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# Trade Secret Rising: Protecting Equivalency Test Research and Development Investments After *Momenta v. Amphastar*

Hannah-Alise Rogers

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# TRADE SECRET RISING: PROTECTING EQUIVALENCY TEST RESEARCH AND DEVELOPMENT INVESTMENTS AFTER *MOMENTA V. AMPHASTAR*

*Hannah-Alise Rogers\**

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## I. INTRODUCTION

The United States has the largest and fastest growing drug market in the world, and the demand for generic drugs is steadily growing.<sup>1</sup> The pharmaceutical industry is responsible for over three million American jobs, and pharmaceutical companies invest millions of dollars in promoting the research and development of new and generic drugs.<sup>2</sup> In order to retain their competitive advantage, most pharmaceutical drug manufacturers seek patent protection.<sup>3</sup> Manufacturers have learned to think creatively, using a variety of patents—including method, design—and research tool patents—in order to fully protect their lucrative inventions. Congress encourages biomedical research and technological innovation through the patent system.<sup>4</sup> Congress heavily regulates the pharmaceutical industry both directly through status such as the Federal Food, Drug, and Cosmetics Act<sup>5</sup> and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act),<sup>6</sup> and indirectly through regulations promulgated by the Food and Drug Administration (FDA).<sup>7</sup> Several volumes of the Code of Federal Regulations are specifically dedicated to describing what manufacturers must do in order to market a drug in the United States.<sup>8</sup>

Due to recent congressional legislation and judicial decisions, however, generic drug manufacturers have lost some previously afforded patent protections,<sup>9</sup> specifically with respect to their bioequivalency test method patents. For example, the safe harbor provision of the Hatch-Waxman Act allows competing drug manufacturers to “borrow” information within the patents of their competitors so long as they agree to use the patents in furtherance of submitting information to the FDA.<sup>10</sup> Competing generic drug manufacturers, for example, can take bioequivalency tests disclosed in the

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<sup>1</sup> *The U.S. Pharmaceutical Industry*, SELECTUSA.GOV, <http://selectusa.commerce.gov/industry-snapshots/pharmaceutical-and-biotech-industries-united-states> (last visited Oct. 14, 2014).

<sup>2</sup> *Id.*

<sup>3</sup> *Getting Generic Drugs Q & A*, FEDERAL TRADE COMM’N, <http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions> (last visited Sept. 30, 2014).

<sup>4</sup> JOSEPH MILLER & LYDIA LOREN, *INTELLECTUAL PROPERTY LAW: CASES AND MATERIALS* 118 (Ver. 3.1 2013).

<sup>5</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938).

<sup>6</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>7</sup> 21 C.F.R. § 1 (2013).

<sup>8</sup> *Id.*

<sup>9</sup> *See, e.g.,* *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012); *Teva Pharm., USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

<sup>10</sup> 35 U.S.C. § 271(e)(1) (2013).

applications of their competitors and use the tests to manufacture their own generic drugs. A bioequivalency test is a method of testing a generic drug that proves that it is equivalent to a name brand drug that has already received FDA approval. All generic drug applications must demonstrate bioequivalency, thus the tests are extremely valuable. Unfortunately, bioequivalency testing methods can be very costly and time consuming to develop, so generic manufacturers patent the tests in an effort to protect them from use by competitors. The safe harbor provision has thus thwarted the protection scheme on which generic manufacturers depended.

The Federal Circuit recently expanded the scope of the safe harbor provision in 2012 in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*<sup>11</sup> A majority of the Federal Circuit in *Momenta* held that via the safe harbor provision, competing generic pharmaceutical manufacturers could use each other's patented bioequivalency testing methods for pre-clinical research and manufacturing without incurring infringement liability.<sup>12</sup> In 2003, Amphastar became the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA) to the FDA to market Enoxaparin, a generic version of the name brand drug Lovenox, which is used to prevent blood clots.<sup>13</sup> As a result of submitting the ANDA, Aventis, the manufacturer of Lovenox, sued Amphastar; after several years of expensive patent litigation, the FDA granted Amphastar's ANDA, allowing it to manufacture enoxaparin.<sup>14</sup> In the meantime, however, before the FDA granted Amphastar's ANDA for enoxaparin, Momenta "borrowed" Amphastar's bioequivalency test, which was publicly disclosed in Amphastar's ANDA and used the test to beat Amphastar to the market by more than a year.<sup>15</sup> This one year boost resulting from "borrowing" Amphastar's patent for bioequivalency allowed Momenta a monopoly on the generic market, resulting in profits of over \$260 million per quarter.<sup>16</sup>

This Note argues that the Federal Circuit's holding in *Momenta* threatens manufacturers with a devastating loss of previously available patent protection for measuring the bioequivalency of generic drugs. The Note concludes that trade secret law is the best alternative to patent protection until Congress decides to narrow the scope of the Hatch-Waxman Act's safe harbor provision. Due to the high cost of submitting a New Drug Application or an ANDA to

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<sup>11</sup> *Momenta Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

<sup>12</sup> *Id.* at 1361.

<sup>13</sup> *Id.* at 1351.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

the FDA, generic drug manufacturers want to seek protection for their bioequivalency tests so that consumers can reap the benefits of competition. In other words, giving generic manufacturers the ability to protect their bioequivalency tests would incentivize the production of generic drugs, which would in turn benefit consumers. However, in light of *Momenta*, this protection is no longer available through patent law.<sup>17</sup> Additionally, the Federal Circuit's interpretation of Hatch-Waxman's safe harbor provision has frustrated the generic drug manufacturer's ability to protect its research and development investments. Fortunately, a solution exists for generic drug manufacturers who wish to shield their tests and methods for bioequivalency from the hungry eyes of their competitors. Despite the numerous regulations governing disclosure of information submitted to the FDA, including most notably the Freedom of Information Act (FOIA), generic drug manufacturers, using a heightened degree of care, can protect bioequivalency tests as trade secrets.

Part II of this Note first describes the FDA's method of regulating generic drugs, including the process of submitting an ANDA, to demonstrate why this process is important to the patent protection which *Momenta* has recently frustrated for manufacturers. This section then explains how some of the information submitted to the FDA in furtherance of the ANDA can be protected through trade secret law instead of through patent law.

Part II next reviews the relevant parts of the Hatch-Waxman Act and specifically focuses on the evolution of the safe harbor provision, codified at 35 U.S.C. § 271(e)(1). Moreover, this Part explores prior United States Supreme Court opinions leading up to *Momenta* which have interpreted the safe harbor provision and demonstrates that the scope of the safe harbor provision has been expanded to such an extent that protection via method patents for bioequivalency tests is no longer available.

Additionally, Part II summarizes the current state of trade secret law and demonstrates how a bioequivalency test could qualify as a trade secret. This part also discusses the four potential threats of disclosure that a bioequivalency test trade secret could face, including FOIA requests, FDA use, and litigation; related threats, including the common law right of public access and discovery requests.

Part III argues that trade secret law is not only available to generic manufacturers but is ultimately a better alternative to protecting bioequivalency tests than patent law. Part III demonstrates how generic manufacturers can overcome threats of disclosure of their trade secrets presentation FOIA requests, FDA use and disclosure, and litigation.

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<sup>17</sup> *Id.* at 1362.

## II. BACKGROUND

### A. FDA SUBMISSION REQUIREMENTS FOR GENERIC DRUGS

Under the Food, Drug and Cosmetics Act of 1938, Congress delegated to the FDA the power to enact specific regulations concerning requirements for marketing new and generic drugs.<sup>18</sup> A new drug or generic bioequivalent may not be placed on the market without prior FDA approval.<sup>19</sup> The process for gaining FDA approval is quite extensive, so this Note only discusses the most relevant and important requirements relating to generic drugs.

First, in order to gain FDA approval to manufacture a generic drug, the manufacturer must submit an ANDA. The application must be within one of the FDA's delineated categories of acceptable drug products.<sup>20</sup> ANDAs may be submitted for "[d]rug products that are bioequivalent, or the same as a listed [i.e. name brand] drug. For determining the suitability of an [ANDA], the term 'same as' means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use."<sup>21</sup> Within sixty days of receiving an ANDA, the FDA will conduct a preliminary review of the application to determine whether it may be filed.<sup>22</sup> If the filing of an application is permitted, the party can submit it, and the FDA will then either send an approval of the application or deny it within 180 days of submission.<sup>23</sup>

A central requirement for a successful ANDA is that the generic drug must be the bioequivalent of the listed (i.e., name brand) drug.<sup>24</sup> A bioequivalency test is defined as "[i]nformation that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies."<sup>25</sup> In other words, rather than submitting a New Drug Application, a manufacturer who wants to produce a generic version of an already existing drug proves in its ANDA that the generic is the same as the name brand drug; as a result, generic drug manufacturers are not required to demonstrate safety or efficacy of the drug in their ANDA, since these were already demonstrated in the application of the original manufacturer.<sup>26</sup> Bioequivalency tests are thus of critical

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<sup>18</sup> P.L. 75-717, 52 Stat. 1040 (1938).

<sup>19</sup> 21 C.F.R. § 314.105(a) (2013).

<sup>20</sup> *Id.* § 314.92(a).

<sup>21</sup> *Id.* § 314.92(a)(1). For more on the requirements for the acceptable types of drug products, see *id.* §§ 314.92(a)(1), 314.122.

<sup>22</sup> *Id.* § 314.101(a)(1).

<sup>23</sup> *Id.* § 314.100(a).

<sup>24</sup> *Id.* § 314.94(a)(7).

<sup>25</sup> *Id.* § 314.94(7)(i).

<sup>26</sup> See *supra* note 1.

importance to ANDAs, and even the analytical and statistical methods used in determining bioequivalency are subjected to FDA regulation.<sup>27</sup>

In addition, a completed ANDA form must contain the following parts: a table of contents; a basis for submission (meaning the application must refer to a listed drug); the conditions under which the drug can be used; the drug's active ingredients (which must be the same as the active ingredients in the listed drug); the route of administration, strength, and dosage form of the drug (which must be the same as those in the listed drug); bio-equivalence (discussed further below); the labeling and proposed labeling for the drug; the chemistry, manufacturing process, and controls of the drug; any drug samples requested by the FDA; any patent certifications used in the manufacture of the drug; and a statement of financial certification or disclosure.<sup>28</sup> Additionally, "[a] complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval."<sup>29</sup> As discussed in Part III, the FDA may freely use the information that it receives in an ANDA, and the FDA, like other Federal Agencies, has a broad disclosure policy, meaning that the FDA allows the public to obtain Agency information whenever appropriate.<sup>30</sup>

Once a method for determining bioequivalency is established, generic drugs can be quickly and more easily produced because the drug manufacturers can demonstrate that the generic is the same as the listed drug, which has already extensively tested by the FDA. Generic competitors thus have a great incentive to steal these bioequivalency testing methods in order to accelerate the process of submitting an ANDA. Because the process of developing a bioequivalency test can be expensive and time consuming, generic drug manufacturers need assurance that the tests will receive some type of protection in order to incentivize their development.<sup>31</sup> Given the breadth of information, time, and money required to submit an ANDA, generic manufacturers seek patent protection in order to make their investments worthwhile.

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<sup>27</sup> 21 C.F.R. § 314.94(7)(iii); *see also id.* §§ 56.104, 56.105 (providing exceptions to normal IRB requirements).

<sup>28</sup> *Id.* §§ 314.94(a)(1)–(12).

<sup>29</sup> *Id.* § 314.94(7)(i).

<sup>30</sup> *See infra* text accompanying note 162 and discussion that follows.

<sup>31</sup> *See, e.g.,* *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012) (plaintiff patent holder sought enforcement of its method patent for a bioequivalency test); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.) (involving a similar fact pattern).

## B. THE SCOPE OF THE SAFE HARBOR PROVISION OF THE HATCH-WAXMAN ACT

In order to demonstrate the breath of the problem that the Federal Circuit's ruling in *Momenta v. Amphastar* has caused, this section discusses how the FDA's regulations regarding generic drugs intersect with the Hatch-Waxman Act. The relationship between the Hatch-Waxman Act and RDA regulations is critical for understanding why the Federal Circuit's holding in *Momenta* frustrated the usefulness of patent protection for bioequivalency research and development. In order to fully understand the goals and problems of the Hatch-Waxman Act, it is first helpful to review the history which led to the statute's enactment.

Before the Hatch-Waxman Act became effective in September of 1984, there were no statutory provisions to protect pharmaceutical companies from a competitor's allegations of patent infringement when they used another's patented technology to perform pre-approval clinical research.<sup>32</sup> Congress enacted the Act's safe harbor provision "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 a patent infringement."<sup>33</sup> The Act specifically overruled the Federal Circuit's opinion in *Roche Prods. v. Bolar Pharmaceutical Co.*<sup>34</sup> *Roche* held that a competing drug manufacturer infringes by using a competitor's patent for pre-clinical research because borrowing patented information for research purposes falls outside of the scope of the experimental use rule,<sup>35</sup> which "ends with an actual reduction to practice."<sup>36</sup> The Federal Circuit declared, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of scientific inquiry, when that inquiry has definite, cognizable, and not insubstantial commercial purposes."<sup>37</sup> This precedent left no protection to pharmaceutical companies alleged to infringe by competitors when they used another's patented technology to perform FDA pre-approved clinical research.

The safe harbor provision of the Hatch-Waxman Act,<sup>38</sup> now clarifies:

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<sup>32</sup> *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>33</sup> H.R. REP. NO. 98-857, pt. 1, at 45 (1984) (quoting *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1362 (Rader, C.J., dissenting)).

<sup>34</sup> *Id.* pt. 2, at 27.

<sup>35</sup> *Roche Prods.*, 733 F.2d at 863. The experimental use rule is "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement [and] is not an infringement of the rights of the patentee." *Id.* at 862 (internal quotations omitted) (internal citations omitted).

<sup>36</sup> *Nordberg Inc. v. Telsmith, Inc.*, 881 F. Supp. 1252, 1285 (E.D. Wis. 1995) (internal quotation marks omitted).

<sup>37</sup> *Roche Prods.*, 733 F.2d at 863.

<sup>38</sup> H.R. REP. NO. 98-857, pt. 2, at 27 (1984).



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 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.<sup>39</sup>

Since the passage of the statute, the Supreme Court has interpreted its meaning fairly expansively.<sup>40</sup> This Note will next briefly summarize the Supreme Court's interpretations of the safe harbor provision, leading to the Federal Circuit's most recent expansion in *Momenta*.

The controversy over the scope of the safe harbor provision began early in the statute's history; the Supreme Court first interpreted the safe harbor provision only six years after it was enacted in *Eli Lilly & Co. v. Medtronic, Inc.*<sup>41</sup> *Eli Lilly* concerned whether the safe harbor provision applied to patented medical devices in addition to prescription drugs.<sup>42</sup> The Supreme Court broadened the application of the statute to not only to drug patents, but also to medical devices.<sup>43</sup> In writing for the majority, Justice Scalia reached this expansive holding by citing the Act's purpose according to the legislative history "to respond to two unintended distortions on the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval."<sup>44</sup> According to the majority, Congress designed the safe harbor provision to prevent the patentee from having an extended monopoly on the market simply by virtue of the amount of time it takes another company to produce a bioequivalent drug.<sup>45</sup> The majority additionally argued that the statute "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval."<sup>46</sup>

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<sup>39</sup> 35 U.S.C. § 271(e)(1) (2012).

<sup>40</sup> See 496 U.S. at 665 (finding no infringement under § 271(e)(1) in the case of a patented medical device); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (holding that the use of a patented compound was protected by § 271(e)(1) as long as it was reasonable to believe that the compound tested could be submitted to the FDA at some later time and the experiments for which the compound was used would produce information relevant to an application).

<sup>41</sup> 496 U.S. 661.

<sup>42</sup> *Id.* at 663.

<sup>43</sup> *Id.* at 665.

<sup>44</sup> *Id.* at 669.

<sup>45</sup> *Id.* at 672–73.

<sup>46</sup> *Id.* at 671.

However, Justices Kennedy and White dissented, arguing the safe harbor provision should not apply to anything beyond obtaining market approval for a drug, and that the statute should not apply to “all” products regulated by the FDA.<sup>47</sup> Justice Kennedy explained that the testing of medical devices should not be protected by the safe harbor because Congress could not have intended for such an extraordinary meaning of the specific language in the statute.<sup>48</sup>

In 2005, the Supreme Court again interpreted the scope of the safe harbor provision in *Merck KGaA v. Integra Life Sciences I, Ltd.*<sup>49</sup> *Merck* posed the question of whether a manufacturer could use patented inventions during preclinical research under the immunity of the safe harbor provision when the results were not actually submitted to the FDA.<sup>50</sup> Justice Scalia delivered a short, and probably too informal, unanimous opinion, holding that the safe harbor provision’s exception to infringement:

[N]ecessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.<sup>51</sup>

Thus, the *Merck* Court again widened the scope of the safe harbor provision.

Following suit, the Federal Circuit further expanded the safe harbor provision of the Hatch-Waxman Act in *Momenta v. Amphastar*. The issue in *Momenta* was whether the defendant generic manufacturer lawfully used the plaintiff competitor’s patented test for bioequivalency to test its own form of the generic drug Enoxaparin.<sup>52</sup> Defendant Amphastar argued that it did not infringe because it used the plaintiff’s patent to test their own version of the generic drug Enoxaparin and submitted these test results to the FDA, therefore falling within the scope of the safe harbor.<sup>53</sup> The court agreed with the defendant that its use of momenta’s bioequivalency test for Enoxaparin was “solely for uses reasonably related to the development and submission of information under a Federal law”; and thus was permissible under the safe

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<sup>47</sup> *Id.* at 680 (Kennedy, J., dissenting).

<sup>48</sup> *Id.*

<sup>49</sup> 545 U.S. 193 (2005).

<sup>50</sup> *Id.* at 195.

<sup>51</sup> *Id.* at 202.

<sup>52</sup> *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1350 (Fed. Cir. 2012).

<sup>53</sup> *Id.* at 1352–53.

harbor provision.<sup>54</sup> The majority relied primarily on the text of the statute to support its position, arguing specifically that the phrase ‘under a federal law’ “extend[ed] beyond just the ‘most barebones information’ required by the FDA, and instead encompass[ed] all ‘materials the FDA demands in the regulatory process.’”<sup>55</sup> Chief Judge Rader, however, relied on congressional purpose to dictate a different result.<sup>56</sup>

In a strong dissent, Chief Judge Rader argued that Amphastar’s actions exceeded the scope of the safe harbor provision because Amphastar used Momenta’s patent for more than the mere submission of information to the FDA.<sup>57</sup> In his view, “Amphastar stepped in and took Momenta’s patented invention without permission and used it to manufacture each commercial batch [of Enoxaparin] it sells on the market.”<sup>58</sup> Additionally, the fact that Amphastar could only compete with Momenta by using its patent strengthened Chief Judge Rader’s conclusion that the safe harbor provision should be more limited in scope.<sup>59</sup> In reaching this conclusion, Chief Judge Rader relied on legislative history to support his argument that Congress did not intend to give manufacturers the right to use another’s patented process to place a competing drug on the market,<sup>60</sup> and criticized the majority for totally ignoring it.<sup>61</sup> The safe harbor provision, he noted, was a congressional compromise because of its limited scope in time, quantity, and type.<sup>62</sup> The time period covered by the safe harbor was only for pre-market approval; in other words, after the FDA approves the drug, the safe harbor provision does not protect further marketing activities.<sup>63</sup> In terms of the safe harbor provision’s limitations on quantity and type, Chief Judge Rader explained that the statute “only applies to experimentation—and therefore would have limited impact on the patentee’s exclusivity during the life of the patent.”<sup>64</sup> In all, Chief Judge Rader concluded that the safe harbor provision did not protect Amphastar from its use of

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<sup>54</sup> *Id.* at 1353 (quoting 35 U.S.C. § 271(e)(1)).

<sup>55</sup> *Id.* at 1356 (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1683 (2012)).

<sup>56</sup> *Id.* at 1362 (Rader, J., dissenting).

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 1362–63 (quoting H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984)).

<sup>61</sup> *Id.* at 1366.

<sup>62</sup> *Id.* at 1365 (citing *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcom. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 696 (1984) (letter from Pharmaceutical Manufacturers Association)).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 1365–66 (citing H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984)).

Momenta's patented bioequivalency test because Amphastar continued to use the test after it gained FDA approval, thus destroying Momenta's right to exclude.<sup>65</sup> As he lamented, "This result will render worthless manufacturing test method patents."<sup>66</sup>

Chief Judge Rader reached this fear that test method patents would no longer offer protection to patent holders by considering the implications of the majority's holding.<sup>67</sup> He argued that the majority of the Supreme Court and the Federal Circuit have interpreted the safe harbor provision so broadly as to allow competitors to use patented testing methods not just for pre-clinical research but also for manufacturing.<sup>68</sup> Patents exist to define the exclusion rights of their holders,<sup>69</sup> but the exclusion rights in this scenario have been all but snatched away, presenting a problem for generic drug manufacturers who spend millions of dollars developing tests to determine bioequivalency, and then seek to protect these tests from the hungry eyes of their competitors.

#### C. A BRIEF OVERVIEW OF PATENT PROTECTION

In order to understand what generic manufacturers have lost by their inability to protect their bioequivalency tests via patent law, this section briefly reviews the protection that manufacturers would receive from patents absent the *Momenta v. Amphastar* holding. Patent law's origin rests in the United States Constitution,<sup>70</sup> which has been codified to protect "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" that is invented or discovered.<sup>71</sup> In order to receive patent protection for an invention falling within one of these eligible categories, one must disclose his or her invention to the Patent Trademark Office (PTO)<sup>72</sup> and meet the other statutory requirements of novelty and non-obviousness.<sup>73</sup> Patent law's scheme of protection of information via this disclosure process could be seen as the opposite of trade secret protection, which attempts to retain the value of information by protecting it against public disclosure.<sup>74</sup>

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<sup>65</sup> *Id.* at 1367.

<sup>66</sup> *Id.* at 1362.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 1361. *See also* Merck KGaA v. Integra Life Sciences I, Ltd., 545 U.S. 1953 (2005).

<sup>69</sup> *Id.*

<sup>70</sup> U.S. CONST. art. 1, § 8, cl. 8.

<sup>71</sup> 35 U.S.C. § 101 (2006).

<sup>72</sup> MILLER & LOREN, *supra* note 4, at 117.

<sup>73</sup> 35 U.S.C. §§ 102–103.

<sup>74</sup> MILLER & LOREN, *supra* note 4, at 27.

Assuming that all the requirements for a valid patent are met,<sup>75</sup> the patentee receives protection for his or her invention for a period of twenty years.<sup>76</sup> During this time, the patentee holds an exclusive right to use the patented process, machine, manufacture, or composition of matter.<sup>77</sup> In the context of bioequivalency testing methods of pharmaceutical drugs testing, the applicable patent eligible category is “process.” Therefore, this Note proceeds referring solely to “process” patents, also known as method patents.

If a patentee discovers that another entity is performing its patented process, the patentee can sue this competitor for infringement.<sup>78</sup> If a court finds that the competitor infringes, the patentee is entitled to monetary damages and/or an injunction.<sup>79</sup> Overall, patent protection is bent towards protection for an invention via disclosure of that invention,<sup>80</sup> unlike trade secret protection, discussed below, which affords protection for inventions by keeping them a secret.<sup>81</sup>

#### D. A LOOK AT THE STATE OF TRADE SECRET LAW AND THE POTENTIAL THREATS OF DISCLOSURE

A generic manufacturer need not register its bioequivalency test as a trade secret, but in order to qualify for trade secret protection, a bioequivalency test must meet the legal definition of a “trade secret.”<sup>82</sup> This part examines several common definitions of “trade secret,” which will be used in Part III to demonstrate how a bioequivalency test fits within the scope of protectability. This section also briefly introduces the ways in which a bioequivalency test protected by trade secret law can be disclosed, including through a FOIA request, FDA use, discovery requests, and the common law right of public access.

Although trade secret law originally evolved under state common law, the Uniform Trade Secrets Act (UTSA),<sup>83</sup> was created to make state trade secret law more homogenous and has been adopted by all but three states.<sup>84</sup> The

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<sup>75</sup> For more information on the requirements for a valid patent, see *id.* at 129–54. *See also* 35 U.S.C. §§ 101–103, 112.

<sup>76</sup> 35 U.S.C. § 187.

<sup>77</sup> *Id.* § 254.

<sup>78</sup> *See id.* § 255.

<sup>79</sup> *Id.* §§ 277–278.

<sup>80</sup> *Id.* § 118.

<sup>81</sup> *Id.* § 27.

<sup>82</sup> MILLER & LOREN, *supra* note 4, at 27.

<sup>83</sup> Unif. Trade Secrets Act (1979) (amended 1985).

<sup>84</sup> MILLER & LOREN, *supra* note 4, at 28.

following discussion refers to the UTSA as adopted by New Jersey, a state home to a large percentage of the United States' drug manufacturers.<sup>85</sup>

The New Jersey UTSA outlines the definition of a 'trade secret' and the circumstances under which a trade secret can be misappropriated:

“[T]rade secret” means information, held by one or more people, without regard to form, including a formula . . . method . . . technique . . . or process that: (1) derives independent economic value . . . from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.<sup>86</sup>

The UTSA thus provides direction to generic drug manufacturers seeking to protect their bioequivalency testing methods via trade secret law. However, each manufacturer should look at the specific adoption of the UTSA in their state in order to fully understand the scope of the trade secret protection offered.<sup>87</sup>

In addition to the UTSA, the FDA also promulgates rules and regulations regarding trade secrets, so is important for generic manufacturers to keep the FDA's definition of “trade secret” in mind when submitting their ANDAs.<sup>88</sup> Because the FDA receives a great deal of information from generic drug manufacturers, disclosure of this information to the public is of high importance to a manufacturer seeking protection. The FDA's provisions regarding the protection of submitted information strikingly states that “[t]he [FDA] will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information.”<sup>89</sup> It continues: “Except where specifically exempt pursuant to the

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<sup>85</sup> *Pharmaceuticals*, STATE OF NEW JERSEY BUSINESS PORTAL, <http://www.nj.gov/njbusiness/industry/pharmaceutical/> (last visited Sept. 30, 2014).

<sup>86</sup> N.J. STAT. ANN. § 56:15-2 (West 2012).

<sup>87</sup> With the exception of Massachusetts and New York, each state has adopted some form of the UTSA. While the laws are similar, it is helpful to refer to a state's specific version of the UTSA as a measure of precaution. For a full list of each state's UTSA law, see *Trade Secrets Laws: State Law*, ORRICK, HERRINGTON & SUTCLIFF, LLP, <http://blogs.orrick.com/trade-secrets-watch/trade-secrets-laws/> (last visited Nov. 13, 2014).

<sup>88</sup> See 21 C.F.R. § 20.61 (2013).

<sup>89</sup> *Id.* § 20.20(a).

provisions of this part, all FDA records shall be made available for public disclosure.”<sup>90</sup>

Due to the FDA’s proclivity towards disclosure of information, the FDA’s definition of “trade secret” is essential for the protection of information.<sup>91</sup> Courts have grappled with how expansively to construe the definition,<sup>92</sup> which reads:

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.<sup>93</sup>

Because requests for information made under the FOIA are a common way in which information known by the FDA can be disclosed, generic manufacturers will likely want to know whether trade secrets that are submitted to the FDA as a part of an ANDA could be disclosed by a FOIA request.<sup>94</sup> The Freedom of Information Act first became effective in 1967, and controls the public disclosure of previously unreleased information from federal agencies.<sup>95</sup> The primary purpose of the FOIA is to enable the public to access government records in order to gain a greater understanding of the government.<sup>96</sup> FOIA disclosures include everything from substantive and procedural rules regarding disclosure of information,<sup>97</sup> administrative case law reporting,<sup>98</sup> and statements of policy and agency interpretations.<sup>99</sup> Perhaps the most controversial part of FOIA is found in section 3:

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<sup>90</sup> *Id.* § 20.20(b).

<sup>91</sup> *Id.* § 20.61(a) (“The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.”).

<sup>92</sup> *See, e.g.*, *Public Citizen Health Research Group v. Food & Drug Admin.*, 704 F.2d 1280 (D.C. Cir. 1983).

<sup>93</sup> 21 C.F.R. § 20.61(a).

<sup>94</sup> Pub. L. No. 89-487, 80 Stat. 250 (1967) (codified at 5 U.S.C. § 552).

<sup>95</sup> *What is FOIA*, FOIA.GOV, <http://www.foia.gov/about.html> (last visited Nov. 14, 2014).

<sup>96</sup> *Id.*

<sup>97</sup> 5 U.S.C. § 552(a)(1)(A)–(E) (2012).

<sup>98</sup> *Id.* § 552(a)(2)(A).

<sup>99</sup> *Id.* § 552(a)(2)(B).

Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon *any* request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, *shall* make the records promptly available to any person.<sup>100</sup>

The agency must also perform a reasonable search to find the information<sup>101</sup> and must provide the information in the format requested.<sup>102</sup> Like many other federal agencies, the FDA has its own Freedom of Information Act Office, called the Food and Drug Administration Division of Freedom of Information,<sup>103</sup> wherein a person who is seeking information from the FDA must submit a request.<sup>104</sup>

Although the FOIA attempts to make as much agency information available to the public as possible, there are some exceptions to what information a petitioner can receive. For example, agencies may withhold information that is labeled confidential for the purposes of national security by an executive order,<sup>105</sup> information that is solely related to agency personnel rules,<sup>106</sup> and information that is “exempted from disclosure by statute.”<sup>107</sup> For information to be exempt by a specific statute, the statute must be clear as to what type of information may be withheld<sup>108</sup> and must cite to the FOIA, in limited circumstances.<sup>109</sup> Finally, exceptions to FOIA also exist for “trade secrets and commercial or financial information obtained from a person and privileged or confidential,”<sup>110</sup> agency memorandums,<sup>111</sup> and medical/personnel files.<sup>112</sup> Although an exemption exists

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<sup>100</sup> *Id.* § 552(a)(3) (emphasis added).

<sup>101</sup> *Id.* § 552(a)(3)(C).

<sup>102</sup> *Id.* § 552(a)(3)(B).

<sup>103</sup> 21 C.F.R. § 20.30(a) (2013).

<sup>104</sup> *Id.* § 20.30(b).

<sup>105</sup> 5 U.S.C. § 552(b)(1)(A) (2012).

<sup>106</sup> *Id.* § 552(b)(2).

<sup>107</sup> *Id.* § 552(b)(3) (to be exempted, the statute in question must “(i) require[] that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establish[] particular criteria for withholding or refer[] to particular types of matters to be withheld; and (B) . . . specifically cite [] to this paragraph.” (*id.* § 552(b)(3)(A)(i)–(ii); (B))).

<sup>108</sup> *Id.* § 552(b)(3)(A)(i)–(ii).

<sup>109</sup> *Id.* § 552(b)(3)(B).

<sup>110</sup> *Id.* § 552(b)(4).

<sup>111</sup> *Id.* § 552(b)(5).

<sup>112</sup> *Id.* § 552(b)(6).



for trade secrets, manufacturers will have concerns that their bioequivalency tests, which are worth millions of dollars, may not fit within the scope of protection.

Hypothetically, if a generic manufacturer were to choose to protect its bioequivalency test via trade secret law, a competitor could try to access the test information by submitting a FOIA request for it. Anyone who wishes to request information from the FDA must submit a FOIA request in writing to the FDA's headquarters in Maryland.<sup>113</sup> The writing must reasonably set forth the information being requested.<sup>114</sup> So long as the writing reasonably details the information sought, "[e]very reasonable effort shall be made by the [FDA] to assist in the identification and location of the records sought."<sup>115</sup> The person submitting the request must also pay a fee, the amount of which is determined by the type of information requested.<sup>116</sup> If the confidentiality of requested information is uncertain, the FDA will contact the entity who submitted the information and/or who will "be affected by its disclosure before determining" whether to disclose the information.<sup>117</sup>

If the FDA rejects a request for information, "the decision constitutes final agency action that is subject to judicial review."<sup>118</sup> The person requesting the information will be notified of the FDA's rejection and will then have five days after receipt of notification to file a suit in a United States District Court.<sup>119</sup> When trade secret information is requested and disclosure is denied,<sup>120</sup> the FDA will inform the person who submitted the record that he or she must come and defend the record's confidentiality in court.<sup>121</sup> The statute reads, "If the affected person fails to intervene to defend the exempt status of the records . . . the [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require the [FDA] to promptly make the records available for public disclosure."<sup>122</sup> Thus, the FDA expects the person who submits information classified as a trade secret to defend this status if it is challenged. While defending the trade secret status is not mandatory under the statute, it factors into the FDA's decision of whether or not to disclose the information.<sup>123</sup>

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<sup>113</sup> 21 C.F.R. § 20.40(a) (2013).

<sup>114</sup> *Id.* § 20.40(b).

<sup>115</sup> *Id.* § 20.40(b)(2).

<sup>116</sup> *See id.* § 20.45(a)(1)–(3).

<sup>117</sup> *Id.* § 20.47.

<sup>118</sup> *Id.* § 20.48.

<sup>119</sup> *Id.*

<sup>120</sup> Disclosures are denied under 21 C.F.R. § 20.61.

<sup>121</sup> 21 C.F.R. § 20.55.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

Finally, even if a generic manufacturer meets the FDA's definition of trade secret when submitting an ANDA and the FDA's disclosure of the information via a FOIA request is limited, both the common law right of public access<sup>124</sup> and discovery requests<sup>125</sup> pose additional threats for generic manufacturers who wish to protect their trade secrets. The common law right of public access can arise during or after a lawsuit and poses a threat to generic manufacturers' ability to protect bioequivalency tests, as courts strive to maintain open records of judicial proceedings. The Second Circuit explains in *Nycomed US, Inc. v. Glenmark Generics, Inc.*, that the right of public access allows open access to judicial documents to provide information to the public in hopes of making the courts appear more legitimate.<sup>126</sup> For the purposes of this Note, the definition of "judicial documents" is particularly relevant because as the Second Circuit declared in *Lugosh v. Pyramid Co. of Onondaga*, judicial documents are presumed to be open to public access, as described in Part III.<sup>127</sup>

In *Stern v. Cosby*, the Second Circuit additionally developed a three-part test to determine whether a judicial document is subject to the common law right of public disclosure.<sup>128</sup> "First, the court must determine whether the documents are indeed judicial documents . . . Second, if the documents are judicial documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it."<sup>129</sup> Altogether the right of public access threatens disclosure of trade secrets. However, a generic manufacturer can successfully argue that bioequivalency tests disclosed in ANDAs should not be subject to the common law right of public access.<sup>130</sup>

Likewise, discovery requests also pose a threat to generic manufacturers who could protect their bioequivalency tests as trade secrets. The Federal Rules of Civil Procedure do not contain an absolute privilege for trade secrets that are requested during discovery,<sup>131</sup> but Rules 26 and 45 can help generic

<sup>124</sup> See, e.g., *Stern v. Cosby*, 529 F. Supp. 2d 417 (S.D.N.Y. 2007).

<sup>125</sup> See, e.g., *Massey Coal Services, Inc. v. Victaulic Co. of Am.*, 249 F.R.D. 477 (S.D. W. Va. 2008).

<sup>126</sup> *Nycomed US, Inc. v. Glenmark Generics, Inc.*, No. 08-CV-5023 (CBA), 2010.

<sup>127</sup> 435 F.3d 110, 122 (2d Cir. 2006) (quoting *FTC v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 409 (1st Cir. 1987)) ("[R]elevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings become documents to which the presumption of public access applies.>").

<sup>128</sup> *Stern v. Cosby*, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007).

<sup>129</sup> *Id.* (quoted in *Nycomed US, Inc. v. Glenmark Generics, Inc.*, 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.) (internal quotation marks omitted)).

<sup>130</sup> See *infra* notes 196–208.

<sup>131</sup> See generally *Paulsen v. Case Corp.*, 168 F.R.D. 285 (C.D. Cal. 1996).

manufacturers to protect their bioequivalency test trade secrets from disclosure during litigation. Rule 26 provides a scenario in which a party may receive a protective order from the court in order to guard against the disclosure of a trade secret<sup>132</sup>: “The motion must include a certification that the movant has in good faith conferred or attempted to confer with other affected parties in an effort to resolve the dispute without court action.”<sup>133</sup> Then, the rule states, “the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense” by several following methods.<sup>134</sup> One of the following ways to protect a party includes: “requiring that a trade secret or other confidential research development, or commercial information not be revealed or be revealed only in a specific way.”<sup>135</sup> Because any relevant evidence will lend a presumption of admissibility, the party seeking protection has the burden of proof that the information should not be disclosed.<sup>136</sup> Thus, although there is no per se protection of trade secrets in the Federal Rules of Civil Procedure,<sup>137</sup> generic manufacturers could use Rule 26 and case law relating to discovery and the common law right of public access to argue that their bioequivalency tests protected as trade secrets should not be disclosed.

Like Rule 26, Rule 45 also helps ensure that trade secrets are not wrongfully disclosed during discovery by protecting trade secrets from subpoenas. A subpoena is an order from a government agency, usually a court, which compels a witness to testify or produce evidence.<sup>138</sup> In relevant part, Rule 45 states, “To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information. . . .”<sup>139</sup> Subsequent case law has stated that when a court is deciding whether to quash a subpoena which seeks information marked as a trade secret, “a court must evaluate all the circumstances and balance, *inter alia*, the requesting party’s need for the information and the potential prejudice imposed on the requested party.”<sup>140</sup> Furthermore, the factors to be balanced include “the relevance of the discovery

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<sup>132</sup> FED. R. CIV. P. 26(c)(1).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 26(c)(1)(G).

<sup>136</sup> *In re Fosamax Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 70246, at \*31 (S.D.N.Y.).

<sup>137</sup> *See* Paulsen v. Case Corp., 168 F.R.D. 285, 289 (C.D. Cal. 1996).

<sup>138</sup> Merriam Webster, *Subpoena*, MERRIAM WEBSTER ONLINE, <http://www.merriam-webster.com/dictionary/subpoena> (last visited Sept. 30, 2014).

<sup>139</sup> FED. R. CIV. P. 45(d)(3)(B)(i).

<sup>140</sup> *Insulate America v. Masco Corp.*, 227 F.R.D. 427, 432 (W.D.N.C. 2005) (citations omitted).

sought, the requesting party's need, and the potential hardship to the party subject to the subpoena.<sup>141</sup>

Altogether, the numerous rules that govern the FDA's submission of information, FOIA requests, the FDA's use, the common law right of public access, and discovery requests could each pose a threat to manufacturers who wish to protect their bioequivalency tests via trade secret law. Nevertheless, there are various situations in which a competing drug manufacturer could attempt to access a bioequivalency test protected by trade secret law, as next explained in Part III. These situations include disclosure requests from third parties,<sup>142</sup> threats of disclosure or use by the FDA,<sup>143</sup> and the threat of disclosure during litigation through the assertion of common law right of public access or a discovery request.<sup>144</sup> A generic manufacturer seeking to protect its bioequivalency test via trade secret law should pay close attention to the way courts define the scope of trade secret and the various methods that competitors can use to seek disclosure of trade secret information.

### III. ANALYSIS

Given *Momenta's* holding that the safe harbor provision of the Hatch-Waxman Act encompasses a drug manufacturer's use of another's bioequivalency testing methods for pre-clinical research and manufacturing, patent law offers little to no protection for generic manufacturers who wish to protect their bioequivalency tests from appropriation by competitors.<sup>145</sup> Because FDA regulations of ANDAs are complex and require each manufacturer to make a specific showing of how it meets the requirements to legally manufacture a drug, as discussed above, the FDA requires generic drug manufacturers to disclose their bioequivalency testing methods to ensure that a drug in production is both safe and effective.<sup>146</sup> Due to the extensive information required by the FDA, ANDAs are therefore expensive to produce. Moreover, since bioequivalency tests can be difficult, time consuming, and expensive to develop, generic manufacturers often use patent protection to

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<sup>141</sup> *Dorel Juvenile Grps., Inc. v. Summer Infant, Inc.*, C 06-91 S, 2006 U.S. Dist. LEXIS 77906 (D.R.I. Oct. 11, 2006) (quoting *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1024 (Fed. Cir. 1986)).

<sup>142</sup> *See* *Public Citizen Health Research Group v. Food & Drug Admin.*, 704 F.2d 1280 (D.C. Cir. 1983).

<sup>143</sup> *See* *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (involving a similar situation in the Environmental Protection Agency).

<sup>144</sup> *See* *Nycomed US, Inc. v. Glenmark Generics, Inc.*, 2010 U.S. Dist. LEXIS 20788 (S.D.N.Y.).

<sup>145</sup> *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Rader, J., dissenting).

<sup>146</sup> *See supra* notes 17–25 and accompanying text.

make investment in bioequivalency testing methods worthwhile. However, after the *Momenta* holding, adequate patent protection of bioequivalency tests has been lost, leaving generic manufacturers little incentive to invest in their development. Nevertheless, trade secret law endures to protect generic drug manufacturers' bioequivalency tests from appropriation by competitors. This Note argues that trade secret is in fact the best and most natural method for protecting bioequivalency tests after *Momenta*, and therefore seeks to advise generic drug manufacturers of the potential hurdles to overcome in gaining such protection.

This section first discusses the scope of the definition of trade secret in various contexts, keeping in mind that competitors who seek the information will try to attack the definitions of both the UTSA and the FDA. Next, this section explores the different ways for generic manufacturers to overcome potential threats of misappropriation, in particular by jumping three different anticipated hurdles to trade secret protection. These hurdles are: a FOIA request made by a third party, potential use and disclosure of protected information via FDA regulations, and disclosure during litigation via the common law right of public access and the discovery process. Finally, this section argues how each of these potential threats to protecting bioequivalency tests can be avoided.

#### A. THE SCOPE OF THE DEFINITION OF "TRADE SECRET"

Before seeking trade secret protection for a bioequivalency testing method, it is important to look at the exact definition of "trade secret" in order to understand exactly what can be protected. As was explored above, there are different working definitions of what constitutes a trade secret, and each is important in different contexts.<sup>147</sup> Generic manufacturers seeking to protect their bioequivalency tests via trade secret law should take care to distinguish these definitions from each other and understand when each definition applies. Two of the relevant definitions of trade secret are the UTSA definition<sup>148</sup> and the FDA's definition.<sup>149</sup>

A bioequivalency testing method would be considered a 'trade secret' for the purposes of both the UTSA and the FDA's definitions. The UTSA has a broad definition of "trade secret," including formulas, methods, techniques, or processes.<sup>150</sup> Similarly the FDA, defines a trade secret as, "[A]ny commercial

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<sup>147</sup> See *supra* notes 77–87 and accompanying text.

<sup>148</sup> See *supra* note 92.

<sup>149</sup> 21 C.F.R. § 20.61 (2013). See also *supra* note 93.

<sup>150</sup> See *supra* note 92.

valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort.”<sup>151</sup> A bioequivalency test would easily classify as a trade secret under either of these definitions as a formula is used for the purposes of demonstrating that a generic drug is the bioequivalent of, or the same as, the name brand.<sup>152</sup> Since bioequivalency testing methods should meet either the UTSA or FDA definition of trade secret, generic manufacturers do retain an incentive for economic investment in their development, despite the inadequacy of patent protection to do the same after the *Momenta* court’s holding.

#### B. THE THREAT OF DISCLOSURE

Once a generic manufacturer decides to protect bioequivalency test as a trade secret, there are three potential ways in which a generic drug manufacturer’s trade secret could be disclosed: first, through a FOIA request; second, through use by the FDA itself; and third, through an assertion of the common law right of public access during the discovery process of litigation.

1. *Overcoming the Threat of Disclosure Via a FOIA Request.* The D.C. Circuit’s discussion of the scope of trade secret protection in the FOIA context in *Public Citizen Health Research Group v. Food & Drug Administration* demonstrates that this scope is broad enough to protect bioequivalency tests.<sup>153</sup> In *Public Citizen Health*, the plaintiff consumer advocacy group sought information from the FDA regarding the safety and effectiveness of an intraocular lens that had been on the market for several years.<sup>154</sup> The manufacturer of the intraocular lenses submitted clinical test results to the FDA, and the manufacturer objected to the disclosure of these results to the petitioner, who had made a FOIA request for them.<sup>155</sup> The court was asked to determine whether the requested records were “immune from disclosure under Exemptions 3 and 4 of the FOIA.”<sup>156</sup> As the court explained, “[t]hese exemptions allow the court to withhold, respectively, (1) records that are ‘specifically exempted from disclosure by statute’ if the relevant statute satisfies one of two limiting conditions and (2) ‘trade secrets and

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<sup>151</sup> 21 C.F.R. § 20.61.

<sup>152</sup> See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1350 (Fed. Cir. 2012) (discussing the “sufficient information [needed] to establish that the generic drug has the same active ingredients as the reference drug”).

<sup>153</sup> *Public Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280 (D.C. Cir. 1983).

<sup>154</sup> *Id.* at 1283.

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at 1282.

commercial or financial information obtained from a person and privileged or confidential.”<sup>157</sup> In affirming in part and reversing in part, the D.C. Circuit held that the district court “erred in its application of Exemption 3 and adopted an overly broad construction of the term ‘trade secrets’ in Exemption 4”; therefore, the court partially granted the petitioner’s request for the drug manufacturer’s clinical test results.<sup>158</sup>

The court’s discussion of Exemption 4, and more specifically whether “the requested documents constitute ‘trade secrets’ [and are therefore] exempt from disclosure”<sup>159</sup> illustrates that manufacturers can shield bioequivalency tests from third parties urging disclosure through a FOIA request by protecting them as trade secrets. After evaluating several different definitions of “trade secrets” at common law, and finding that the Restatement of Torts’s expansive definition<sup>160</sup> “would classify virtually all undisclosed health and safety testing data as trade secrets,”<sup>161</sup> the court settled on a more restrictive definition to adopt in FOIA cases.<sup>162</sup> “Defined in its narrower common law sense,” a trade secret is “a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation of substantial effort.”<sup>163</sup> In arguing that this is the best definition of trade secret, the court stated that it “incorporates a direct relationship between the information at issue and the productive process.”<sup>164</sup>

Although the court in *Public Citizen Health* chose the more restrictive definition of trade secret, believing that it “hews more closely to language and legislative intent of FOIA than does the *Restatement* approach,”<sup>165</sup> this definition can still be used to protect bioequivalency testing methods. A bioequivalency testing method should qualify as a trade secret because it is “a commercially

<sup>157</sup> *Id.*; see also 5 U.S.C. § 522(b)(3), (4).

<sup>158</sup> *Public Citizen Health*, 704 F.2d at 1282.

<sup>159</sup> *Id.* at 1286; see also 5 U.S.C. § 522(b)(4).

<sup>160</sup> RESTATEMENT OF TORTS § 757 cmt. b (1939) (“A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.”). The definition of ‘trade secret’ as specified in the Restatement has been adopted by other courts. See, e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

<sup>161</sup> *Public Citizen Health*, 704 F.2d at 1286 (quoting Thomas McGarity & Sidney Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 861 (1980)).

<sup>162</sup> *Id.* at 1286–87.

<sup>163</sup> *Id.* at 1288.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* at 1289.

valuable . . . formula . . . that is used for the making of trade commodities” i.e., a prescription drug, that is the “product of either innovation or substantial effort.”<sup>166</sup> There is no doubt that a bioequivalency test would be considered “commercially valuable”; the competing generic manufacturer in *Momenta*, for example, was able to make over \$260 million per quarter after using the patent holder’s bioequivalency test.<sup>167</sup> Furthermore, a bioequivalency test certainly qualifies as a formula, as it is used for the making of pharmaceutical drugs, which also constitute “trade commodities.” There is also a direct relationship between the bioequivalency testing methods and the productive process of manufacturing drugs, unlike the information requested in *Public Citizen Health*.<sup>168</sup> Thus, even under the more restrictive definition of ‘trade secret’ as used by the D.C. Circuit and some other courts in determining the possibility of disclosure via a FOIA request, a generic manufacturer should be able to protect bioequivalency tests as trade secrets and will be immune from disclosure under Exemption 4 of FOIA.<sup>169</sup>

2. *Overcoming Threats of Disclosure Via the FDA’s Use and Disclosure of Trade Secrets.* In addition to FOIA requests, competitors could potentially gain access to bioequivalency tests protected by trade secret law through the FDA’s own use and disclosure of the protected information. While it is true that bioequivalency test trade secrets would have to be disclosed to the FDA in order to submit an ANDA, generic manufacturers should be assured that the FDA can only disclose protected information to third parties under limited circumstances.<sup>170</sup>

The Supreme Court addressed the question of when an agency may use and disclose information that is freely submitted by a manufacturer seeking agency approval to produce a product in *Ruckelshaus v. Monsanto*,<sup>171</sup> whose reasoning can be applied to bioequivalency tests to demonstrate that the scope of trade secret protection is broad enough to prevent the FDA from disclosing the information. The issue in the case was whether a pesticide manufacturer who submitted an application for market approval of its pesticide to the Environmental Protection Agency (EPA) could claim trade secret protection

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<sup>166</sup> *Id.*

<sup>167</sup> *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1351 (Fed. Cir. 2012).

<sup>168</sup> *See* 704 F.2d at 1290 (“[W]e conclude that [the records at issue] are not protected under the first prong of Exception 4. The relationship of the requested information to the productive process is tangential at best . . .”).

<sup>169</sup> 5 U.S.C. § 522(b)(4).

<sup>170</sup> *See* *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).

<sup>171</sup> *Id.* at 990.



for health and safety information submitted as part of the application.<sup>172</sup> Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which gave the EPA the authority to regulate the sale of pesticides.<sup>173</sup> In order to market a pesticide in the United States, a manufacturer must gain EPA approval,<sup>174</sup> which parallels the requirement that a generic manufacturer must have FDA approval in order to market a generic drug.

Monsanto, a company that developed and manufactured pesticides, submitted an application to the EPA for approval to market a new chemical.<sup>175</sup> Throughout the application process, Monsanto took special care to protect health and safety data that they used to test the chemical.<sup>176</sup> The company spent approximately \$23.6 million in order to generate this information, and did not want the EPA to use it to test other chemicals.<sup>177</sup> Under the FIFRA statute, however, the EPA was allowed to use information submitted for the registration of a pesticide to evaluate subsequent applications, and the statute also allowed the EPA to publicly disclose some of the submitted information.<sup>178</sup> The statute was silent with regard to the disclosure of health and safety information, which the manufacturer was seeking to protect.<sup>179</sup> The stakes of the case were raised because like developing and marketing a generic drug,<sup>180</sup> manufacturing a pesticide requires expenditures of between five and fifteen million dollars annually over several years.<sup>181</sup> When the EPA tried to use and disclose Monsanto's health and safety information, the company sued, claiming that the EPA's use of its health and safety data constituted a taking and was prohibited under the Takings Clause of the Fifth Amendment.<sup>182</sup>

The Supreme Court asked whether Monsanto had a property interest in the health and safety data, and if it did, whether the EPA's use of the data

<sup>172</sup> *Id.* at 998.

<sup>173</sup> 61 Stat. 163 (1947), *codified at* 7 U.S.C. §§ 136–136y (2012).

<sup>174</sup> *Ruckelshaus*, 467 U.S. at 991.

<sup>175</sup> *Id.* at 997–98.

<sup>176</sup> *Id.* at 998.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.* at 990.

<sup>179</sup> *Id.* at 991.

<sup>180</sup> Although the cost of developing and manufacturing a generic drug is only about 15% of the price of developing and manufacturing a new, brand name drug (Facts about Generic Drugs, U.S. Food & Drug Admin., <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.html> (last updated Sept. 19, 2012)), manufacturing a generic can still cost between \$120–\$150 million (*ABC News, Bitter Medicine: Pills, Profits and the Public Health*, ABC TELEVISION BROADCAST, May 29, 2002, LEXIS, News Library, Transcripts File).

<sup>181</sup> *Ruckelshaus*, 467 U.S. at 998.

<sup>182</sup> *Id.* at 1001; *see also* U.S. CONST. amend. V (“[N]or shall private property be taken for public use, without just compensation.”).

constituted a taking.<sup>183</sup> Because Monsanto asserted that the data was a trade secret, the Court chose the Restatement of Torts' definition of 'trade secret' for the purposes of deciding the case.<sup>184</sup> According to the Restatement, a trade secret is "any . . . compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."<sup>185</sup> The Court found that Monsanto did have a property right protectable by the Fifth Amendment in the data.<sup>186</sup> However, the Court also ruled that, "[A]s long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."<sup>187</sup> In other words, because Monsanto was on notice during some of the relevant statutory period that the EPA could use the information to evaluate other chemicals and could subject it to public disclosure, the EPA's use of the information could not constitute a taking for the purposes of the Fifth Amendment. The Court further noted that some of the EPA's disclosure of health and safety information constituted a taking,<sup>188</sup> because Monsanto classified the submitted information as a trade secret, which, for a certain period before the statute was amended, was permitted.<sup>189</sup>

*Ruckelshaus* offers a lesson to generic drug manufacturers about the limits of the protection offered by trade secret law for their bioequivalency tests. So long as a bioequivalency test meets the appropriate requirements for a trade secret under the Restatement of Torts, a manufacturer has a property interest in the test.<sup>190</sup> This is important because if the test constitutes property, then some immunity against disclosure would apply, and the FDA will not have freedom to disclose the information to whomever asks. However, the holding of *Ruckelshaus* indicates that this exclusion right is not unlimited and that courts would likely be unsympathetic to a generic manufacturer who submitted information to the FDA knowing that the FDA was able to use and disclose certain information.<sup>191</sup> Thus, it is important for generic manufacturers to take precautions demonstrating the value of a bioequivalency test and its utmost

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<sup>183</sup> *Ruckelshaus*, 467 U.S. at 1000.

<sup>184</sup> *Id.* at 1001.

<sup>185</sup> *Id.* (quoting RESTATEMENT OF TORTS § 757 cmt. b).

<sup>186</sup> *Id.* at 1003–04.

<sup>187</sup> *Id.* at 1007.

<sup>188</sup> *Id.* at 1010.

<sup>189</sup> *Id.* at 1011.

<sup>190</sup> *Id.* at 1003–04.

<sup>191</sup> *See id.* at 1007.

importance to the process of manufacturing a generic drug, as did the petitioner in *Ruckelshaus* with the health and safety information pertaining to its pesticide.

Section 20 of the Code of Federal Regulations is particularly instructive as to the FDA's rights to information submitted to it by generic drug manufacturers.<sup>192</sup> The FDA's policy is to make the fullest disclosure of information possible, except when the information falls into a protected category, one of which is a trade secret.<sup>193</sup> For this reason, it is important that drug manufacturers classify bioequivalency tests as trade secrets from the time of their first application for FDA approval. Furthermore, the court will often ascertain the actual value of submitted information by looking at the submitter's own efforts to protect it,<sup>194</sup> so generic manufacturers should take measures to protect the submitted information. For example, in *Ruckelshaus*, the Court noted, "Monsanto has instituted stringent security measures to ensure the secrecy of the data."<sup>195</sup> Thus, if generic manufacturers take steps to protect their bioequivalency tests from disclosure before the information is submitted to the FDA, this evidence of the tests' value would cut in favor of the manufacturer were the FDA to consider disclosure. While the *Ruckelshaus* Court noted that "the Trade Secrets Act is not a guarantee of confidentiality to submitters of data,"<sup>196</sup> classifying information as a trade secret *before* submitting the information to the FDA can offer the submitter greater protection.

3. *Overcoming Potential Litigation-Related Threats of Disclosure Right of Public Access.* In addition to the threats of disclosure posed by FOIA requests and FDA use of the information, litigation proceedings, and specifically discovery requests, pose a third potential threat of disclosure. For example, if a generic manufacturer were to be sued by a competitor or third party, the generic manufacturer will be concerned that a bioequivalency trade secret could be subject to disclosure through a discovery request. While the Federal Rules of Civil Procedure contain specific provisions to protect litigating parties from the disclosure of trade secrets during the discovery process,<sup>197</sup> generic manufacturers will want to take special precautions in order to receive full protection for their bioequivalency tests. Case law can additionally protect a

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<sup>192</sup> See *supra* notes 84–85 and accompanying text.

<sup>193</sup> See *supra* notes 85–104 and accompanying text.

<sup>194</sup> *Ruckelshaus*, 467 U.S. at 1002.

<sup>195</sup> *Id.* at 998.

<sup>196</sup> *Id.* at 1008.

<sup>197</sup> FED. R. CIV. P. 26(c)(1)(G); *id.* § 45(d)(3)(B).

generic manufacturer's bioequivalency tests from litigation-related threats of disclosure.<sup>198</sup>

The threat of trade secret disclosure posed by the discovery process can be very serious because of the common law right of public access.<sup>199</sup> As the court notes in *Nycomed*, “The courts have long recognized a common law right of public access to judicial documents.”<sup>200</sup> The primary theory behind the doctrine of the right of public access is related to the desire for the general public to perceive the court as an independent and legitimate body.<sup>201</sup> The Second Circuit has noted, “The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like fiat and requires rigorous justification.”<sup>202</sup> Thus, courts are strict about maintaining public access to judicial documents in order to maintain legitimacy and provide information for the general public. However, the court's desire conflicts with a generic drug manufacturer's interest in keeping information about bioequivalency tests hidden.

If a trade secret cannot withstand the common law right of public access, trade secret protection is of little use to generic manufacturers who face a discovery request by an opposing party for documents containing information related to bioequivalency testing methods. Although the common law right of public access can make the process of protection tricky for generic manufacturers, generic manufacturers can use the Second Circuit's three part test to determine whether a judicial document should be susceptible to the common law right of public access<sup>203</sup> in order to argue against disclosure.

The Second Circuit has stated that when judicial documents are requested, the presumption is that they are susceptible to public access.<sup>204</sup> Courts do err on the side of disclosure, but the common law right of public access is not absolute.<sup>205</sup> The Second Circuit's test to determine whether a judicial document is subject to the common law right of public access, as mentioned previously, involves three steps<sup>206</sup>: “First, the court must determine whether the documents are indeed judicial documents . . . Second, if the documents are judicial

<sup>198</sup> See, e.g., *Nycomed US, Inc. v. Glenmark Generics, Inc.*, No. 08-CV-5023(CBA), 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.).

<sup>199</sup> *Id.*

<sup>200</sup> *Id.* at \*7 (quoting *Stern v. Cosby*, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2006)).

<sup>201</sup> *Id.*

<sup>202</sup> *Id.* (quoting *United States v. Aref*, 533 F.3d 72, 83 (2d Cir. 2008)).

<sup>203</sup> See *supra* notes 128–29.

<sup>204</sup> See *United States v. Amodeo*, 71 F.3d 1044, 1047–49 (2d Cir. 1995).

<sup>205</sup> See *Nixon v. Warner Commc's, Inc.*, 435 U.S. 589, 598 (1978).

<sup>206</sup> *Stern v. Cosby*, 529 F. Supp. 2d 417, 420 (S.D.N.Y. 2007). See also *supra* notes 128–29.

documents, the court must determine the weight of the presumption [of disclosure]. . . . Third, once the weight of the presumption is determined, a court must balance competing considerations against it.”<sup>207</sup>

It is likely that, were the situation to arise, a generic manufacturer could successfully argue that a bioequivalency test protected as a trade secret should not be susceptible to the common law right of public access under the Second Circuit’s analysis.<sup>208</sup> Looking at the first factor—“whether the documents were judicial documents to which the public had a right of access”<sup>209</sup>—a manufacturer could likely end the inquiry here. The definition of “judicial documents,” as discussed in Part II.C,<sup>210</sup> is “relevant documents which are submitted to, and accepted by, a court of competent jurisdiction in the course of adjudicatory proceedings, [and] become documents to which the presumption of public access applies.”<sup>211</sup> Thus, the only way that the definition would apply is if the documents with the relevant trade secret information were requested by or submitted to a court, which is not likely to be necessary unless the lawsuit concerns the bioequivalency testing method itself.

In addition, even if a court does request documents containing trade secrets, generic manufacturers could argue against disclosure based on the theory behind the common law right itself. For example, if the goal of this doctrine of the right to public access is to portray the court as a legitimate and independent body that can be trusted and respected, then the disclosure of a document upon which a manufacturer has built its business could be harmful to the court’s reputation. Inventors, manufacturers, and producers of lucrative goods would hesitate to turn to the courts for a remedy if the court would simply disclose their trade secrets to the first person who asks.

Turning to the second factor, “the weight of the presumption of disclosure,”<sup>212</sup> a generic manufacturer would again have a strong argument against disclosure. As the court notes, “[T]he weight of the presumption depends on the ‘role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the

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<sup>207</sup> *Stern*, 529 F. Supp. 2d at 420 (quoted in *Nycomed US, Inc. v. Glenmark Generics, Inc.*, 2010 U.S. Dist. LEXIS 20788 (E.D.N.Y.)) (internal quotation marks omitted).

<sup>208</sup> See *supra* notes 128–29.

<sup>209</sup> See *supra* notes 128–29.

<sup>210</sup> See *supra* note 127.

<sup>211</sup> *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 122 (2d Cir. 2006) (quoting *FTC v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 409 (1st Cir. 1987)).

<sup>212</sup> *Stern*, 529 F. Supp. 2d at 420.

federal courts.’<sup>213</sup> In other words, due to the high value of a bioequivalency test being kept a secret from competing manufacturers, the presumption of disclosure by the court would not be high and would favor the position of a generic manufacturer. The court further states the inquiry is often based largely on whether the information sought to be disclosed is germane to the litigation, especially if the information is used for a motion to dismiss.<sup>214</sup> Thus, for the purposes of a generic manufacturer protecting a bioequivalency test, unless the test itself was of central importance to the litigation, the presumption would weigh in favor of nondisclosure. Furthermore, keeping in mind the purpose of the doctrine, it makes sense that the presumption is stronger when the information is related to a motion to dismiss, because if the court dismisses a case based on a motion, it needs to show good cause for the dismissal.

Finally, when looking at the third factor—competing considerations against the presumption<sup>215</sup>—it is likely that the generic manufacturer would be able to win the battle over disclosure at this step, if they could not do so via steps one or two. As mentioned above, if courts will disclose lucrative, competition-driving methods and formulas to the public during litigation, generic manufacturers seeking protection will not seek judicial remedies. Furthermore, a manufacturer’s active and vigorous defense of a trade secret is itself evidence of its value. If public disclosure via the common law right of public access causes the generic manufacturer to lose its competitive advantage, as well as the millions of dollars it invested in development of the secret,<sup>216</sup> the presumption would favor disclosure. As demonstrated in *Momenta*, bioequivalency tests offer a competitive advantage to generic companies who develop them.<sup>217</sup> Because so much of the generic manufacturer’s competitive advantage is stored in the bioequivalency test, the court would be reticent to subject this precious and valuable information to judicial disclosure.

For example, in *Nycomed*, the defendant sought to have the plaintiff’s brief containing motions to amend the pleadings exempted from the common law right of public access, as the brief allegedly contained information that the defendant considered confidential.<sup>218</sup> Defendant Glenmark argued that because

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<sup>213</sup> *Nycomed US, Inc. v. Glenmark Generics, Inc.*, No. 08-CV-5023(CBA), 2010 U.S. Dist. LEXIS 20788, at \*9 (E.D.N.Y. 2010) (quoting *United States v. Amodeo*, 71 F.3d 1044, 1049 (2d Cir. 1995)) (internal citations omitted).

<sup>214</sup> *Id.*

<sup>215</sup> *Id.* at \*8.

<sup>216</sup> *See, e.g., Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1351 (Fed. Cir. 2012).

<sup>217</sup> *Id.*

<sup>218</sup> *Nycomed*, 2010 U.S. District LEXIS 20788, at \*12.

two paragraphs of the plaintiff's motion contained confidential information related to Glenmark's ANDA, this information was exempt from public disclosure.<sup>219</sup> The court, however, disagreed. This situation is easily distinguishable from the hypothetical situation in which a third party is invoking the doctrine of public access against a generic manufacturer with the hope of gaining access to a bioequivalency test protected via trade secret law, because information protected as trade secret would not be found in an opposing party's brief to start with, if it was actually a secret. In *Nycomed*, the defendant sought to protect information contained in the plaintiff's brief; surely an opposing party's motion to amend the pleadings should not contain information related to a vigorously protected trade secret in the first place, if the alleged trade secret were really a secret. After reviewing the FDA's relevant provisions regarding the disclosure of pending ANDA's, the court notes, "Certainly, any information that is already public, or is independently made public, cannot be deemed confidential."<sup>220</sup> The court also noted that the FDA's regulations guarded only against disclosure by the FDA and not the common law right of public access.<sup>221</sup> Thus, so long as the generic manufacturer actually treats the bioequivalency test information allegedly within the scope of the common law right of public access as a legitimate secret, the presumption against disclosure during litigation should cut in favor of the generic manufacturer.

In addition to the potential for disclosure due to a competitor's assertion of the common law doctrine of public access during litigation, the discovery rules could also pose a legitimate threat to generic manufacturers who seek to protect their bioequivalency tests. As several cases have noted, there is no absolute privilege which protects trade secrets from disclosure under the Federal Rules of Civil Procedure.<sup>222</sup> However, many cases have noted that courts should try to avoid unnecessary disclosure of trade secrets during discovery.<sup>223</sup> Rules 26 and 45 of the Federal Rules of Civil Procedure both discuss 'trade secrets,'<sup>224</sup> and often work together to protect parties from disclosure.<sup>225</sup>

In *Massey Coal Services, Inc.*, for example, the court explained the circumstances under which a court can issue a protective order pursuant to Rule

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<sup>219</sup> *Id.* at \*15.

<sup>220</sup> *Id.* at \*16.

<sup>221</sup> *Id.*

<sup>222</sup> *Paulsen v. Case Corp.*, 168 F.R.D. 285, 289 (C.D. Cal. 1996).

<sup>223</sup> *Hamilton v. State Farm Mut. Auto. Ins. Co.*, 204 F.R.D. 420, 422 (S.D. Ind. 2001).

<sup>224</sup> See FED. R. CIV. P. 26, 45; see also text accompanying notes 131–36 for a review of rules 26 and 45.

<sup>225</sup> See generally *In re Fosamax Prods. Liab. Litig.*, No. 1:06-MO-1789(JCF), 2009 U.S. Dist. LEXIS 70246, at \*30 (S.D.N.Y.).

26(c)(1)(G) to prevent a party from having to disclose a trade secret during the discovery stage of litigation.<sup>226</sup> The plaintiff, Massey Coal, sued defendant, Victaulic, for various counts of breach of contract and misrepresentation.<sup>227</sup> The defendants manufactured and installed piping that the plaintiff used in its coalmines; when the pipes failed, the defendants admitted there was a problem but would not provide further information.<sup>228</sup> Before the hearing, the judge issued a protective order for “documents or other materials . . . subject to disclosure . . . [that are] confidential and should not be disclosed other than in connection with this action.”<sup>229</sup> The defendant disclosed to the plaintiffs several documents marked ‘CONFIDENTIAL’ per the protective order, a few of which demonstrated that the defendants knew that a chemical used to make the pipes was potentially causing the pipes to fail. Because the pipes were used to carry drinking water throughout the county, the plaintiffs made a motion to disclose the information to the Public Service Authority.<sup>230</sup> The defendant objected, invoking protection from Rule 26(c)(1)(G)<sup>231</sup> and arguing that the documents contained commercially valuable information.<sup>232</sup> For the purposes of analysis, the court noted that Rule 26(c)(1) “treats equally a trade secret or other confidential commercial information.”

Ultimately, the trial judge held that the documents were not protectable via Rule 26(c)(1),<sup>233</sup> but the reasoning of the court is helpful in understanding the scope of the protection offered under 26(c)(1). In order to get a protective order for discovered documents under 26(c)(1), the party possessing the documents must show “good cause” for protection, including, most relevantly, “undue burden or expense.”<sup>234</sup> Essentially, the defendants in this case argued that “severe economic damage” would result from disclosure.<sup>235</sup> However, the court noted, “Broad allegations of harm, unsubstantiated by specific examples . . . do not satisfy the Rule 26(c) test. Moreover, the harm must be significant, not a mere trifle.”<sup>236</sup> Additionally, the court stated that the

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<sup>226</sup> *Massey Coal Servs., Inc. v. Victaulic Co. of Am.*, 249 F.R.D. 477 (S.D.W. Va. 2008).

<sup>227</sup> *Id.* at 478.

<sup>228</sup> *Id.*

<sup>229</sup> *Id.* at 479.

<sup>230</sup> *Id.*

<sup>231</sup> *Id.* at 482 (internal quotations omitted) (internal citations omitted).

<sup>232</sup> *Id.*

<sup>233</sup> *Id.* at 484.

<sup>234</sup> *Id.* at 480; *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1987) (addressing the “standard for determining whether [d]efendants have shown good cause for a protective order” (citations omitted)). *See also* FED. R. CIV. P. 23(c)(1); *supra* text accompanying note 134.

<sup>235</sup> *Massey Coal Servs., Inc.*, 249 F.R.D. 477.

<sup>236</sup> *Id.* at 481 (citation omitted).



defendants had made no showing that they had undertaken efforts to keep the documents a secret,<sup>237</sup> that the defendants had not objected to disclosure of the documents to the plaintiffs, that the documents were contained in the court's public record, and that the defendants did not file a motion to seal the documents.<sup>238</sup> In light of these facts, the court reasoned that the documents were not commercially valuable and were not protectable.<sup>239</sup> The trial judge further stated that even if the disclosure of the documents to the state public health authorities would cause embarrassment to the defendants, the embarrassment was not a concern of the court and would not protect the documents from disclosure.<sup>240</sup>

In light of the *Massey* court's holding and reasoning, if a generic manufacturer protecting a bioequivalency test via trade secret law wishes to prevent disclosure via Rule 26(c)(1), it must show "good cause" for a protective order by demonstrating "undue burden or expense."<sup>241</sup> The manufacturer should provide the court with "specific examples or articulated reasoning"<sup>242</sup> that disclosure of the trade secret would cause substantial economic harm to the manufacturer. Further, the manufacturer should show that this harm will be significant, and "not a mere trifle."<sup>243</sup> Generic manufacturers should also consider factors commonly used to measure secrecy, found in the Restatement of Torts. Such factors can include:

[T]he extent to which the information is known by employees and others involved in the business . . . the extent of measures taken by the business to guard the secrecy of the information . . . the value of the information to the business and to its competitors . . . and the amount of effort or money expended in developing the information.<sup>244</sup>

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<sup>237</sup> *Id.* at 483.

<sup>238</sup> *Id.* at 484.

<sup>239</sup> *Id.* at 482–83.

<sup>240</sup> *Id.* at 484.

<sup>241</sup> *See* *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1987); *see also* FED. R. CIV. P. 26(c)(1).

<sup>242</sup> *Cipollone*, 785 F.2d at 1121.

<sup>243</sup> *Id.*

<sup>244</sup> *Massey Coal Servs., Inc.*, 249 F.R.D. at 482.

Again, since bioequivalency tests take substantial time, effort, and funding to create, they are critical to a generic manufacturer's market competitiveness.<sup>245</sup> Therefore, the manufacturer should take great care in maintaining their secrecy, for example, by limiting the number of employees who have the formulas, making employees sign confidentiality agreements and covenants not to compete, and maintaining a financially reasonable amount of computer system security. If a generic manufacturer is sued, it should be fairly simple to demonstrate to the court that documents containing the specific bioequivalency formula should either not be disclosed because they are not germane to the lawsuit, or that they should be privileged and confidential due to their economically valuable nature.

In addition, Rule 45 of the Federal Rules of Civil Procedure,<sup>246</sup> which governs subpoenas, could also benefit a generic manufacturer seeking to protect a bioequivalency test through trade secret law during litigation. A generic manufacturer's bioequivalency test trade secret will lose its value if disclosed; given the test's high value, generic manufacturers will want to be aware of the risk of being subpoenaed so that they can demonstrate, if necessary, why a bioequivalency test trade secret should not be disclosed. When determining whether or not to quash a subpoena that could potentially pose a threat of disclosure to a generic manufacturer's bioequivalency test trade secret, the court will balance the burden of disclosure with the potential need/use of the information.<sup>247</sup>

Although there is also no per se protection for trade secrets under Rule 45, it is likely that a generic manufacturer would be able to withstand disclosure of a bioequivalency test in the event of a subpoena. For example, *In re Fosamax* demonstrates that drug manufacturers can make a variety of creative arguments to successfully quash a subpoena that would result in disclosure. A group of plaintiffs sued defendant drug company, Merck & Co., alleging that a drug they manufactured, Fosamax, caused adverse side effects.<sup>248</sup> The plaintiffs issued a subpoena to Dr. Bruce Psaty from the National Academy of Sciences to testify about a drug safety report that he conducted under the direction of the FDA.<sup>249</sup>

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<sup>245</sup> See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1351–52 (Fed. Cir. 2012); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 16, 2013).

<sup>246</sup> FED. R. CIV. P. 45.

<sup>247</sup> See *supra* notes 138–41 and accompanying text.

<sup>248</sup> *In re Fosamax Prods. Liab. Litig.*, No. 1:06-MO-1789(JFK)(JLF), 2009 U.S. Dist. LEXIS 70246, at \*26 (S.D.N.Y. Aug. 4, 2009).

<sup>249</sup> *Id.* at \*28.

Dr. Psaty moved to quash the subpoena under Rule 45(d)(3)(B),<sup>250</sup> alleging that he never studied the drug in question;<sup>251</sup> furthermore, the defendant urged that even if Dr. Psaty testified, it was unclear whether he would be required to disclose confidential information or trade secrets.<sup>252</sup> In making its decision, the court tried to balance the burden between necessity of the testimony and the undue burden on the defendant to produce the information, ultimately quashing the subpoena.<sup>253</sup> In considering whether there is an undue burden on the defendant, the court assesses the personal hardship to the party protecting the information and the wider social consequences of disclosing the information.<sup>254</sup> Here, the court noted that if Dr. Psaty were required to testify, “the resulting social impact would be far more serious. Compelling testimony from a third party researcher risks chilling participation in beneficial public research.”<sup>255</sup> Thus, the court recognized the value of trade secrets, suggesting other courts will also protect them from disclosure during the discovery process by quashing a subpoena that would reveal them.

When comparing this case with the potential disclosure of a generic manufacturer’s bioequivalency test, generic manufacturers who receive subpoenas would likely not be required to disclose trade secrets if called to testify. Even if the testimony sought were important to the case, the balancing of the burden between necessity of the testimony and the undue burden placed on the defendant would likely weigh in favor of quashing the subpoena. The personal hardship to the generic manufacturer would be catastrophic, resulting in the loss of millions of dollars in profits or the loss of commercial market advantage.<sup>256</sup> In addition, the consideration of wider social impact would weigh in favor of suppressing the subpoena, because requiring generic drug manufacturers to disclose trade secrets could have a chilling effect on beneficial scientific research.

Generic manufacturers provide a valuable service to consumers by lowering the cost of drugs. However, because the Federal Circuit’s expansive reading of

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<sup>250</sup> *Id.* at \*27. See also FED. R. CIV. P. 45(d)(3)(B)(i)–(ii) (“To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information; or (ii) disclosing an unretained expert’s opinion or information that does not describe specific occurrences in dispute and results from the expert’s study that was not requested by a party.”).

<sup>251</sup> *In re Fosamax Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 70246, at \*28.

<sup>252</sup> *Id.* at \*30.

<sup>253</sup> *Id.* at \*33–34.

<sup>254</sup> *Id.* at \*34.

<sup>255</sup> *Id.* at \*35.

<sup>256</sup> See, e.g., *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

the safe harbor provision in *Momenta v. Amphastar* gives generic manufacturers little protection for their bioequivalency tests through patent law,<sup>257</sup> the incentive to produce generic drugs will likely decrease if another method of protection is not found. Although trade secret law does not provide per se protection from disclosure,<sup>258</sup> generic manufacturers could still find adequate protection through trade secret law if they overcome the obstacles previously mentioned in the context of FOIA requests, FDA use of the information, and litigation.

Although FOIA encourages the broad disclosure of government-held information, a generic manufacturer can demonstrate to the FDA's FOIA office that bioequivalency test trade secrets are immune from disclosure. The generic manufacturer can point to the definition of trade secret adopted in *Public Citizen Health* to argue that a bioequivalency test qualifies as a trade secret, exempting it from disclosure. Generic manufacturers can also overcome the threat of disclosure posed by the FDA's potential use or disclosure of the information, because the FDA is only allowed to disclose protected information submitted to it by a third party under limited circumstances. Because generic manufacturers have a property interest in their bioequivalency test trade secrets, the FDA has a limited amount of power to disclose this information; so long as a generic manufacturer treats the bioequivalency test as a trade secret, the threat of disclosure by the FDA is manageable. Finally, litigation-related threats of disclosure, specifically the common law right of public access and discovery requests made by parties to a litigation, can also be overcome by generic manufacturers. The test developed by the Second Circuit in *Stern v. Cosby* can be used to show that the presumption in favor of disclosure present in the common law right of public access can be avoided by generic manufacturers protecting bioequivalency tests as trade secrets. Furthermore, generic manufacturers could also protect their bioequivalency test trade secrets from disclosure via discovery requests through the protection offered by Federal Rules of Civil Procedure 26 and 45. This Note has therefore demonstrated that generic manufacturers could successfully protect their bioequivalency research and development investments from use by competitors through the use of trade secret law.

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<sup>257</sup> *Id.* at 1361.

<sup>258</sup> *United States v. Int'l Bus. Mach. Corp.*, 67 F.R.D. 40, 42 n.1 (S.D.N.Y. 1975) (holding that "trade secrets and other confidential commercial information enjoy no privilege from disclosure although courts may choose to protect such information").

## IV. CONCLUSION

Altogether, this Note has explored the impact and the consequences of the recent holding in *Momenta* and one potential solution to the problems created by the Federal Circuit.<sup>259</sup> The *Momenta* majority held that a generic manufacturer who uses the patented bioequivalency test of a competitor is protected from liability by way of the safe harbor provision of the Hatch Waxman Act.<sup>260</sup> As Chief Judge Rader points out in his dissent, the majority's holding effectively renders all patents on bioequivalency testing methods worthless,<sup>261</sup> an effect confirmed by later proceedings.<sup>262</sup> In light of the *Momenta* holding, generic manufacturers are now in need of a way to protect their bioequivalency testing methods from use by their competitors. This Note has demonstrated that trade secret law can provide a viable alternative to patent protection for generic manufacturers, at least in the absence of any action by Congress to address the Federal Circuit's expansive reading of the safe harbor provision in *Momenta v. Amphastar*.

Generic manufacturers can protect their bioequivalency tests through trade secret law by overcoming obstacles in three potentially threatening contexts. Generic manufacturers can overcome the threat of disclosure from a FOIA request by arguing that bioequivalency tests fit within the scope of the definition of "trade secret" and constitute commercially valuable information. Second, generic manufacturers can withstand the threat of disclosure through the FDA's own use of the information by again arguing that a bioequivalency test constitutes a trade secret, under the specific FDA definition and by showing positive steps taken to treat the information as a secret, meeting the Second Circuit's test. Third, generic manufacturers can address the threat arising from the common law right of public access by arguing that the purpose of the right is for the public to view the court as a legitimate institution, and that this purpose would be defeated if the court disclosed a manufacturer's extremely valuable information to competitors. Finally, generic manufacturers can use trade secret law to protect bioequivalency tests despite the threat of disclosure from litigation by invoking Federal Rules of Civil Procedure 26(c) against discovery requests for documents and Rule 45 against subpoenas.

Ideally, Congress will recognize the Federal Circuit's unfortunate holding in *Momenta* with corrective legislation to restore the power of patent protection to

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<sup>259</sup> *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1368 (Fed. Cir. 2012).

<sup>260</sup> *Id.* at 1361.

<sup>261</sup> *Id.* at 1362 (Rader, J., dissenting).

<sup>262</sup> See *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y.).

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generic manufacturers. However, in the meantime, or indefinitely into the future if necessary, trade secret law can provide an alternative to patent protection for generic manufacturers who desire to protect their bioequivalency tests from the hungry eyes of their competitors.

