Any Port in a Storm: The Hatch-Waxman’s (Ever Expanding) Safe Harbor Provision

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Thomas Jefferson, Benjamin Franklin, and the multitude of men and women who helped establish the United States were visionaries in many ways. One of the most important of which was to provide Congress with the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” While the drafters of the Constitution likely understood that this provision, a mere 27 words, would lead to many patents, they likely did not realize that their actions would help foster the incredible inventions and discoveries we have today. Additionally, while the drafters of the Constitution gave Congress the power to regulate this patent system as Congress saw fit, the Founding Fathers did not intend for certain patent holders to have their rights stifled by future legislative, regulatory, or judicial proceedings. However, in the wake of the Federal Circuit’s recent decisions in Classen Immunotherapies, Inc. v. Biogen IDEC and Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, the right of patent owners, having patents directed to drugs, medical devices, and other products that require regulatory approval under a Federal law, to pursue infringers has been significantly limited. These decisions could result in a diminished economic value of such patents.

For more than two centuries, Congress has balanced this Constitutional grant. Congress has granted inventors the exclusive right to exclude others from their invention, but only for a limited time, so that no one person has a long-term monopoly on a product or process. Since the first Patent Act of 1790, Congress has enacted numerous legislation governing patents. However, Congress has never attempted to render the patent system ineffective, instead attempting to level the playing field for future inventors and the public, even when the statutes that Congress has enacted have modified or introduced new limitations to address the ever-changing technological landscape.

One such statute, the Drug Price Competition and Patent Term Restoration Act, or the “Hatch-Waxman Act,” was passed to address patent issues related to the amendments to the Federal Food, Drug and Cosmetic Act (the FFDCA) in 1962. This statute effectively granted a patent holder an additional patent term while one or more third parties sought regulatory approval. However, recent decisions interpreting a small but important provision of the Hatch-Waxman Act have left this area of law unclear, potentially giving drug manufacturers free reign, regardless of the relevant patents.

The Safe Harbor provision, as codified at 35 U.S.C. § 271(e)(1) and enacted to level the playing field between generic drug manufacturers and holders of patents covering the drug formulations, protects a party against patent infringement in limited circumstances. The statute protects a party using a patented invention “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.” However, in light of the Federal Circuit’s decisions in Classen Immunotherapies, Inc. v. Biogen IDEC and Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc., the Safe Harbor provision has made it difficult for manufacturers and courts alike to make well-grounded decisions in this area in the wake of the conflicting rulings.

This article explores the Safe Harbor provision and how this provision should be interpreted in the future. In doing so, the history of the FFDCA and the Hatch-Waxman Act will be explored, as well as related precedential court opinions, to understand
Congress' motives in enacting the Safe Harbor provision and the provision's intended scope.

Prior to the Hatch-Waxman Act

The Safe Harbor provision and the Hatch-Waxman Act were born from the need for additional safety and efficacy regulations in pharmaceutical drug testing, to protect the public from dangerous and ineffective pharmaceutical drugs. While the FFDCA addressed this lack of governmental oversight, an "artificial" patent term extension was created due to the lengthy nature of the investigatory period. As a result, Congress enacted the Safe Harbor provision of the Hatch-Waxman Act.

Prior to 1962, the FFDCA only controlled the labeling, contents, and safety of medications, in addition to the marketing and distribution processes of medication in the United States.4 The Federal Drug Administration (FDA) had no power to control the effectiveness of medications at the time. However, in 1957, the sale of a drug intending to alleviate morning sickness in women caused Congress to realize that a more thorough examination of pharmaceuticals was needed prior to market approval. This examination paved the way for the regulations by which the FDA governs pharmaceuticals today.

In 1957, the William S. Merrill Company was selling a sedative called thalidomide in Canada and throughout Europe. Thalidomide was intended to alleviate morning sickness in women during pregnancy. Unbeknownst to the medical community, thalidomide caused birth defects in newborn babies or stillbirths, and thousands of children were born with no limbs or truncated limbs.5

During this period, the Merrill Company was attempting to gain FDA approval for thalidomide in the United States. Thalidomide never reached the US market, however, thanks in part to the medical officer Frances Kelsey, PhD, MD, who would not approve thalidomide for lack of data.6 Nevertheless, it was clear that the FFDCA needed to be updated to provide the FDA with additional tools to protect patients.

Accordingly, in 1962, Congress passed legislation drafted by United States Senator Estes Kefauver and US Representative Oren Harris, providing the FDA with additional authority. These amendments included, inter alia, efficacy requirements based on clinical studies before the medications were approved for distribution in the market.7 Thus, before any drug was approved for market use, the manufacturer or distributor was required to show the safety and efficacy of the drug. While this statutory scheme created long-necessitated safety requirements for pharmaceuticals and allowed the FDA to regulate the drug industry, the updated FFDCA eventually created issues for generic drug companies attempting to gain FDA approval once the patent term of a patented drug ran out.

The Hatch-Waxman Act

In the wake of the 1962 Kefauver-Harris amendment to the FFDCA, pharmaceutical drugs need to pass safety and efficacy tests. However, these experiments take time, sometimes years.8 Furthermore, if the pharmaceutical drug was covered by a patent, which is almost certainly the case, testing and human experimentation could not occur until after the term of the patent had expired. Thus, patent owners with patents covering products requiring federal regulatory approval, that is, pharmaceutical drugs, essentially retained an extended patent term of several years. This issue came to bear during patent infringement proceedings in Roche Products, Inc. v. Bolar Pharmaceutical Company, Inc.

Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.

Roche Products (Roche) was the assignee of US Patent No. 3,299,053 (the '053 patent), with claims directed to a chemical compound for flurazepam hydrochloride, a compound used in sleeping pills.9 In 1983, Bolar Pharmaceutical Company (Bolar) became interested in exploring the development of a generic drug having the same properties as the compound claimed in the '053 patent.10

Under 35 U.S.C. § 271(a), "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent." Nevertheless, in 1983, before the expiration of the '053 patent, Bolar obtained a small quantity of flurazepam hydrochloride from a foreign manufacturer to begin the process of forming dosage capsules and performing experiments to obtain the requisite information to submit to the FDA.11

Roche pursued infringement proceedings against Bolar as a result of Bolar's actions. During these proceedings, Roche requested a motion
for preliminary injunction, alleging the “use of a patented drug for federally mandated premarket ing tests is a use in violation of the patent laws.” (Emphasis in original). However, the district court denied Roche’s motion, stating that Bolar’s use was not an infringement of Roche’s patent rights under Section 271(a). Roche appealed to the Federal Circuit, which overturned and remanded.

In its decision, the Federal Circuit noted that any “use of a patented invention, without either manufacture or sale, is actionable.” Bolar asserted that its use of flurazepam hydrochloride was exempted from the use prohibition. Bolar argued, inter alia, that public policy is not in favor of artificially extending the patent term by requiring the submission of data to a federal regulatory board. The court, however, disagreed.

In defending its actions, Bolar argued that a new exception prohibition was necessary to address the conflict between the safety and efficacy requirements for the generic drug under the FFDCA, which can take several years, and the prohibition against beginning safety and efficacy experiments until after the expiration of the patent term. At the time of the decision, the patent law granted inventors 17 years of exclusivity from the date the patent was issued. Currently, inventors enjoy a 20 year patent term, beginning from the earliest effective filing date of the patent. Regardless of length of the patent term granted by the statute, the FFDCA effectively granted an additional two or more years of exclusivity to the patent owner. The court acknowledged this conflict, but stated correctly, that the mere fact that later statutes may affect earlier legislation is not a reason for the court to rewrite the law. The Federal Circuit noted in its decision that repeals of statute by implication are strongly disfavored.

In holding for Roche, the Federal Circuit determined that Bolar’s experimental use of the flurazepam hydrochloride was an infringing use under 35 U.S.C. § 271(a), and that an experimental use of a patented drug, even for the limited use of testing for the FDA, is an act of infringement. In its decision, the court noted Congress’ recognition of the economic impacts of the FFDCA. Nevertheless, the court properly refused to address these issues, paving the way for Congress to pass the Hatch-Waxman Act and the Safe Harbor provision of 35 U.S.C. § 271(e)(1), which superseded the decision in Roche Pharmaceuticals.

The Safe Harbor Provision of the Hatch-Waxman Act

Prior to the Federal Circuit’s ruling in Roche Products, Congress understood the economic implications of the FFDCA, and had begun the process of developing legislation to address these implications. The purpose of the Hatch-Waxman Act was to provide low-cost generic drugs to consumers and to provide a more streamlined approval process to approve these drugs.

One of the provisions of the Hatch-Waxman Act specifically addressed the issue presented in Roche Products: Is the experimental use of a patented drug to produce data for submission to a federal regulatory board infringement? Although the court in Roche Products properly held such actions constituted patent infringement in accordance with the law at the time, Congress understood this was bad public policy. In fact, Congress specifically referenced the Federal Circuit’s decision in Roche Products, noting that any experimental use of a drug during the life of the patent would not harm the patent owner’s exclusive rights, “but prevention of [experimental use for regulatory approval] would extend the patent owner’s commercial exclusivity beyond the patent expiration date.” Accordingly, Congress passed Section 202 of the Hatch-Waxman Act to create the Safe Harbor provision.

The Safe Harbor provision, as codified at 35 U.S.C. § 271(e)(1), recites

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.
The legislative history makes evident that the purpose of 35 U.S.C. § 271(e)(1) “is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not patent infringement.”\(^{23}\) (Emphasis added). In addition, the legislative history emphasizes that Congress’ intent is not to permit the sale of the drug. Instead, the Safe Harbor provision permits the “commercial sale of research quantities of active ingredients” in order to develop information “which is required to obtain approval of the drug.”\(^{24}\) Thus, Congress’ intent in passing the Safe Harbor provision was to provide a limited exception for the experimental use of a patented drug. This limited exception was to allow the submission of data related to the experimental use only to obtain approval for the drug. Accordingly, any other use of a patented drug or process for making a patented drug would be an infringing use that is not exempt from Section 271(a).

**Interpreting Hatch-Waxman and the Safe Harbor Provision**

Since the inception of Section 271(e)(1), many courts have incrementally defined the contours of the statute. The Supreme Court’s decision in *Eli Lilly and Co. v. Medtronic, Inc.*,\(^{25}\) provides one of the earliest insights into the interpretation of the Safe Harbor provision and the extent to which the Safe Harbor provision exempts accused infringers.

**Eli Lilly and Co. v. Medtronic, Inc.**

The predecessor-in-interest of Eli Lilly and Co. (hereinafter Eli Lilly), which owned patents directed to a cardiac defibrillator, filed an action in US district court against Medtronic. In its complaint, Eli Lilly alleged infringement of its patents by Medtronic’s implantable cardiac defibrillator.\(^{26}\) A jury verdict found for Eli Lilly, and the district court entered a permanent injunction against infringement of both patents.\(^{27}\) The Federal Circuit reversed and remanded. The Federal Circuit held that no infringement existed if Medtronic’s use of the cardiac defibrillator was solely for developing information to be submitted to the FDA for regulatory approval of the implantable cardiac defibrillator.\(^{28}\) The Supreme Court granted certiorari and upheld the Federal Circuit’s decision.\(^{29}\)

The Safe Harbor provision recites, *inter alia*, “a Federal law which regulates the manufacture, use, or sale of drugs.” In construing the words of the statute, the Supreme Court determined that “a Federal law,” as recited in Section 271(e)(1), could mean one section of a statute, or could pertain to an entire statutory scheme of regulation under the Federal law.\(^{30}\) The Court preferred the latter interpretation. The Court found there were much easier and clearer ways in which the statute could have been worded if Congress had intended for medical devices to be excluded from the Safe Harbor provision, such as specifically excluding the medical devices, which Congress did with new animal drugs and veterinary biological products.\(^{31}\)

In its holding, the Court also examined Section 201 of the Hatch-Waxman Act, which provides a possible five year patent term extension for patents of products relating to a human drug, medical device, food additive, or color additive if, *inter alia*, the products were subject to a regulatory review prior to the commercial marketing or use of the product.\(^{32}\) The Supreme Court did not believe Congress intended to exclude medical devices from the Safe Harbor provision, which would allow medical devices to gain a potential five-year period of exclusivity from the beginning of the patent term, while also gaining an artificial two-year period, or longer, at the end of the patent term.

The issue presented in *Roche Products* would persist if the Supreme Court only had applied the Safe Harbor provision to drugs and not medical devices, only for a smaller class of patents. However, as discussed *supra*, Congress, in enacting the Hatch-Waxman Act and the Safe Harbor provision, clearly intended to solve the issue presented in *Roche Products*, which was the following:

[D]oes the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use, which, unless licensed, the patent statute makes actionable?\(^{33}\)

In summarizing, the Court understood that there was no perfect interpretation of 35 U.S.C. § 271(e)(1).\(^{34}\) However, the Court determined that, in view of the legislative history and other sections of the Hatch-Waxman Act that applied patent term extensions to medical devices as well as drugs, Congress clearly intended for the Safe
The Supreme Court's holding in *Eli Lilly* indicated that 35 U.S.C. §§ 271(e)(1) needed clarification, and that the statute could, and should, be clarified by looking to the legislative history and the Hatch-Waxman Act in its entirety.\textsuperscript{35}

**Balancing the Safe Harbor Provision**

After the decision in *Eli Lilly*, it was clear that Congress' intent when drafting the Safe Harbor provision was not clearly stated in the statute. For example, if Congress was attempting to exclude medical devices, Congress knew that the FFDCA applied to both drugs and medical devices, and there would have been no reason to allow patent owners of medical devices to enjoy this additional patent term while patent owners of drugs did not. Accordingly, the Supreme Court properly held that the Safe Harbor provision applied to all products subject to regulatory approval under the FFDCA, other than those specifically excluded by Section 202 of the Hatch-Waxman Act—new animal drugs and veterinary biological products.

The Federal Circuit decided two cases concerning the time frame in which the Safe Harbor would apply. In the first case, *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit properly determined that the Safe Harbor provision only applies to information routinely being reported during premarket approval, not for submissions after marketing approval has been obtained.\textsuperscript{36} However, a year later, the Federal Circuit held in *Momenta* that the Safe Harbor provision applies to any submission of data for regulatory approval under a Federal law at any time. Interestingly, the panel in *Momenta* included Chief Judge Rader, who wrote the decision for the majority in *Classen*, and Circuit Judge Moore, who wrote the dissent in *Classen*. The court in *Momenta* attempted to reconcile its decision with the holding in *Classen*. However, as discussed in the dissent by Chief Judge Rader and discussed infra, the court in *Momenta* improperly applied the Safe Harbor provision to postmarket activities requiring federal regulatory activities. By its decision in *Momenta*, the Federal Circuit effectively has given any accused infringer safety, so long as the infringer's activities reasonably relate to developing information, which a federal regulatory agency may require to be submitted.

**Classen Immunotherapies, Inc. v. Biogen IDEC**

In the Federal Circuit's first decision on when the Hatch-Waxman Act's Safe Harbor provision applies, the court properly held in *Classen* that the Safe Harbor provision applies only to the submission of data to facilitate premarket, regulatory approval under a Federal law.

Classen owned multiple patents relating to a method of lowering the risk of immune disorders by, *inter alia*, immunizing a patient in accordance with a determined schedule.\textsuperscript{37} During litigation, Classen alleged Biogen and GlaxoSmithKline (together, Biogen) infringed Classen's patents by participating in studies to evaluate childhood vaccinations and determine the timing of immunizing patients based on the data obtained from the studies.\textsuperscript{38} In addition, Classen alleged that Biogen induced infringement by licensing technology to third parties, by providing instructions to carry out vaccinations based on evaluation of patient data.\textsuperscript{39} The district court ruled that Biogen was protected by the Safe-Harbor provision, but the Federal Circuit properly vacated the decision.\textsuperscript{40}

In making its decision, the court discussed the legislative history of the Hatch-Waxman Act. Specifically, the court noted that Congress only intended the Safe Harbor provision apply to information that would be reasonably related to a submission of information to obtain "premarketing approval of generic drugs."\textsuperscript{41} Moreover, the court noted that the Hatch-Waxman Act does not apply to "information that may be routinely reported to the FDA, long after marketing approval has been obtained."\textsuperscript{42} In other words, Congress only intended the Safe Harbor provision to apply to premarket approval of drugs, not activities that would allow an infringer to make economic gains by using a patented method or product.

To bolster its argument, the Federal Circuit cited *Eli Lilly*, where the Supreme Court stated that activities do not constitute infringement if the activities are undertaken to provide data of the type reasonably related to information required to be submitted to obtain regulatory approval, that is, premarketing testing.\textsuperscript{43} In addition, the Federal Circuit cited to *Merck v. Integra Lifesciences*. The Supreme
Court determined in *Merck* that 35 U.S.C. § 271(e)(1) protected infringing activities, when the activities developed information required to be submitted for an investigational new drug application or new drug application (i.e., premarket approval), regardless if the information actually is submitted. The Supreme Court in *Merck* understood that the data may not be submitted to the FDA for certain reasons, such as a determination that the drug will be unsuccessful. However, the Supreme Court held that the *premarketing* research would still be protected, understanding that the experiments in developing these products is just that—an experiment.

In her dissent, Circuit Judge Moore disagreed with the majority's opinion, stating that 35 U.S.C. § 271(e)(1) broadly applies to any actions reasonably related to the development and submission of any data under a Federal regulatory law. However, if the Court were to adopt Judge Moore’s interpretation, anyone could infringe a patent related to drugs or medical devices, so long as records were kept that would be "reasonably related" to the development and submission of information under Federal law for regulatory purposes. Chief Judge Rader raised this point in his dissent in *Momenta*, stating that the FDA has wide discretion to inspect records of drug manufacturers or sellers. The FDA requires that drug manufacturers and sellers maintain numerous records, which the FDA can inspect at any time. Thus, manufacturers and sellers can argue that any use, be it the making, using, or selling of a patent drug or medical device, is reasonably related to the development of information to be submitted to the FDA. Thus, if the Court were to interpret the Safe Harbor provision as suggested by Judge Moore, almost any infringing activity would be protected, essentially making patents for drugs and medical devices worthless.

Accordingly, the Court properly held that the Safe Harbor provision only applies when the actions are reasonably related to the development and submission of information under a Federal law to obtain premarket regulatory approval. If the Safe Harbor provision were extended any further, arguably all infringing uses would be protected. However, the Federal Circuit did just that in *Momenta*.

**Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals**

The Federal Circuit had a second opportunity to address the Safe Harbor provision of the Hatch-Waxman Act a year after its decision in *Classen*. However, in deciding *Momenta*, Circuit Judge Dyk essentially agreed with Judge Moore’s dissent in *Classen*, and the majority held that the Safe Harbor provision extends to more than just premarket approval activities. While Judge Moore attempted to reconcile the *Momenta* holding with the *Classen* decision, Chief Judge Rader wrote a strong dissenting opinion, correctly noting that the issues in *Momenta* and *Classen* were similar, and the Safe Harbor provision applies only to premarket approval of drugs and medical devices.

The patent at issue in *Momenta*, US Patent 7,575,886 (the ‘886 patent), includes claims directed to, *inter alia*, methods for producing a blood thinning drug enoxaparin, which is a generic version of the brand-name drug Lovenox. The patent also included methods for analyzing a test sample of the drug compared to a reference standard. Momenta alleged that Amphastar infringed the ‘886 patent by manufacturing the generic form of enoxaparin using the claimed method and by analyzing the enoxaparin using the claimed method for analysis. In issuing a preliminary injunction against Amphastar, the district court acknowledged that the FDA requires an analysis of each batch of the enoxaparin drug to ensure that each batch has the same chemical composition. However, the district court held that this testing does not fall within the protective limits of the Safe Harbor provision because Amphastar already had received regulatory approval for enoxaparin, as discussed in *Classen*.

The Federal Circuit reversed the district court’s decision, holding that the Safe Harbor provision is not limited to regulatory approval and extends to postapproval activities.

In its decision, the Federal Circuit found that there was no need for further inquiry of the language of Section 271(e)(1), because "Congress could not have been clearer in its choice of words." The court went on to state that the broad language of the statute is unambiguous. The Federal Circuit also stated that Congress intended the law to apply to the development and submission of information under any federal law, not "just the submission of information pursuant to the [FFDCA],” generally, or the Abbreviated New Drug Application (ANDA) of the FFDCA, specifically. Furthermore, the court pointed to Congress’ explicit exclusion of animal drugs and veterinary
biological products as support for its “plain meaning” analysis of the statute. The court stated that if Congress only wanted the Safe Harbor provision to apply to ANDAs or similar submissions, then Congress would have explicitly included this in the statute. The court refused to import limitations of Section 202 (35 U.S.C. § 271(e)(2)), which specifically references applications submitted under the FFDCA.

In support of its holding, the Federal Circuit stated that its analysis was no different from the Supreme Court’s analysis in Eli Lilly & Co. v. Medtronic, Inc. As discussed, supra, the Supreme Court determined that, by examining the entire statutory scheme of the Hatch-Waxman Act, the Safe Harbor provision applied to both drugs and medical devices. The Supreme Court came to this conclusion by examining other provisions of the Hatch-Waxman Act. However, the Federal Circuit refused to examine the Safe Harbor exception in light of the surrounding provisions. Instead, the court in this instance examined the Safe Harbor provision in a vacuum, contradicting itself along the way by not following the analysis of the Supreme Court in Eli Lilly.

Moreover, the Federal Circuit attempted to show that the Supreme Court in Merck KGaA allows an accused infringer to hide within the Safe Harbor provision if any use of a patented compound is reasonably related to the submission of information under any Federal law. It is true that Merck determined that Section 271(e)(1) is not limited only to information to be included in a submission to the FDA for the filing of an ANDA or other regulatory approval. However, the Supreme Court also stated that the Safe Harbor provision applied “as long as there is a reasonable basis for believing that the experiments will produce ‘the types of information that are relevant to an IND or NDA’.” In other words, the information that is obtained by an accused infringer does not have to be submitted to the FDA. This allows accused infringers to experiment with patented compounds to determine if the patented compounds are viable.

Nevertheless, the infringing activity that is being performed must be “reasonably related” to the development and submission of information that could be submitted “on the road to regulatory approval.” (Emphasis added). In other words, the information does not necessarily have to be submitted, but the actions must be “reasonably related” to information that could be submitted for regulatory approval, that is, premarket approval of a drug or medical device. Any postapproval actions, regardless if the information is required by the FDA, merely allows the accused infringer to make economic gains from the patented product or method, to the harm of the patent owner.

The majority cites the FDA regulation for releasing a drug into the public domain. This regulation requires that “for each batch of drug product, there shall be appropriate laboratory determination of... the identity and strength of each active ingredient...” While the FDA requires that records related to safety and efficacy tests be maintained for a certain period of time, the FDA does not require submission of these records, as the drug at this stage has already been approved. As noted by Chief Judge Rader in his dissent, Section 271(e)(1) requires that the data be submitted pursuant to a Federal law for regulatory approval. Nevertheless, the majority attempts to reconcile that maintaining data, which may be inspected by the FDA, is the same as submitting data pursuant to a Federal regulation for drug approval. However, the submission of data and the maintenance of data are in fact opposite actions.

In addition, Chief Judge Rader points out Congress’ only reason for passing the Safe Harbor provision—to overturn the court’s ruling in Roche Products. As discussed supra, the Federal Circuit in Roche Products determined that experimental data, the purpose of which was obtained only to seek FDA approval of enoxaparin, was an infringing use. However, in passing the Hatch-Waxman Act, Congress determined that experimental data of this kind, when FDA approval of a drug is sought, does not adversely affect the patent owner’s exclusive rights. The clear intent of Congress shows that Section 271(e)(1) applies only to premarket approval of drugs and medical devices, not information collected after approval has been obtained. Otherwise, the majority’s “interpretation of § 271(e)(1) would essentially render manufacturing method patents worthless.”

The court in Momenta allowed Biogen to circumvent a valid patent by applying the Safe Harbor provision to postmarket approval, simply because this data may be inspected by the FDA. Furthermore, instead of requiring Biogen to
determine a different method of developing this data, the Court sanctioned Biogen’s trespass to the patented method of developing this data, which was infringed each and every time a new batch of the drug was made and tested. This was clearly never the intention of Congress in passing the Hatch-Waxman Act and the Safe Harbor provision, but has given infringers a strong defense for explaining infringing activities in the future.

**Moderating the Safe Harbor**

In view of the Federal Circuit’s recent decisions in *Classen* and *Momenta*, the state of the Safe Harbor provision is unclear. While the court in *Momenta* attempts to reconcile its decision with the holding in *Classen*, the two decisions cannot be reconciled. Furthermore, the court in *Momenta* discounts the legislative intent in creating the Safe Harbor provision, which was to provide an exception to patent infringement only in limited cases where premarket regulatory approval under a Federal law is sought.

In a subsequent decision, the Federal Circuit must either review the Safe Harbor provision *en banc*, or the Supreme Court must weigh in on the issue. The amount of money invested in research and development of drug patents, both the method of making the product and the product itself, is too great, only to have the patent unenforceable because the Federal Circuit in *Momenta* essentially granted any infringer of a drug product safe harbor, so long as the infringer maintains data records which may be reviewed by a federal agency.

The courts should overturn the *Momenta* decision because it is clear, from both the legislative intent and the history of understanding the Hatch-Waxman Act, that Congress intended the Safe Harbor provision to apply only to premarket approval experimentation. The question now is simple: Can a patent owner ever again enforce a drug patent, or will the Safe Harbor, as interpreted by the Federal Circuit’s decision in *Momenta*, protect accused infringers forever? Those parties seeking to place boundaries on the Safe Harbor provision after *Momenta* would be well-advised to consider the nature of the activity for which the Safe Harbor extends. Perhaps the occasional batch testing, even if after regulatory approval, stands in contrast to the continuous administration of drugs and the subsequent data collection at issue in *Classen*. On the other hand, those parties who are of the view that *Momenta* provides clear field for postapproval activity should proceed with caution on the same grounds.

**Conclusion**

If drug manufacturers and the FDA knew the safety and efficacy of each and every drug, the experiments required for regulatory approval under Federal laws would be unnecessary, and the Safe Harbor provision would be unnecessary. However, if the Safe Harbor provision were extended to postmarket activities, the patent owner would have a worthless patent. Furthermore, it is not being argued that the Safe Harbor provision extends to all premarket activities. Instead, the Safe Harbor provision should apply only to premarket activities “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,” as recited in 35 U.S.C. § 271(e)(1).

By applying the Safe Harbor provision in this manner, patent owners will enjoy economic benefits and exclusivity provided by their ownership of the patent, without being able to take advantage of some artificial patent term extension. The Hatch-Waxman Act and the Safe Harbor provision were intended to benefit the public, by allowing safe and effective drugs to be supplied at a lower cost at the end of a patent term. However, by applying the Safe Harbor provision to postmarket activities, the value of a patent is diminished, if not completely worthless, and provides infringers with an almost perfect defense to infringement, without any public benefit. If the Safe Harbor continues to be applied in this way, drug manufacturers may decide to limit investment in certain areas, thereby negatively impacting the public. If pharmaceutical companies fear that the Safe Harbor provision will effectively grant a pass to any infringing use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical companies will be hesitant to invest the necessary use by generic drug makers, pharmaceutical 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the method of testing the drug. Therefore, drug and medical device companies may consider filing patents with claims drawn the drug or medical device product, or only to the method of producing the drug or medical device. By having patent claims directed to the product or only the method of producing the product, any use of the product would be an infringement of the patent under Classen, regardless of the FDA’s testing requirements. Accordingly, while the law is currently unclear, drug and medical device companies should consider filing claims directed to the specific product or to methods of making the product. Such patents will help protect the research and development investments of these companies and will allow companies to develop drugs and medical devices to benefit the public.

Notes
6. Id.
7. Id. § 102.
9. Id.
10. Id.
11. Id.
12. Id.
13. Id. at 861.
14. Id. at 860.
16. Roche at 862.
17. Id. at 863.
18. Id. at 864.
19. Id. at 860.
21. Id. at 46.
22. Id. at 45.
23. Id.
24. Id.
26. Id. at 664.
27. Id.
28. Id.
29. Id. at 662.
30. Id. at 666.
31. Id. at 667.
32. Id.
33. Roche at 861.
34. Eli Lilly at 679.
35. Id. at 672-673, 678.
36. Classen at 1070.
37. Id. at 1066.
38. Id. at 1070.
39. Id.
40. Id. at 1057.
41. Id. at 1071.
42. Id. at 1070.
43. Id. at 1071, citing Eli Lilly at 664.
44. Id.
45. Id. at 1083.
46. Momenta at 1367 (Rader, dissenting).
47. Classen at 1072.
48. Momenta at 1351.
49. Id. at 1352.
50. Id. at 1352-1353.
51. Id. at 1353.
52. Id. at 1354.
53. Id.
54. Id. at 1355.
55. Id.
56. Id.
58. Momenta at 1356.
59. Merck at 206.
60. Id. at 208, quoting Brief for United States as Amicus Curiae 23.
61. Id. at 207.
63. 21 C.F.R. § 211.165(d) (2014).
64. Momenta at 1367 (Rader, dissenting).
65. Id.
66. Momenta at 1362.
67. Id. at 1363.
68. Id. at 1370 (Rader, dissenting).