steps:

33. A method for creating and using data associated with a commercially available product, wherein the method comprises the steps of:

(STEP 1) - accessing at least one data source, comprising together or separately, adverse event data associated with exposure to or use of the product and commercial data regarding marketing, sales, probability or related information pertaining to the product;

(STEP 2) - analyzing the accessed data to **identify** (i) at least one new adverse event associated with exposure to or use of the product, (ii) **at least one new use** for the product responsive to identification of the at least one new adverse event, and

(STEP 3) - (iii) the potential **commercial value** of the at least one new use for the product; and

(STEP 4) - commercializing the newly identified product information based upon the analyzed data.

Claim 36. The method of claim 33, **wherein the commercializing step comprises**

(STEP 5) - formatting the data relating to at least one new adverse event associated with exposure to, or use

of the product, or **documenting same**, such that a manufacturer or distributor of the product **must inform** consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.

Claim 131. The method of claim 36, **wherein commercializing further comprises (STEP 6) - documenting inventorship**.

The Product-by-Process claims:

Claim 84. A proprietary kit comprising:
(i) **product** and
(ii) **documentation** notifying a user of the product of at least one new adverse event relating to the product, wherein determination of the new adverse event is based upon the data provided by the method of claim 73.

Although steps (i), (ii) and (iii) of claim 33 may sound like the same type of activity that may be undertaken to obtain FDA approval, these accused steps were performed for USPTO submission and the results are submitted to the USPTO, not the FDA. The steps actually cover a re-analysis of information already submitted to the FDA for the distinctly separate commercial evaluation for submission to the USPTO and for profit through commercialization i.e. step (4). The re-use of the data from clinical trials for the purpose of filing a patent application is also not "solely for uses reasonably related to the development and submission of information" for submission to the FDA. The information has already been generated and

submitted, re-use is not generation or submission. Thus the safe harbor of 35 U.S.C. §271(e)1 should not apply.

Commercialization, as defined in the reexamination and discussed in the specification of the '472 patent can be any "commercializes the proprietary information by manufacturing and/or distributing (or causing to be manufactured and/or distributed) products or devices incorporating the proprietary information, and then selling the products or devices." ('472 patent, column 19: lines 57-62) Commercialization includes: "commercializes the proprietary information in the information storage device 22 by selling or licensing the proprietary information to a third party." ('472 patent, column 18: lines 51-55) The sale of the Skelaxin product is commercialization and the sale of the business along with the patent protection to third party King Pharmaceuticals was another act of commercialization by Elan.

The Federal Circuit acknowledges the breath of commercialization, stating that "commercializing an invention, which requires introducing an invention into commerce, or making preparations to do so" (Appx. 28a). Elan's patent applications and related documents demonstrate that Elan used the claimed methods of the Plaintiff's '472 patent in its "making preparations to do so" and to generate its own patentable invention. Use of another's patented invention is, according to the Federal Circuit, an act of commercialization and is an act of infringement.

B. Earlier Proceedings

Procedural History

Classen evaluated information in Elan's patents and concluded Elan completed the steps of the claims in the patent. Based upon these evaluations Plaintiff-Appellant Classen Immunotherapies, Inc. ("Classen") filed suit on November 2, 2004, asserting infringement under 35 USC §271, of United States Letters Patent Numbers ***6,219,674*** ("the '674 patent") and ***6,584,472*** ("the '472 patent").

The District Court in its decision (Appx. 3a) adopted verbatim the Statement of the Case set forth by the Federal Circuit in *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 894–96 (Fed. Cir. 2015) (Appx. 19a), we do the same:

> In December 2001 and March 2002, Elan filed two patent applications in the United States Patent and Trademark Office ("PTO") based on its clinical bioavailability data. The second application is a continuation of the first and shares the same specification. Those applications issued as *U.S. Patents 6,407,128* and *6,683,102* ("the Elan patents"). However, all claims of the Elan patents were later invalidated in light of prior art. *King Pharms., Inc. v. Eon Labs., Inc., 616 F.3d 1267, 1283 (Fed. Cir. 2010)*.
>
> Classen owns the '472 patent, which is directed to a method for accessing and analyzing data on a commercially available drug to identify a new

use of that drug, and then commercializing that new use.

Classen sued Elan in 2004, alleging that Elan infringed the '472 patent when it studied the effect of food on the bioavailability of Skelaxin, used the clinical data to identify a new use of the drug, and commercialized the new use. *Classen*, 466 F.Supp.2d at 624. Elan moved for summary judgment of noninfringement. The district court granted the motion in 2006, finding Elan protected by the safe harbor provision of § 271(e)(1) because Elan submitted its clinical data to the FDA with its citizen petition and sNDA, and thus its activities were "reasonably related to the submission of information" under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id.* at 625.

The lawsuit was then stayed pending an *ex parte* reexamination of the '472 patent, during which the PTO cancelled 107 of the 137 originally issued claims. Of the remaining claims, only claims 36, 42, 48–50, 59, 73–76, 84, 131, and 135 were asserted against Elan. Prior to issuing the reexamination certificate, the PTO Examiner stated, as reasons for patentability, that the "prior art of record fails to teach or fairly suggest the limitation of 'a manufacturer or distributor of the product must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product.

> After the reexamination certificate issued in 2010, Classen filed a motion in the district court seeking to lift the stay and to vacate the 2006 summary judgment. Classen argued that our decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) warranted reconsideration of the summary judgment because we held in *Biogen* that certain post-approval routine submissions to the FDA are outside the safe harbor of § 271(e)(1). In response, the district court lifted the stay but denied reconsideration of its 2006 decision. The court concluded that Elan was protected by the safe harbor under both *Biogen* and our subsequent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). The court reasoned that unlike *Biogen*, where the post-approval submissions were routine, Elan's submissions to the FDA were "not routine" because they were necessary to update the Skelaxin product label and to change the FDA-approval process for generic versions of Skelaxin. *Classen*, 981 F.Supp.2d at 421–22 .
>
> On the parties' joint motion, the district court entered final judgment of noninfringement under Rule 54(b) of the Federal Rules of Civil Procedure.

The District Court's decision (Appx. 31a) was appealed and then partially vacated by the Federal Circuit and remanded (Appx. 17a). The District Court reconsidered and ruled on September 27, 2016 (Appx.

3a) The District Court (Appx. 6a) summarized the intervening proceedings:

> On May 13, 2015, the Federal Circuit vacated and remanded Judge Quarles' 2012 judgment of non-infringement in favor of Elan. (ECF No. 232.) In its opinion remanding this case to this Court, the Federal Circuit concluded that "the district court correctly decided that § 271(e)(1) exempts Elan's activities reasonably relating to developing clinical data on its approved drug Skelaxin® ("Skelaxin") and submitting that information to the Food and Drug Administration ("FDA") in a citizen petition and a supplemental new drug application ("sNDA")." *Classen*, 786 F.3d at 894. However, the court also found that because Judge Quarles' opinion did not address Plaintiff's "assert[ion] that certain activities that occurred after the FDA submissions infringed the '472 patent and that those activities are not exempt under the safe harbor of § 271(e)(1)," remand was appropriate. *Id.* Accordingly, the sole question now before this court is whether Elan's "post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor." *Id.* at 898-99.

Second hearing and oral arguments. Oral arguments were made before the Federal Circuit in Oct 04, 2017 . The Federal circuit rendered a decision on the case October 17, 2017 .

C. The District Court's 35 U.S.C. §271(e)1 **Rulings**

The District Court under Judge Quarles originally moved against Classen under 35 U.S.C. §271(e)1 in its initial decision of 2006 (Appx. 44a). The District Court under Judge Quarles reconsidered his decision in 2013 under Rule 60(b) (Appx. 31a) because two relevant rulings by the CAFC occurred after 2006. The court considered both *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) and *Momenta Pharmaceuticals, Inc. v.Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012). The District Court reasoned that unlike *Biogen*, where the post-approval submissions were routine, Elan's submissions to the FDA were "not routine" because they were necessary to update the Skelaxin product label and to changethe FDA-approval process for generic versions of Skelaxin (Appx. 42a).

On remand from the Circuit Court, the District Court properly framed the issue on remand as:

> Accordingly, the sole question now before this court is whether Elan's "post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor." (Appx. 6a)

The District Court explained its reasoning with siding with the defendant:

> This Court's conclusion that Elan's post-submission activities fit within the scope of § 271(e)(1)'s safe harbor is further supported by *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982

> F.2d 1520, 1523–24 (Fed.Cir. 1992). As the Federal Circuit explained, *Telectronics* stands for the proposition that "the subsequent disclosure or use of *information* obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided that the subsequent disclosure or use is itself not an *act of infringement* of the asserted claims." *Classen*, 786 F.3d at 898 (emphasis in original) (citing *Telectronics*, 982 F.2d. at 1523-24). On this basis, the defendant in *Telectronics* remained within the safe harbor when it "present[ed] clinical trial data at a cardiology conference, report[ed] clinical trial progress to investors, analysts and journalists, and describe[ed] clinical trial results in a private fund-raising memorandum."*Id.* The alleged acts of commercialization by Elan—the filing of patent applications based on the reanalyzed clinical data and the sale of Skelaxin with the revised label containing information derived from the clinical trial—appear, contrary to Classen's argument, far less "commercial" in nature than those activities deemed protected in *Telectronics*. Accordingly, these activities remain within the scope of § 271(e)(1)'s safe harbor, and Elan is entitled to summary judgment. (Appx. 13a)

i. The District Court Erred in Extending 35 U.S.C. §271(e)1 to Post Commercialization Activities

Classen's assertion is simple, 35 U.S.C. §271(e)1 applies a safe harbor for use of an complete "invention" it does not provide safe harbor when a step of an

invention may be used for submitting data to the FDA. The method claims in suit include commercialization steps and the "kit" claims in suit cover the sale of a drug with documentation informing of the patented new use. Both the "commercialization" steps and the sale occur after FDA approval are unrelated to FDA approval. Use of the "invention", because of these steps, is thus not "solely for use" related to the submission to the FDA. Thus Classen is squarely opposite to *Teletronics*. It is fundamental patent law that claims must be evaluated as a whole, and a method claim is only infringed when all of its steps are performed. Thus, even if a part of the process were to fall within FDA reporting, the patented process as a whole would not and thus the infringing activity would not be protected by the safe harbor. In its ruling the District Court extended the safe harbor under *Teletronics* by ignoring sections of the *Teletronics* ruling which read "*provided that the subsequent disclosure or use is itself not an act of infringement of the asserted claims*" Id 982 F.2d 1520, 1523–24 (Fed.Cir. 1992).

ii. The District Court Erred in Extending Merck v. Integra to the Use of Research Tools

The Supreme Court commented in *Merck v. Integra*, 125 S.Ct. 2372 (2005) in Footnote 7 on p. 2382 regarding the Appeals Court's suggestion for a limited construction of the provision to avoid depriving so-called "research tools" of the complete value of their patents. The Court stated "We therefore need not and do not-express a view about whether, or to what extent, 271(e)(1) exempts from infringement the use of "research tools" in the development of information for the regulatory process." The District Court in the

current case widened this supreme court decision to include an research tool covered in patent '472.

iii. The District Court Erred in Extending 35 U.S.C. §271(e)1 to Use of Data.

35 U.S.C. §271(e)1 provides safe harbor for use of an "invention" "soley" for the creation of data to submit to the FDA. 35 U.S.C. §271(e)1 does not per se provide safe harbor for using data . In the current case the claimed "invention" covers screening data which may have previously been submitted to the FDA. Elan is accused of screening data previously submitted to the FDA to find patentable information to submit to the USPTO. The District Court ruled that "data" was protected. "The alleged acts of commercialization by Elan—the filing of patent applications based on the reanalyzed clinical data and the sale of Skelaxin with the revised label containing information derived from the clinical trial—appear, contrary to Classen's argument, far less "commercial" in nature than those activities deemed protected in *Telectronics.* (id Appx at 13a) However this is an expansion of the law to date which provided safe harbor for using an "invention". Data and inventions are two separate entities, and data can be created without use on any patented invention. Classen does not contend that the data submitted to the FDA was created by infringing its patented invention. Classen claims that analyzing data previously submitted to the FDA to find patentable information to submit to the USPTO is an act of infringement which is not protected under 35 U.S.C. §271(e)(1).

The district court erroneous ruling was based on expanding the ruling in *Telectronics Pacing Sys. v.*

Ventritex, Inc., 982 F.2d 1520, 1523–24 (Fed. Cir. 1992). In *Teltronics* the patent in suit covered an implatable defibrillator. The patented technology was used by a competitor to generate data to seek FDA submission. The court ruled that the generated data could be used for marketing purposes and other commercial activities and these commercial activates did not negate the safe harbor provided by 35 U.S.C. §271(e)1 for using the patented device for creating the data to submit to the FDA when seeking marketing approval.

In the present case the court expanded the ruling on *Teltronics* to indicate that commercial use of all data submitted to the FDA is protected, regardless of whether it was created using an patented invention or not, including when the product was already approved for marketing and being sold at the time of the alleged infringement as is alleged in the current case. The fact that the creation of the data did not infringe a single step of the claims and that the product was already on the market when the data was created was moot to the District Court's decision. According to the District Court in the current case the use of the data was still protected under the safe harbor of 35 U.S.C. §271(e)1 as is use of a patented research tool even if the research tool uses the data in only one of its many steps. The current ruling would provide safe harbor for use of almost any research tool that uses or created data submitted to the FDA.

iv. The Distric Court Erred in Extending 35 U.S.C. §271(e)1 to Sale a Product by Process after FDA Marketing Approval.

The court erred in expanding the ruling in *Teltronics* and extending 35 U.S.C. §271(e)1 to provide protection to any use of "data" submitted to the FDA, as described in iii above. The court further erred in extending the safe harbor protection of the FDA data include protecting commercial sale of a product created by a process that utilizes data submitted to the FDA.

The court stated:

> "making and selling Skelaxin with the revised label that contained the information derived from the clinical study" fall squarely within the safe harbor of § 271(e)(1). (id , Appx. 11a)

v. The District Court's Litmus Test for Applying the Safe Harbor of 35 U.S.C. §271(e)1 is Arbitrary and Not Consistent with the Intention of the Law.

In 2011, the Federal Circuit for the first time examined the issue of the applicability of the safe harbor to cover post-approval activity in *Classen Immunotherapies, Inc. v. Biogen IDEC* , 659 F.3d 1057 (Fed. Cir. 2011), a case involving other patents owned by Classen that are similar to those at issue in this case. In this case the CAFC created what has become a litmus test for determining when 35 U.S.C. §271(e)1 applies to research tools covering post marketing activity.

On remand from the Supreme Court, the Federal Circuit in *Classen v. Biogen* considered whether the so-called "safe harbor" provision of Section 271(e)(1) is limited to activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration. *Classen v. Biogen* , 659 F.3d at 1070. The Biogen court ruled that it was so limited: "Classen is correct, for § 271(e)(1) provides an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products. The statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained. *Id* at 1070."

In coming to this conclusion, the Federal Circuit noted that every decision examining the statute has appreciated that § 271(e)(1) is directed to ***premarketing*** approval of generic counterparts before patent expiration. *Id* . at 1071. Thus, a competitor is allowed to experiment prior to receiving regulatory approval without fear of patent infringement suits. By contrast, the activities engaged in by Biogen were "not related to producing information for an IND or NDA, and are not a 'phase of research' possibly leading to marketing approval" *Id* . at 1072. Accordingly, Section 271(e)(1) does not apply to those activities.

This litmus test for applying 35 U.S.C. §271(e)1 to post marketing use of patented research tools led to confusion and opposite conclusion by two panels, differing by only one judge at the CAFC, in decisions on a patents owned by Momenta Pharmaceuticals. In *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.* , 686 F.3d 1348, 1356 (Fed. Cir. 2012, Momenta I) and

Momenta Pharm., Inc. v. Teva Pharm. USA, Inc., 809 F.3d 610, 620 (Fed. Cir. 2015, Momenta II) the case involved a patent claiming methods of analyzing the chemical structures of a generic version of the anticoagulating drug enoxaparin. This method had to be practiced during the approval process for the drug to be put on the market and had to be continued to be practiced for each batch, as a continuing part of the approval process to ensure that its manufacture conforms to the requirements for the FDA's continuing marketing approval.

In *Momenta I*, the infringing chemical analysis of generic enoxaparin that was done was directly related to fulfilling the conditions of the FDA approval, and maintaining Amphastar's ability to continue to market its generic version of enoxaparin. That is why the post-marketing approval activities of Amphastar were not considered "routine." The CAFC ruled against Momenta, allowing Amphastar safe harbor to use Momenta's patent under 35 U.S.C. §271(e)1.

The Court in *Momenta I* distinguished the facts versus those in *Classen Immunotherapies, Inc. v. Biogen IDEC* , 659 F.3d 1057 (Fed. Cir. 2011), by pointing out that:

> [T]he information [generated by Amphastar] is necessary both to the continued approval of the ANDA and to the ability to market the generic drug. Here, the submissions are not "routine submissions" to the FDA, but instead are submissions that are required to maintain FDA approval. Amphastar is required to conduct a laboratory determination to identify the

> strength of the active ingredient for each batch of enoxaparin…. the situation here, where a drug has received approval, but it is nevertheless kept from the market based on an FDA mandated testing requirement. 686 F. 3d at 1358-59.

A second CAFC panel came to an opposite conclusion regarding applying the safe harbor under 35 U.S.C. §271(e)1 to Momenta's patent In *Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.*, 809 F.3d 610, 620 (Fed. Cir. 2015, Momenta II).

> The court in *Momenta I* described Amphastar's submissions as "anything but 'routine,'" 686 F.3d at 1358, a reference to *Classen*'s statement that § 271(e)(1) "does not apply to information that may be *routinely reported* to the FDA, long after marketing approval has been obtained," 659 F.3d at 1070 (emphasis added). With the benefit of additional briefing in the current appeals, which reflects the full district court record developed by all parties after the preliminary injunction phase, we conclude Amphastar's submissions are appropriately characterized as "routine." 809 F.3d at 625.
>
> The routine record retention requirements associated with testing and other aspects of the commercial production process contrast with non-routine submissions that may occur both pre- and post-approval, such as the submission of investigational new drug applications ("INDs"), new drug applications ("NDAs"), supplemental NDAs, or other post-approval research results.

> *See, e.g.*, 21 U.S.C. § 356b ("Reports of postmarketing studies"); *id.*§ 355c(b)(1) (post-approval pediatric data submissions); *id.* § 355(e) (withdrawal of drug approval based upon "new information"); *id.* § 355(*o*)(4) (labeling changes based upon new safety information); *id.* § 355-1 ("Risk evaluation and mitigation strategies"). The routine quality control testing of each batch of generic enoxaparin as part of the post approval, commercial production process is therefore not "reasonably related to the development and submission of information" to the FDA, and it was clearly erroneous to conclude otherwise. 809 F.3d at 626

The court cited the following:

> "*see also* H.R. Rep. No. 98–857, pt. 2, at 30 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2714 (Under § 271(e)(1) "the generic manufacturer is not permitted to market the patented drug product during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA *for approval*." (emphasis added)" 809 F.3d at 622-623.

The litmus test for the applying the safe harbor under 35 U.S.C. §271(e) to research tools used for post marketing activity has now been solidified by the Circuit Court. As it now stands if the FDA requires use of the tool post market approval it is "routine" and the safe harbor does not apply but if the company voluntarily used the research tool (to seek marketing approval or label changes) then the safe harbor is

applied. The apparent reversal on applying 35 U.S.C. §271(e)1 is proof that the Circuit Court's litmus test is arbitrary besides being contrary to the law limiting 35 U.S.C. §271(e)1 to premarketing approval activities.

The facts in the current case are in contrast to those in the Momenta's case. Elan's Skelaxin is not a generic drug and had already been approved by the FDA for commercial marketing when Elan allegedly used Classen's patented research tool to obtain its new patents on Skelaxin . None of the activities undertaken by Elan that are accused by Classen of infringing were undertaken to either obtain or maintain that FDA marketing approval. There was no mandated testing as was the case in *Momenta*. Elan's accused infringing activity was simply to determine that a therapeutic use of Skelaxin was potentially patentable (i.e. new), which it was not required to do by the FDA, either as part of its original approval of that drug, part of continued approval or otherwise.

Likewise, Elan's conduct does not fall within the purview of 271(e)(1). Elan is accused of post approval re-patenting, not pre-approval experimentation. Elan is accused of using study data to identify a new use of the drug, then commercializing that drug through, among other things, patenting that new use – activities that are covered by the claims of the '472 Patent, but fall outside of the safe harbor protection of 35 U.S.C. §271(e)(1). The commercial activities of Elan have nothing to do with the IND or NDA for Skelaxin which occurred a decade earlier , and by their very nature must fall outside of the scope of section 271(e)(1). The fact that Elan also applied for a label change at the FDA, to include safety information, does not somehow

extend the safe harbor into post approval activities. Skelaxin was on the market years before the accused activities and was not in need of any further FDA approval.

The Circuit Court's litmus test for applying 35 U.S.C. §271(e)(1) is arbitrary. In a separate family of patents of Classen the Circuit court ruled that the safe harbor of 35 U.S.C. §271(e)(1) did not apply because the accused infringing activity was "not related to producing information for an IND or NDA, and are not a 'phase of research' possibly leading to marketing approval" *Classen Immunotherapies, Inc. v. Biogen IDEC* , 659 F.3d at 1072 (Fed. Cir. 2011). In a different case separate panels used very different criteria for determining if the safe harbor should apply. As discussed above two separate panels came to opposite conclusions on whether the activities covered by Momenta's patents are "routine" or "non -routine". In the *Momenta II* case the court extended the safe harbor to cover all "non-routine" submissions and defined these: "non-routine submissions that may occur both pre- and post-approval, such as the submission of investigational new drug applications ("INDs"), new drug applications ("NDAs"), supplemental NDAs, or other post-approval research results. *See, e.g.*, 21 U.S.C. § 356b ("Reports of postmarketing studies"); *id.*§ 355c(b)(1) (post-approval pediatric data submissions); *id.* § 355(e) (withdrawal of drug approval based upon "new information"); *id.* § 355(*o*)(4) (labeling changes based upon new safety information); *id.* § 355-1 ("Risk evaluation and mitigation strategies"). 809 F.3d at 626.

The problem is the court applies the safe harbor to use of a research tool for "non-routine" submissions

to the FDA but not to uses that are deemed "routine" submission to the FDA. According to the court in the current case, performing research on one's product after market approval and updating the label is "non-routine" thus protected under the safe harbor of 35 U.S.C. §271(e)1. It is highly possible that the use of a patented research tool could be "non-routine" in 2018 but "routine" in 2019 because the FDA required or highly recommended its use in 2019. The submission could be "non routine" for the innovator pharmaceutical company but the FDA could then adopt the standard and make it "routine" for competitors in later years as allegedly occurred with Momenta's technology. In such an example the identical use can be infringement in 2019 but not in 2018. This is obviously very arbitrary.

D. The Federal Circuit's Panel Decision

The Circuit Court

The Federal Circuit's decision (Appx. 2a) in its entirety reads:

> **AFFIRMED.** ***See*** **Fed. Cir. R. 36.**

The Circuit Court left unchanged the District Court's ruling that provided the defendants safe harbor under 35 U.S.C. §271(e)1. The Circuit Court's decision confirms a broadening of 35 U.S.C. §271(e)1 by redefining the definition of "non routine" used in the court's litmus test for covering post market approval use of research tools, as described in *Classen Immunotherapies, Inc. v. Biogen IDEC* , 659 F.3d 1057 (Fed. Cir. 2011).

The Circuit Court decision is also in direct opposition to a decision of a different panel of the Circuit Court in *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 894–96 (Fed. Cir. 2015) (Appx. 28a), which stated that Classen presented a different factual situation and *Telectronics* was inapplicable:

> "Here, unlike in *Telectronics*, Classen alleges that Elan's post-submission *activities* using the clinical data for non-regulatory purposes *infringed* the claims of Classen's *'472 patent*. Specifically, Classen asserts that Elan's filing of patent applications based on the clinical data infringed the method claims and that Elan's sale of Skelaxin with the revised label containing information derived from the clinical trial infringed the kit claims."

REASONS FOR GRANTING THE PETITION

There are several reasons for granting this petition. The USSC decision *Merck v. Integra*, 125 S.Ct. 2372 (2005) left open the enforceability of research tool patents. The CAFC has been unable to provide an coherent decision on this subject as it applies to use of research tools after market approval of a product. In the Momenta case, the CAFC ruled twice with different results each time. In the current case the case went before the CAFC twice and got different opinions each time. A large part of the problem is the litmus test the Circuit Court is now trying to employ is arbitrary and is not supported by the law. The problem is the court applies the safe harbor to use of a research tool that is "non routine" but not to uses that are deemed "routine" to the submission to the FDA. In the

Momenta case, Monenta's patented research tool was initially ruled to be "non- routine" (covered by a safe harbor) and then later ruled to be "routine" (not covered by the safe harbor). The current case relates to use of a research tool that has been ruled to be "non-routine" to the submission to the FDA. According to the court, performing research on one's product after market approval and updating the label is "non-routine" thus protected under the safe harbor of 35 U.S.C. §271(e)1 . However in a similar case on patents owned by Classen the CAFC took the opposite stance, ruling that submitting vaccine safety data to the FDA and using such data was not covered under the safe harbor of 35 U.S.C. §271(e)1 *Classen Immunotherapies, Inc. v. Biogen IDEC* , 659 F.3d 1057 (Fed. Cir. 2011).

I. This Court Should Review The Federal Circuit's Decision Regarding 35 U.S.C. §271(e)1 in this Case.

The current case is unique compared to the most previous case ruled on by the USSC regarding 35 U.S.C. §271(e)1 because it involves use post marketing approval. The case in contrast to Momenta involves use of a research tool that the court ruled is "non-routine" for the submission to the FDA and covered by the safe harbor. The safe harbor of 35 U.S.C. §271(e)1 was written to support pre-marketing development of generic products, the discrimination on applying safe harbor was use for pre-marketing development versus post marketing sales. The CAFC's new litmus test for use in post marketing approval is not supported by the law.

II. These Issues Have Paramount Importance For Patent Litigation And Are Ripe For Review By This Court.

Generic challenges to pharmaceutical patents has increased substantially in recent years in part at the urging of the US government. This has placed a large strain on an over worked court system. Uncertainty in the outcomes is an disincentive to attracting investors needed to develop new pharmaceuticals. There is an need for the court to set a clear message of what is the extent of protection under 35 U.S.C. §271(e)1.

The Supreme Court briefly discussed the impact on *Merck Integra* on the infantile research tool industry. The Classen's '472 patent included a research tool for commercializing drug adverse event information. The current decision creates confusion among those in the research tool industry. A clear decision by the Supreme Court could reassure investors and help build this vital industry. A clear decision would reduce the burden in an over worked court system.

CONCLUSION

The petition for writ of certiorari should be granted.

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