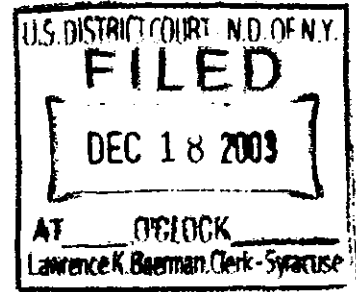


UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK



NORBROOK LABORATORIES LIMITED,

Plaintiff,

v.

5:03-CV-165 (HGM/GLS)

G.C. HANFORD MANUFACTURING COMPANY
doing business as **HANFORD PHARMACEUTICALS,**

Defendant.

APPEARANCES:

OF COUNSEL:

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HOWARD G. MUNSON, SR.J.

MEMORANDUM AND ORDER

In an order dated July 2, 2003, the court granted plaintiff's motion for a preliminary injunction and denied defendant's motion for judgment as a matter of law. The present



memorandum sets forth the reasons for the court's decision on the parties' respective motions as required by Federal Rules of Civil Procedure 52(a) and 65(d).

BACKGROUND

I. The Parties

A. Plaintiff

Plaintiff, Norbrook Laboratories Limited ("Norbrook"), is a corporation organized under the laws of Northern Ireland, with its principal place of business located at Station Works, Newry BT35 6JP, County Down, Northern Ireland. Established in 1968 by Dr. Edward Haughey,¹ Norbrook researches, develops, markets, and distributes its own line of veterinary pharmaceuticals to over 110 countries, including the United States. Dkt. No. 1, Compl. at ¶ 2; Dkt. No. 66, Trial Tr. at 10. In addition, Norbrook manufactures antibiotics, steroids, and anthelmintics. Dkt. No. 66, Trial Tr. at 6. Norbrook employs approximately 1,000 people worldwide, 750 to 800 of whom are employed at Norbrook's Northern Ireland headquarters. Norbrook's annual revenue [REDACTED]. [REDACTED]. Norbrook manufactures Penicillin G Procaine, ("PGP"), an injectable veterinary penicillin, in liquid suspension form. In 2002, Norbrook sold approximately [REDACTED].

B. Defendant

Defendant, G.C. Hanford Manufacturing Company, doing business as Hanford Pharmaceuticals ("Hanford"), is a corporation organized under the laws of the State of New York, with its principal place of business located at 304 Oneida Street, Syracuse, New York 13216.

¹Dr. Haughey owns Norbrook and serves as its chief executive officer and chairman. Dkt. No. 66, Trial Tr. at 31.

Established in 1846, Hanford is a pharmaceutical contract manufacturer specializing in injectable cephalosporins, penicillins and penicillin derivatives, including penicillin suspensions, for veterinary use. Dkt. No. 1, Compl. at ¶ 3 and <http://www.gchanford.com/index1.html>. Hanford employs about 300 people and since 1981, has sold penicillin products in the United States exclusively. Dkt. No. 68, Trial Tr. at 300-01. The parties directly compete in the United States market for injectable veterinary penicillin products. Dkt. No. 1, Compl. at ¶ 4.

II. Procedural History

On February 7, 2003, Norbrook, filed a complaint against Hanford alleging: (1) misappropriation of trade secrets and confidential information; (2) unfair competition; (3) tortious interference with contract; (4) aiding and abetting breach of fiduciary duty; and, (5) unjust enrichment in violation of New York State law. Norbrook argued that Hanford's consultancy with a former Norbrook employee, Dr. Phillip Quinn, resulted in the misappropriation of one of its trade secrets (referred to herein as "Norbrook's *in situ* method"), specifically, a method used to manufacture a final dosage form of veterinary penicillin known as penicillin G procaine ("PGP"). Norbrook alleged that Hanford sought to obtain the Norbrook Process in order to gain an unfair and unearned competitive advantage and eliminate Norbrook as a competitor in the United States market for veterinary penicillin. Dkt. No. 1, Compl. at ¶¶ 37-67.

Within days of filing its complaint, Norbrook moved for expedited discovery and a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, seeking to enjoin Hanford from, *inter alia*, manufacturing, marketing, selling, advertising for sale or in any other way dealing in injectable antibiotics comprising the suspension of PGP where the product is manufactured using any part of Norbrook's *in situ* method or confidential information. Dkt. No. 36,

Mot. for Prelim. Inj. On March 21, 2003, the court granted Norbrook's motion for expedited discovery and directed the parties to appear for a preliminary injunction hearing to commence on May 29, 2003. In April of 2003, the parties reached an impasse regarding certain discovery issues and requested the court's intervention to clarify and/or resolve those discovery disputes. On April 24, 2003, the court issued a Memorandum-Decision and Order resolving those issues and expedited discovery proceeded without further delay. *See* Dkt. No. 39.

As the hearing date approached, Norbrook discovered that Hanford had received the preliminary approval of the United States Food and Drug Administration ("FDA") to commence production of a veterinary penicillin manufactured by a process unlike the process previously used by Hanford in the manufacture of its PGP. Shortly thereafter, the parties entered into a stipulation and agreement whereby: (1) Norbrook would not seek a temporary restraining order ("TRO") prior to May 29, 2003; (2) Hanford could complete its "validation lots" and proceed to obtain final approval from the FDA; (3) Hanford would not promote or advertise its products manufactured with the disputed process nor solicit, offer or accept the sale of products manufactured with the disputed process prior to June 10, 2003; and, (4) Hanford would not offer evidence at the Preliminary Injunction Hearing with respect to Norbrook's actions or forbearance, from and after May 1, 2003, in respect of (a) Hanford's production of product under the disputed *in situ* method; (b) Hanford's pursuit of FDA approval; and (c) the Stipulation itself. *See* Dkt. No. 47, Stipulation and Order.²

The court subsequently conducted a hearing on Norbrook's motion for a preliminary injunction on May 29-30, June 2-4, 11-13, and 17, 2003, in Syracuse, New York. Prior to and during

²The parties agreed to extend the terms and conditions of the Stipulation and Order until June 18, 2003, in anticipation of the preliminary injunction hearing's conclusion and thereafter until July 2, 2003. *See* Dkt. No. 55, Stipulation and Order; Dkt. No. 79, Stipulation and Order.

the preliminary injunction hearing, Hanford moved: (1) to preclude Norbrook's "new" legal theory (May 27, 2003), Dkt. No. 51, Mot. to Preclude; (2) to preclude Norbrook's new witness, Steven Mitchell (May 27, 2003), Dkt. No. 51, Mot. to Preclude; (3) to preclude the expert testimony of Dr. Thomas Needham (May 27, 2003), Dkt. No. 52, Mot. to Preclude; (4) to preclude the testimony of Stephen M. Lemanczyk (June 2, 2003), Dkt. No. 68, Trial Tr. at 407-13; and, (5) for judgment as a matter of law dismissing Norbrook's motion for a preliminary injunction (June 12, 2003), Dkt. No. 72, Trial Tr. at 820-30. The court: (1) reserved decision on Hanford's motion to preclude Norbrook's "new" legal theory, Dkt. No. 54, Minute Entry; (2) denied Hanford's motions to preclude the testimony of Mr. Mitchell and the expert testimony of Dr. Needham, Dkt. No. 66, Trial Tr. at 118, and Dkt. No. 72, Trial Tr. at 830, respectively; and, (3) denied Hanford's motion to preclude Mr. Lemanczyk's testimony finding that there was "no basis in fact for [the] motion in any regard." Dkt. No. 69, Trial Tr. at 423. The court has also since denied Hanford's motion for judgment as a matter of law. *See* Dkt. No. 80, Decision and Order. During the preliminary injunction hearing, Norbrook moved: (1) for the imposition of a TRO (June 4, 2003), Dkt. No. 70, Trial Tr. at 657; and (2) to strike testimony of Peter C. Ward concerning sales projections and to compel production of documents related to advertising, sales, and marketing material (June 11, 2003), Dkt. No. 60, Pl.'s Mot. To Strike Test. and Compel Produc. of Docs.; Dkt. No. 71, Trial Tr. at 668-73. The court denied Norbrook's motion for a TRO and reserved decision on its motion to strike testimony and compel the production of documents. *See* Dkt. No.70, Trial Tr. at 660 and Dkt. No.71, Trial Tr. at 674, respectively.

FINDINGS OF FACT

I. FDA Approval

There are two FDA-approved methods to manufacture PGP injections: the conventional and *in situ* methods. Under the Federal Food, Drug and Cosmetic Act, specifically 21 U.S.C. § 360b, in order to sell PGP injectable suspensions in the United States, the seller must have an FDA approved New Animal Drug Application (“NADA”). An approved NADA signifies a product’s safety and effectiveness for its intended use “and that the methods, facilities and controls used for the manufacturing, processing and packaging of the drug are adequate to preserve its identity, strength, quality and purity.” <http://www.fda.gov/cvm/index/other/nadaappr.htm>.

A. The Conventional Method

The conventional method is relatively simple. First, a third party supplier combines aqueous solutions of penicillin G potassium and procaine hydrochloride to form a precipitate of PGP in an aqueous solution containing the byproduct of potassium chloride (“KCl”). Second, the supplier filters the solution in order to remove the water and KCl byproduct. Finally, the supplier dries and mills the PGP precipitate to a particle size of approximately ten microns. The primary manufacturer then purchases the dry, sterile, pre-“micronized” powder form of PGP in bulk from the third party supplier, places water in a vat, adds excipients, and then adds the dry, sterile pre-micronized PGP powder. The primary manufacturer then vigorously mixes the ingredients to form a suspension. Dkt. No. 66, Trial Tr. at 61-63; Dkt. No. 73, Trial Tr. at 1002-05, 1008-09, 1037, 1054-55.

Hanford has owned a NADA, “493 NADA,” for PGP injectable suspensions since 1981. Dkt. No. 68, Trial Tr. at 301. Hanford has relied upon this conventional method to manufacture all of its PGP injection products that have reached the marketplace. Hanford purchases dry PGP powder in bulk form from a supplier called Biochemie, which removes the KCl byproduct during the drying process, and then Hanford adds its particular excipients and water to the dry PGP powder. Dkt. No.

66, Trial Tr. at 63-64. Norbrook too used the conventional method to manufacture three different formulations of PGP injections: Norocillin, which used an excipient called lecithin, as well as Pen Strep and Norocillin LA, which not only had different excipients, but also had other active ingredients in addition to PGP. Dkt. No. 66, Trial Tr. at 8-10, Dkt. No. 67, Trial Tr. at 131, 137-38, 140; Pl.'s Exs. 1 and 4. In addition, Norbrook purchased the rights to an FDA, NADA-approved PGP injection formulation from the Maurry Pharmaceutical Company. The Maurry formulation had only PGP as an active ingredient and used different excipients from Norocillin, but unlike its other PGP products, Norbrook could use the Maurry formula, with its FDA approval, to sell PGP product in the United States. Dkt. No 66, Trial Tr. at 23; Pl.'s Ex. 198; Toner Dep. at 130-131. In 1994, however, Norbrook's supplier of penicillin G procaine powder lost its approval from the FDA, which thereby eliminated Norbrook from the market for PGP injectable suspensions in the United States until 1999. Dkt. No. 66, Trial Tr. at 41-42.

B. The In-Situ Method

The *in situ*³ method concerns a manufacturing process for a final dosage form of veterinary penicillin most commonly used with livestock and other farm animals. See Dkt. No. 1, Compl. at ¶ 8. It differs from the conventional method in that it does not utilize the dry, sterile, pre-micronized powder form of PGP; rather, it directly reacts the non-sterile raw ingredients, penicillin G potassium and procaine hydrochloride, sterilizes and adds excipients to them, and then mills the reacted/excipient-coated PGP particles to achieve a desirable particle size distribution without ever having to dry the PGP. Dkt. No. 66, Trial Tr. at 13; Dkt. No. 67, Trial Tr. at 143-47; Toner Dep. at

³The term "*in situ*" means that a reaction occurs in a defined location, and in its conventional usage does not necessarily suggest a reaction that results in a final dosage form. Dkt. No. 70, Trial Tr. at 561-62.

23-25. Specifically, the method consists of a suspension of PGP within a liquid vehicle. Dkt. No. 66, Trial Tr. at 9; Dkt. No. 69, Trial Tr. at 491-92. PGP does not occur naturally: very generally, by combining penicillin G potassium and procaine hydrochloride, they react to form PGP and a potassium hydrochloride byproduct. PGP manufacturers, however, must treat the resultant PGP to ensure sterility and a controlled particle size in order to make the PGP suitable for veterinary applications. Dkt. No. 73, Trial Tr. at 1002-03. Thus, a manufacturer adds excipients, which act as buffers, preservatives, and stabilizers in order to ensure that the PGP particles resuspend properly in the liquid vehicle. In a pharmaceutical application the concern for sterility is obvious, but PGP particle size is critical as well. If the particle size is too small, then the PGP will not stay suspended, too large, and the product will clump in the small-gauge hypodermic needle through which the product is administered thereby causing pain at the site of the injection. Dkt. No. 69, Trial Tr. at 493-94. [REDACTED]

[REDACTED]

Because the *in-situ* method does not use a drying process, it is difficult and prohibitively expensive to remove the KCl byproduct from the final product. The absence of a drying process in the *in-situ* method also prevents the manufacturer from utilizing micronizing techniques to achieve desirable particle size. *Id.* at 13; Dkt. No. 67, Trial Tr. at 143-47. Instead, the manufacturer that relies upon the *in-situ* method must “wet”-mill the reacted product. Dkt. No. 67, Trial Tr. at 159; Dkt. No. 73, Trial Tr. at 1008. The *in-situ* method represents a significant cost savings over the conventional method, for while the penicillin G potassium and procaine hydrochloride used in the *in-situ* method cost about \$9 per kilogram, the dry PGP powder used in the conventional method costs about \$56 per kilogram. Dkt. No. 66, Trial Tr. at 13-14.

II. Impetus for the Lawsuit

In September 2002, Norbrook first learned that Hanford had hired Dr. Phillip Quinn, a former Norbrook employee who had worked extensively in developing the *in situ* method for the manufacture of PGP injections. Norbrook had taken the deposition of Mr. Ward, Hanford's Chief Executive Officer, in aid of Norbrook's Northern Ireland proceedings against Dr. Quinn for publishing defamatory materials concerning Norbrook's PGP injections. After Mr. Ward's depositions, Norbrook made a FOIA request to the FDA to determine whether Hanford had sought to modify its PGP injection manufacturing process since hiring Dr. Quinn. The FDA responded by providing a heavily redacted document. After further investigation, Norbrook concluded that Hanford had applied to the FDA to change its method of manufacture from the conventional method to an *in situ* method. Based on this information and further investigation of counsel, Norbrook sent a cease and desist letter to Hanford on January 15, 2003. This lawsuit followed. Dkt. No. 66, Trial Tr. at 53-54; Dkt. No. 68, Trial Tr. at 349.

III. Norbrook's Development of the *In-Situ* Method

A. Idea for an In-Situ Method

Dr. Haughey first discussed the viability of an *in-situ* method for the manufacture of PGP injections with an American competitor named John D. Coppanis in the early 1970s. Dr. Haughey subsequently directed Norbrook chemists to explore the possibility of using the *in-situ* method, but while they apparently grasped the process on a conceptual level, they consistently concluded that the method was unsuitable for use on a commercial scale. Dkt. No. 66, Trial Tr. at 16-17. By 1986, however, Norbrook's business had grown and become more profitable, such that Dr. Haughey decided that his company could afford to expend greater resources on the speculative research and

development of a commercially viable *in-situ* method. Dkt. No. 66, Trial Tr. at 17.

B. Norbrook Hires Dr. Quinn

In 1986, Norbrook hired Dr. Quinn, who possessed a Ph.D. in chemistry, and assigned him to work exclusively on the development of an *in-situ* manufacturing process for PGP injections. Dkt. No. 66, Trial Tr. at 18. Once hired by Norbrook, Dr. Quinn executed an employment contract and confidentiality agreement, both of which prohibited him from disclosing Norbrook's confidential information to anyone. The contract and confidentiality agreement defined confidential information as the "methods, processes, techniques, shop practices, formulae, compounds, compositions, organisms, equipment, research data, . . . and all other know-how and trade secrets," which Norbrook possesses. Dkt. 66, Trial Tr. at 19-20; Pl.'s Exs. 13 and 15.

C. Norbrook's In-situ Method

Dr. Quinn worked for Norbrook from 1986 to 1992, and during his tenure conducted hundreds of lab-scale trial-and-error experiments to develop an *in-situ* method. Initially, Dr. Quinn adapted the *in situ* method to the Norocillin product, but later he also adapted that *in-situ* method to Norbrook's other formulations, including the Maury formulation, which within Norbrook was known as "Proc Pen U.S." Dkt. No. 69, Trial Tr. at 516-18. The experiments contemplated the various factors or parameters at work in the *in-situ* method: which excipients to add, the order in which to add the ingredients, water ratios, temperatures, particle sizes, mixing and milling methods, mixing rates, etc. Dkt. No. 67, Trial Tr. at 132-35, 141, 517; Pl.'s Ex. 1. In conducting his experiments, Dr. Quinn used a lab-scale "Dynamill," which functioned to reduce the PGP particles to their final size. After the reacting the PGP in the presence of excipients, the entirety of the materials are pumped at a defined rate through the Dynamill, which through the agitation of its beads

breaks down the particles into smaller pieces. See Toner Dep. at 59-60. As a result of Dr. Quinn's experimentation, Norbrook developed sets of manufacturing instructions, which within the company were known as Production Control Records ("PCRs"). The PCRs vary or change based on a number of factors: (1) which formulation of PGP injection is being manufactured; (2) the size, power, or type of equipment used in the manufacturing process for a specific formulation; and, (3) knowledge gained through continued experience with the *in-situ* method. Dkt. No. 67, Trial Tr. at 151-52, 156-57. Dr. Quinn was instrumental in converting his lab-scale experimentation to commercial scale production: he worked with other Norbrook employees in designing and equipping the manufacturing area and "scaled-up" the manufacturing instructions based upon his experimentation with increasing batch sizes. Dkt. No. 67, Trial Tr. at 143-147. By 1988 or 1989, Norbrook produced its first commercial batches of PGP injections but sold them only in the less-regulated African countries. Dkt. No. 66, Trial Tr. at 22-23. By 1991, however, Norbrook was sufficiently confident in its *in-situ* method to approach the FDA for permission to sell PGP injections, manufactured using its *in-situ* method, in the United States. *Id.* at 24-28.

E. Norbrook Obtains FDA Approval

In 1991, Norbrook sought FDA approval of its PGP injections manufactured using its *in situ* method. Pl.'s Ex. 25. The FDA, however, denied Norbrook's initial application because the United States Pharmacopoeia ("USP")⁴ did not recognize the practice of making PGP injections without the

⁴ The "USP works closely with the . . . FDA, the pharmaceutical industry, and the health professions, to establish authoritative drug standards. These standards are enforceable by the FDA and the governments of other countries, and are recognized worldwide as the hallmark of quality." <http://www.usp.org/standards/>. The USP and the National Formulary compile standards for drug identity, strength, quality, purity, packaging, labeling and storage for medicines and other healthcare products. <http://www.usp.org/>.

use of a dry powder form of PGP. Dkt. No. 67, Trial Tr. at 161-62. The FDA deemed the *in situ* method a radical departure from the USP-approved conventional method and in fact referred to the resultant product of the *in situ* method as a "new drug." Pl.'s Ex 5. From 1992 to 1995, Norbrook endeavored to gain the USP's approval of the *in situ* method, and on February 21, 1995, the USP approved it for publication. Dkt. No. 67, Trial Tr. at 162-63, Pl.'s Ex 7. The approval and subsequent publication, as well as the product label, however, do not reveal or explain to even those well-versed in the manufacture of pharmaceuticals how the *in situ* method was developed or how its manufacturing process operated. In essence, no useful knowledge was disclosed. Together, the publication and label merely indicate that the dry, powder form of PGP was not present and that a precipitation reaction between penicillin G potassium and procaine hydrochloride occurred. Dkt. No 73, Trial Tr. at 928-29, 1040-42.

USP approval in hand, in 1997, Norbrook reapplied to the FDA but was again rebuffed. The FDA expressed its concern regarding the presence of KCl in the *in situ* method's PGP injection, a compound not present in the PGP injection derived from the conventional method. Dkt. No. 66, Trial Tr. at 64; Dkt. No. 67, Trial Tr. at 163. While at Norbrook, Dr. Quinn and others attempted to remove KCl from the PGP injection manufactured using the *in situ* method and learned that its removal presented a great challenge in terms of both technology and expense. Dkt. No. 67, Trial Tr. at 158, Pl.'s Exs. 86 and 150. Norbrook presented evidence to the FDA that the presence of KCl in its PGP was not harmful in veterinary applications, and on November 8, 1998, the FDA approved Norbrook's *in situ* method for manufacture of the PGP injection formulation that Norbrook had purchased from Maurry. Dkt. 66, Trial Tr. at 73-74; Dkt. No. 67, Trial Tr. at 164; Pl.'s Ex. 8.

IV. The Value of Norbrook's *In Situ* Method and Its Protective Measures

A. *Investment and Profit*

From the time Dr. Quinn joined Norbrook in 1986 until Norbrook received FDA approval in 1998, Norbrook expended [REDACTED]⁵ in the development and implementation of its *in situ* method, including labor, equipment and building fabrication costs. Dkt. No. 66, Trial Tr. at 31-38; Pl.'s Exs. 35, 36, 37, 38, 40, and 41. Norbrook sells PGP manufactured using the *in situ* method worldwide, but sales in the United States of PGP manufactured using the *in situ* method accounted for eighty-five percent of Norbrook's total sales in the United States, or approximately [REDACTED]. Moreover, Norbrook uses its sales of PGP manufactured using the *in situ* method as a "lever to introduce other products." Dkt. No. 66, Trial Tr. at 54.

B. *Protective Measures*

Norbrook has taken measures to ensure against the unauthorized disclosure of its confidential information, including information about the *in situ* method. Fencing and walls, attended twenty-four hours a day by security personnel, surround Norbrook's facilities in Newry, Northern Ireland while surveillance cameras maintain constant vigilance as well. Dkt. No. 67, Trial Tr. at 165. Norbrook limits access to documents to a select group of employees on a need-to-know basis and stores its documents in locked rooms. *Id.* at 165-66; Pl.'s Exs. 10 and 11. All Norbrook employees regardless of their "security clearance," must sign confidentiality agreements in addition to their employment contracts. The terms of these agreements prevent the unauthorized disclosure of any Norbrook information to any person or company both during employment and after termination of

⁵The court is using the following monetary conversion rate, current as of the writing of this Memorandum - Decision and order: £1.00 = \$1.6988.

employment with Norbrook. Id. at 167-68; Pl.'s Exs. 12 and 14. Moreover, Norbrook's employee handbook outlines its employees' duty not to disclose Norbrook information. Id. at 168-69; Pl.'s Ex. 17. In addition, when Norbrook terminates an employee or receives an employee's resignation, it reminds the employee of his duties under the employment and confidentiality agreements. Id. at 168; Pl.'s Ex. 16. Visitors to Norbrook's facilities must sign a log book and must be accompanied by a Norbrook employee throughout their visit. Visitors are prohibited from bringing any type of recording device or computer on the premises. Dkt. No. 67, Trial Tr. at 169-70; Pl.'s Ex. 18. Norbrook has also protected its confidential information when necessary through litigation: this is not the first time that Norbrook has had to litigate a case involving its trade secrets revealed by Dr. Quinn. Dkt. No. 66, Trial Tr. at 29-30.

V. Dr. Quinn Leaves Norbrook

Dr. Quinn voluntarily resigned from Norbrook in 1992, shortly after the FDA rejected Norbrook's first application to manufacture PGP injections for sales in the United States using the *in situ* method. Id. at 29. Upon his departure, Norbrook reminded Dr. Quinn of his contractual obligations not to disclose any of its trade secrets and confidential information. Pl.'s Ex. 13. Shortly after Dr. Quinn departed from Norbrook, it discovered that he had started a company with another former Norbrook employee, and that in their new venture, they had incorporated technology used in another Norbrook product called "Refoxinide." Norbrook brought suit against Dr. Quinn in Northern Ireland, and he consented to a permanent injunction against any further disclosure of Norbrook information. Notwithstanding the injunction, in 1997, Norbrook again haled Dr. Quinn into court—this time for contempt of the injunction: Dr. Quinn had revealed Norbrook's process for manufacture of another antibiotic, dihydrostreptomycin sulfate. Dkt. No. 66, Trial Tr. at 29. In

addition to the instant lawsuit, Norbrook is currently pursuing a defamation lawsuit against Dr. Quinn in Northern Ireland for his republication of a press release by United States Senator Charles Schumer, which referenced an FDA investigation into Norbrook's PGP injections and the alleged presence of glass and other foreign products in the product. During discovery in the defamation suit, Norbrook uncovered the relationship between Dr. Quinn and Hanford. *Id.* at 48-49; Pl.'s Exs. 42 and 217.

VI. Hanford Responds to Market Share Erosion

A. Hanford's Market Share Erodes

Once Norbrook obtained FDA approval in November 1998 to sell its PGP injections manufactured using the *in situ* method, it made significant inroads into the United States market for veterinary penicillins. Norbrook's lower-priced PGP injections caused considerable damage to Hanford's market share of the same. Hanford found that its customers, "almost without exception," had switched to Norbrook's product. Pl.'s Exs. 58 and 59. [REDACTED]

In order to counteract Norbrook's reentry into the market for PGP injections and the corresponding erosion of Hanford's share in the market, beginning in January 1999, Hanford pursued a three-pronged strategy whereby it: (1) devoted more human and financial resources to more profitable veterinary and powder products; (2) [REDACTED] and, (3) sought to develop a less expensive way to manufacture veterinary penicillins. Dkt. No. 67, Trial Tr. at 304-07. The first two prongs apparently proved very successful for Hanford, but the third prong of its strategy is more germane to the issues present here.

In letters dated March 29, 1999 to Senator Schumer and United States Representative James Walsh, Mr. Ward noted that Norbrook had “apparently developed a streamlined production process” yielding “significant cost advantages” and that Hanford’s own scientists had “sought in vain” to obtain documentation of Norbrook’s new process from the FDA. Pl.’s Exs. 58 and 59; *see also* Dkt. No. 67, Trial Tr. at 194-96. Hanford also inquired of Biochemie as to the possibility of developing a process to manufacture PGP injections in which the drying step was eliminated. Biochemie, however, rejected Hanford’s entreaty because it would require a huge investment and a regulatory change. Dkt. No. 67, Trial Tr. at 192-93; Pl.’s Ex. 145.

B. Hanford Enlists Dr. Quinn

In an effort to regain its competitive footing in the PGP injection market, Hanford enlisted the services of Dr. Quinn. Dr. Quinn apparently contacted Mr. Ward and offered his services. Dkt. No. 67, Trial Tr. at 209. Between May 26, 1999, and September 8, 2000, Hanford placed a minimum of some sixty-one telephone calls or faxes to Dr. Quinn, with many of the telephone calls lasting more than twenty-five minutes. Pl.’s Exs. 199 and 200; Dkt. No. 67, Trial Tr. at 204-10. Although the telephone records give no indication of who within Hanford placed the telephone calls to Dr. Quinn, the testimony suggests that Mr. Ward was the primary point of contact with Dr. Quinn.⁶ Dkt. No. 68, Trial Tr. at 361-62; Cross Dep. at 57.

1. Glass/Foreign Materials

On June 14, 1999, shortly after having contacted Dr. Quinn, Mr. Ward wrote the FDA complaining that tests performed by independent forensic laboratories at Hanford’s behest revealed

⁶The court is aware of Mr. Ward’s testimony to the contrary but finds it self-serving and suspect on this matter. Dkt. No 58, Trial Tr. at 204-10

glass contamination in Norbrook's PGP products. In this same writing, Mr. Ward noted with uncommon acumen that "rumors circulate that . . . [Norbrook's] process includes a glass bead milling step which directly introduces tiny glass beads into the pharmaceutical mixture, presumably to be extracted before final packaging." Pl.'s Ex. 63. While acknowledging that Dr. Quinn informed him of Norbrook's use of a glass bead mill in its *in situ* method, Mr. Ward could not recall when Dr. Quinn conveyed this information to him. Dkt. No. 67, Trial Tr. at 203.

2. Mislabeling

On September 21, 1999, Hanford's Director of Regulatory Affairs, Carl E. Fuller, wrote the FDA and indicated that Norbrook had mislabeled its United States market PGP products by allegedly failing to identify the excipient lecithin on product labels. Hanford alleged that "independent" laboratory tests—in fact, Biochemie conducted the tests—revealed the presence of lecithin, and that Norbrook failed to identify it as an ingredient on its United States market PGP product labels. Pl.'s Ex 65. Norbrook's non-United States market PGP contains lecithin, a fact with which Dr. Quinn was familiar from his experience at Norbrook. Pl.'s Exs. 198 and 1. Subsequent tests, however, conducted on Norbrook's United States market PGP injections did not detect lecithin. Dkt. No. 67, Trial Tr. at 213-17; Dkt. No. 68, Trial Tr. at 368; Pl.'s Exs. 150 and 147.

3. KCl

Hanford also considered petitioning the FDA and/or the USP to limit the amount of KCl permitted in PGP injections, which would thereby force Norbrook's PGP injections into non-compliance. Dkt. No. 67, Trial Tr. at 217-19. Hanford's objection to the presence of KCl was born neither of a concern for safety nor science but rather of a concern for finding a regulatory impediment to Norbrook's PGP injection. Dkt. No. 67, Trial Tr. at 231-34. Dr. Quinn, however,

advised against pursuing this strategy, because if Hanford were to develop/implement the *in situ* method, it would be prohibitively expensive to remove the KCl. Dkt. No. 67, Trial Tr. at 235-36; Dkt. No. 68, Trial Tr. at 364-65.

VII. Hanford Develops/Implements An *In Situ* Method

A. Dr. Quinn's First Meeting With Hanford

Dr. Quinn first visited Hanford's facilities from July 26 through July 28, 1999, to consult with Hanford on developing/implementing an *in situ* method of manufacture for PGP injections. Dkt. No. 67, Trial Tr. at 210, Pl.'s Ex. 53. During this initial visit, Dr. Quinn told Mr. Ward that Norbrook had sued him in the past. Mr. Ward did not inquire as to why and did not ask Dr. Quinn if he had a confidentiality agreement with Norbrook. Dkt. No. 67, Trial Tr. at 244. Hanford, however, required Dr. Quinn to sign a confidentiality agreement. Pl.'s Ex. 53. Hanford paid Dr. Quinn for his work during this visit and reimbursed his travel expenses. Dkt. No. 67, Trial Tr. 210-211, 245; Pl.'s Ex.137. Over the course of the following year, Dr. Quinn's input and work with Hanford on its development/implementation of an *in situ* method was instrumental. Dkt. No. 69, Trial Tr. at 478. Hanford's manufacturing director, Stephen M. Lemanczyk, first learned of the concept of an *in situ* method from Dr. Quinn during this initial visit.⁷ Dkt. No. 68, Trial Tr. at 316, 359-60. Before Dr. Quinn arrived at Hanford, no one there had ever seen any manufacturing instructions or any experimental work concerning the development or implementation of an *in situ* method for manufacturing PGP injections. Dkt. No. 69, Trial Tr. at 476; Dkt. No. 71, Trial Tr. at 678-80. Those at Hanford knew nothing of Dr. Quinn's background except that he had worked at

⁷Mr. Ward directed Mr. Lemanczyk to work exclusively on developing a less expensive way to manufacture penicillin. Mr. Lemanczyk reported directly to Mr. Ward. Dkt. No. 68, Trial Tr. at 316.

Norbrook developing its *in situ* method. Dkt. No. 67, Trial Tr. at 241-244; Dkt. No. 68, Trial Tr. at 360; Dkt. No. 69, Trial Tr. at 472; Dkt. No. 71, Trial Tr. at 684. Hanford's employees were uncomfortable in having Dr. Quinn, as their former competitor, consult on an *in situ* method. Dkt. No. 71, Trial Tr. at 680-81, 684; Cross Dep. at 67, 82-83, and 129. Between Dr. Quinn's first visit and his second in November 1999, Hanford and Dr. Quinn remained in contact: Hanford placed nineteen telephone calls to Dr. Quinn. Pl.'s Ex. 199.

B. Dr. Quinn's Second Meeting With Hanford

Dr. Quinn again visited Hanford from November 9-11, 1999 and consulted on Hanford's development/implementation of an *in situ* method. Pl.'s Ex. 223. Hanford compensated Dr. Quinn for his consultancy services and reimbursed him for his travel expenses. Dkt. No. 67, Trial Tr. at 237-39; Pl.'s Ex 87. The second visit was apparently more detailed in terms of the technical information revealed about the *in situ* method.

Dr. Quinn advised Mr. Lemanczyk on a number of issues concerning the *in situ* method based upon his experience while at Norbrook. As gleaned from Mr. Lemanczyk's notes, those issues included: (1) the difficulty and expense of removing KCl from the *in situ* method's final product; (2) the order of addition of ingredients; the fact that procaine hydrochloride can be heat sterilized; and, (3) the particle size distributions necessary for successful PGP production via the *in situ* method. Pl.'s Exs. 86 and 150; Dkt. No. 68, Trial Tr. at 358, 363-68; Dkt. No. 69, Trial Tr. at 472, Dkt. No. 70, Trial Tr. at 537-45. Mr. Lemanczyk testified that he viewed the information provided by Dr. Quinn during his consultancy as "[Hanford's] information" that "could not be shared." Dkt. No. 68, Trial Tr. at 364.

On November 15, 1999, Hanford's chief scientist, Ronald G. Lauback, wrote a memorandum

to Mr. Ward entitled "Norbrook Update," which indicated that Hanford's entreaties to the FDA regarding the presence of glass and lecithin in Norbrook's PGP injections had apparently fallen on deaf ears, for the FDA had taken no action, and Norbrook remained a competitor in the marketplace. Mr. Lauback's memorandum also addressed the KCl issue noting that Hanford's then forthcoming decision as to whether to pursue the *in situ* method would dictate whether to petition the USP to add a KCl limitation to its standards for penicillin products. Pl.'s Ex. 150.

Mr. Ward agreed with the points addressed in Mr. Lauback's memorandum and within days of receiving it decided to proceed with the development/implementation of the *in situ* method under Dr. Quinn's guidance. Dkt. No. 67, Trial Tr. at 223-24, 234-35, 248-50. On November 23, 1999, Dr. Quinn wrote to Hanford and offered to perform a 1,000-litre trial batch for Hanford at a company in Ireland called Univet, where he was a consultant. Dr. Quinn indicated that he would "spend a couple of days in the laboratory designing the suitable method for the batch manufacture . . . and compiling a Production Control Record." Id. at 250; Pl.'s Ex. 88. The next day, Hanford wrote Dr. Quinn seeking confirmation of "[t]he formulation that will be utilized for the 1,000-litre batch . . . , [t]he finished manufacturing document for the engineering process," [and] "the [m]ill-bead specifications," which were to match Norbrook's bead mill specifications. Pl.'s Ex. 91; Dkt. No. 67, Trial Tr. at 251-52. On December 1, 1999, Dr. Quinn confirmed, *inter alia*: (1) that the formulation would be the "current Hanford formula . . . except for the obvious change [*in situ* method rather than the conventional method] regarding [PGP]," and (2) the bead mill's specifications. Pl.'s Ex. 92. He also indicated his fees for "laboratory trials, batch manufacturing documentation, arranging milling trials, [and] supervision of [the] 1,000-litre batch manufacture." Id.

C. *Dr. Quinn's Small Batch/Gearing Up for the 1,000-Litre Batch*

On December 20, 1999, Dr. Quinn sent Hanford's vice president of marketing and new business development, Gregory T. Cross, the batch manufacturing record that he had followed in producing a small one-litre batch of PGP using the *in situ* method. Dr. Quinn reported that the batch was "UNBELIEVABLE" and that Hanford's formulation was "ideal for the *in situ* process." Pl.'s Ex. 94. Dr. Quinn concluded rhetorically, "Maybe I was lucky??? Maybe NOT!!!!" *Id.* Mr. Cross, however, believed that work rather than luck best explained Dr. Quinn's successful batch and that Dr. Quinn "knew what he was doing." Cross Dep. at 107-08.

That same day, Hanford resolved to ship additional excipients to Ireland sufficient for Dr. Quinn to produce a 1,000-litre batch. Pl.'s Ex. 95. On January 3, 2000, Hanford asked Dr. Quinn to provide particle size specifications for the 1,000-litre batch because Hanford did not have any particle size specifications for the PGP product it produced using the conventional method. Pl.'s Ex. 96; Dkt. No. 68, Trial Tr. at 372-74.

D. *1,000-Litre Batch*

In January 2000, Mr. Lemanczyk and Mr. Cross traveled, at Hanford's expense, to Ireland to meet with Dr. Quinn. They observed Dr. Quinn manufacture the 1,000-litre batch at the Univet facility, photographed the equipment and took notes on the *in situ* method of manufacturing PGP. Dkt. No. 67, Trial Tr. at 263-64; Dkt. No. 68, Trial Tr. at 372-79; Pl.'s Ex. 93, Cross Dep. at 114-16. Beyond Hanford's supplying a list of ingredients used in its conventional manufacturing process, Dr. Quinn was solely responsible for the outcomes of the one-litre and 1,000-litre batches. He prepared the manufacturing instructions and performed all of the necessary work, and Hanford paid him for

his services.⁸ Dkt. No. 68, Trial Tr. at 368-69, 372; Dkt. No. 67, Trial Tr. at 256; Pl.'s Exs. 140, 142 and 143. The success of the 1,000-litre batch was for one of Hanford's expert witnesses, Philip A. Twomey, concrete evidence that Hanford had a successful *in situ* method for manufacturing PGP injections. Dkt. No. 73, Trial Tr. at 1048.

Dr. Quinn also provided Hanford with particle size distribution analyses from the one-litre and 1,000-litre batches, which allowed Hanford to compare them against the particle sizes from Hanford's PGP injections manufactured using the conventional method as well as Norbrook's PGP injections manufactured using the *in situ* method. Pl.'s Exs. 97 and 100; Dkt. No. 68, Trial Tr. at 374, 379, and 388.

E. 1,000-Litre Batch Analysis and Board Approval

By the end of January 2000, based on Dr. Quinn's work, Hanford unveiled a "post pilot plan," which set forth a development/implementation schedule for the *in situ* method and set June 30, 2000, as the date targeted for finalization of the *in situ* method and equipment. Pl.'s Ex. 195. On February 4, 2000, Dr. Quinn provided Hanford with the PCR, including manufacturing instructions, for the 1,000-litre batch. [REDACTED]

[REDACTED]. In subsequent experiments with the *in situ* method, Mr. Lemanczyk tried to add the [REDACTED] as was done in Hanford's conventional process. Mr. Lemanczyk, however, was not satisfied with the results and thereafter added the [REDACTED] as was advised by Dr. Quinn. Dkt. No. 68, Trial Tr. at 382-86; Pl.'s Ex 102.

⁸Over the course of Dr. Quinn's entire consultancy, Hanford paid Dr. Quinn approximately \$22,000, including travel expenses. Dkt. No. 67, Trial Tr. At 211, 238-39, 246; Pl.'s Exs. 87, 137, 130, 142, 143.

During the first half of 2000, Dr. Quinn continued to consult with Hanford and evaluated milling options and other equipment for Hanford's *in situ* method. Pl.'s Ex. 114. Most notably, Dr. Quinn suggested that Hanford investigate microfluidizers as a milling option.⁹ [REDACTED]

[REDACTED]

[REDACTED]

After the meeting, Dr. Quinn returned to Syracuse to meet with Mr. Ward and visit the Hanford facility. Dkt. No. 67, Trial Tr. at 256-57; Dkt. No. 68, Trial Tr. at 278-83, 370-71, 387-88; Pl.'s Exs. 104 and 105. In addition, Dr. Quinn made inquiry to discover what kind of equipment Norbrook was using in the *in situ* method and conveyed his findings to Mr. Lemaczyk. Dkt. No. 68, Trial Tr. at 393-94; Pl.'s Ex 115.

From March through June 2000, Hanford performed alternative milling and stability tests on Dr. Quinn's 1,000-litre batch. Dkt. No. 71, 690-91; Dkt. No. 70, Trial Tr. at 547-50; Pl.'s Ex. 107. Dr. Quinn's batch passed all of Hanford's stability tests.¹⁰ On June 21, 2000, Hanford's Board of Directors approved implementation of the *in situ* method based exclusively on the 1,000-litre batch prepared by Dr. Quinn: between the time that Dr. Quinn prepared the 1,000-litre batch and the time that Hanford's Board of Directors approved implementation of the *in situ* penicillin process, no one

⁹A microfluidizer is a device that pumps liquids at very high pressure and velocity through tiny metal channels at high pressures. It functions to break the reacted and excipient-coated PGP particles, which results in a small uniform particle size distribution. Dkt. No. 72, Trial Tr. at 841-42; *see also* http://www.microfluidicscorp.com/mi_equip.htm. Although the microfluidizer executes its function differently than the bead mill used in Norbrook's *in situ* method, it essentially performs the same function. When Hanford began to experience problems with its microfluidizer, it looked into securing a Dynomill, the same type of bead mill used by Norbrook, as a substitute. Dkt. No. 68, Trial Tr. at 369-70; Pl.'s Ex. 184.

¹⁰Stability tests determine, *inter alia*, whether a suspension will degrade or congeal over time, whether it will resuspend, and whether its pH will remain constant. Dkt. No. 71, Trial Tr. at 690. Accelerated stability tests subject the suspension to more intense conditions so as to accelerate whatever degradation may occur. Dkt. No. 70, Trial Tr. at 548-49.

at Hanford had prepared a single batch. Dkt. No. 68, Trial Tr. at 288-93; Pl.'s Ex. 176. Soon thereafter, Hanford ordered equipment needed for implementing the *in situ* method and hired a contractor to prepare its facility to accommodate the new equipment. *Id.* at 393-94; Dkt. No. 71, Trial Tr. at 691; Pl.'s Exs. 113 and 176.

VIII. The Value of Dr. Quinn's Work For Hanford

Dr. Quinn's work on Hanford's development and implementation of an *in situ* method was invaluable. Hanford's argument that it developed the *in situ* method of manufacture independently of Dr. Quinn finds little support in the record.¹¹ In characterizing Dr. Quinn's work for Hanford, the court has purposefully used both "development" and "implementation" to underscore the following: because of Dr. Quinn's prior experience and knowledge, most poignantly the experience and know-how that he culled from his years of employment at Norbrook, Hanford was able to forgo much of the experimentation normally associated with the development of such a process. Dkt. No. 73, Trial Tr. at 1052-53. Norbrook's expert estimated that Dr. Quinn gave Hanford seventy-five percent of what it needed to manufacture its formulation successfully using an *in situ* method. Dkt. No. 69, Trial Tr. at 513-15. Moreover, one of Hanford's expert witnesses, determined that after Dr. Quinn had completed the 1,000-litre batch in January 2000, Hanford then possessed a successful design for the *in situ* method. Dkt. No. 73, Trial Tr. at 1048. Dr. Quinn's work allowed Hanford to convert its manufacturing process from one that utilized the conventional method to one that utilized the *in situ* method. Dkt. No. 69, Trial Tr. at 504-510.

The work Dr. Quinn performed in December 1999 was particularly important. Mr. Lauback

¹¹Hanford was unaware whether Dr. Quinn's trial and error knowledge "*assisted him while preparing Hanford's in situ process.*" Dkt. No. 51, Def.'s Mot. In Limine, at 5-6 (emphasis added).

testified that whether Hanford would have to alter its FDA-approved formula for PGP injections in adapting it to the *in situ* method would have affected whether Hanford even wished to pursue the *in situ* method. Dkt. No. 71, Trial Tr. at 699-700. Dr. Quinn was able to surmise, based upon his experience and knowledge gained while at Norbrook, that he could adapt Hanford's formula to an *in situ* method and thereby saved Hanford from having to conduct its own trial and error work. Similarly, Hanford benefitted greatly from Mr. Lemanczyk's observation of Dr. Quinn's recreation of the *in situ* method at Univet in Ireland. The method "was easy . . . after seeing how it was made at Univet." Dkt. No. 69, Trial Tr. at 440; *see also* Pl.'s Ex 98; Dkt. No. 68, Trial Tr. at 400-01 (Mr. Cross wrote and Mr. Lemanczyk testified that Dr. Quinn's 1,000-litre batch contributed "markedly to [Hanford's] development efforts.").

Dr. Quinn's manufacturing instructions served as the foundation for the process that Hanford ultimately submitted to the FDA. Mr. Lemanczyk testified, and his handwritten notes confirm, that he relied upon Dr. Quinn's work, in particular, the 1,000-litre Univet batch, in creating Hanford's first set of manufacturing instructions in October 2000. Dkt. No. 68, Trial Tr. at 397-400; Pl.'s Exs. 90 and 157. Hanford did not attempt to produce a batch of PGP, experimental or otherwise, using the *in situ* method until November 16, 2000, or nearly eleven months after Hanford received instructions for a successful *in situ* method of manufacture from Dr. Quinn. Dkt. No. 68, Trial Tr. at 396-97; Dkt. No. 71, Trial Tr. at 693-94; Def.'s Ex. 27. Thereafter, Hanford conducted fourteen trial batches, consisting of nine engineering batches and five full-scale batches, two of which were aborted, before finalizing the manufacturing instructions used in the application to the FDA for approval of its *in situ* method. Dkt. No. 71, Trial Tr. at 694-97; Def.'s Ex. 27. Hanford performed limited testing on these fourteen batches. Dkt. No. 72, Trial Tr. at 807-08; Def.'s Ex. 27. Mr.

Lemanczyk performed the “lion’s share” of the work on the fourteen batches, which he described as “basically tweaking what [Dr. Quinn] had done at Univet.” Dkt. No. 72, Trial Tr. at 809-10; Dkt. No. 69, Trial Tr. at 476-78; Dkt. No. 71, Trial Tr. at 694-95.

Even some of the “tweaking” can be traced directly to Dr. Quinn. Hanford’s document summarizing the fourteen batches noted that the “most significant change” between the conventional method and its *in situ* method [REDACTED]

[REDACTED]. This change mirrors the manufacturing instructions Dr. Quinn provided for the 1,000-litre batch months earlier. Id.; Pl.’s Ex 102.

Hanford’s claim that it hired Dr. Quinn for the simple reason that it did not have the facility to perform its own experiments is not supported by the evidence. According to Hanford, to perform a 1,000-litre trial batch, Hanford would have to shut down its entire facility. Dkt. No. 68, Trial Tr. at 324. Mr. Ward, however, admitted that the engineering runs did not have to be performed in a sterile environment. Id. at 355. Moreover, another Hanford witness, Mike Hange, testified that the experimental work that Hanford finally performed starting in November 2000 was not performed in the full manufacturing suite but rather was completed in stainless steel kettles and buckets. Dkt. No. 72, Trial Tr. at 860. Obviously, Hanford was in a position to try to develop an *in situ* method without Dr. Quinn but elected not to spend the time and effort or incur the risks associated with doing so. Dkt. No. 73, Trial Tr. at 1052-53.

Hanford applied to the FDA to amend its manufacturing process for PGP injections on January 24, 2002. Dkt. No. 68, Trial Tr. at 318; Def.’s Ex 23. The FDA approved Hanford’s application on May 2, 2003. Dkt. No. 72, Trial Tr. at 781. From the time that Hanford submitted

its application until it received approval, Hanford had produced only two batches using the *in situ* method as part of the FDA approval process. Dkt. No. 71, Trial Tr. at 701-02.

The court does not mean to suggest that Hanford failed to conduct *any* independent experimentation or work. For example, Dr. Quinn's manufacturing instructions for the 1,000-litre batch did not disclose any specifics with regard to the parameters at work: temperature, pH, mixing time, mixing rate, the order in which ingredients are added, and rate of addition. While Dr. Quinn's manufacturing instructions indicated the parameters at work in the method, as a result of its engineering batch experimentation, Hanford independently selected the parameters' values. Dkt. No. 70, Trial Tr. at 600-08, 611-28; Dkt. No. 71; Trial Tr. at 761-67. Through his experimentation, Mr. Lemanczyk also discovered that Dr. Quinn's 1,000-litre batch manufacturing instructions called for the addition of an excessive quantity of water to the batch. The excess water so diminished the batch's potency that it would not have been "released" to the market. Dkt. No. 69, Trial Tr. at 431; Dkt. No. 71; Trial Tr. at 742-45. Mr. Lemanczyk later determined the proper amount of water to use. Dkt. No. 69, Trial Tr. at 431. The court, however, finds on the record that Hanford's truly independent work occurred well after the issue was no longer in doubt and the second-string QB had entered the game for mop-up duty.

As discussed more fully below, the information Dr. Quinn provided Hanford about the *in situ* method for manufacturing PGP injections constituted trade secrets belonging to Norbrook: the information Dr. Quinn provided to Hanford was based on the work he completed for Norbrook in developing its *in situ* method. Dkt. No. 69, Trial Tr. 490-91, 514-15, 521; Dkt. No. 70, Trial Tr. 535-48, 550-51, 555; Pl.'s Exs. 86, 94 and 102. Significantly, Dr. Quinn worked with all of the excipients contained in Hanford's formulation while developing Norbrook's *in situ* method. Dkt.

No. 69, Trial Tr. 523, 528-529; Pl.'s Ex 1. It was thus easy for Dr. Quinn to provide Hanford with the information it needed concerning the essential parameters and equipment involved in the *in situ* method.

DISCUSSION

I. Outstanding Motions

Before proceeding further, the court will now rule on the hearing's two outstanding motions. First, the court DENIES Hanford's motion to preclude Norbrook from introducing a "new" legal theory because the court finds that Norbrook did not in fact introduce a new legal theory. Rather, the legal theory Norbrook presented was in accord with the theory presented at the outset and the arguments made prior to and until the preliminary injunction hearing.¹²

Second, the court GRANTS Norbrook's motion to strike the testimony of Mr. Ward concerning Hanford's sales projections for PGP injections manufactured using the *in situ* method and to compel production of documents concerning Hanford's marketing and advertising of products manufactured using the *in situ* method. See Dkt. No. 60, Pl.'s Mot. To Strike Test. and Compel

¹²Hanford sought to preclude Norbrook from introducing evidence that its trade secret was the "trial and error" process that Dr. Quinn engaged in while at Norbrook. Hanford, however, was on notice of the "trial and error" component of Norbrook's theory. In its complaint, Norbrook indicates that it invested "approximately [four] years and considerable expense" to develop its *in situ* method. Dkt. No. 1, Compl. at ¶ 17. In addition, the William Toner's declaration submitted in support of Norbrook's motion for a preliminary injunction and expedited discovery affirmed that

the Norbrook Process required years of experience in combining the primary ingredients . . . under controlled conditions . . . Norbrook became aware of the critical specifics (e.g., temperatures, type of mixing, length and rate of mixing, etc.) only after considerable research and development. The Norbrook Process is not simply the result of chemical and mathematical calculations, but exhaustive trial and error and examination of trial data that allowed Norbrook to become skilled in the art of such a process. Dkt. No. 4, Toner Decl. at ¶¶ 16 and 18.

Furthermore, in its letter to the court dated April 10, 2003, written in response to Hanford's motion to compel Norbrook to identify its trade secret with greater specificity, Norbrook stated that its "process was developed, refined and put into production by [Dr. Quinn] through years of work and literally hundreds of trial batches of product. Norbrook has produced . . . laboratory records from 1985 to 1992—a six-year period, which recounts the painstaking trial and error work that went into the Norbrook process."

Produc. of Docs.

A. Motion to Strike Mr. Ward's Testimony

Rule 37(c)(1) of the Federal Rules of Civil Procedure provides in pertinent part: “[a] party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.”¹³ “Rule 37(c)(1)’s preclusionary sanction is ‘automatic’ absent a determination of either ‘substantial harm’ or ‘harmlessness.’”¹⁴ American Stock Exch., LLC v. Mopex, Inc., 215 F.R.D. 87, 93 (S.D.N.Y. 2002) (citing Salgado v. Gen. Motors Corp., 150 F.3d 735, 742 (7th Cir. 1998). “Substantial justification means ‘justification’ to a degree that could satisfy a reasonable person that parties could differ as to whether the party was required to comply with the disclosure request.” Henrietta D. v. Giuliani, 2001 WL 1602114, at *5 (E.D.N.Y. Dec. 11, 2001) (quoting Nguyen v. IBP, Inc., 162 F.R.D. 675, 680 (D.Kan. 1995)). “The test of substantial justification is satisfied ‘if there exists a genuine dispute concerning compliance.’” Henrietta D. 2001 WL 1602114, at * 5 (quoting Nguyen, 162 F.R.D. at 680). “Failure to comply with the mandate of [Rule 37] is harmless when there is no prejudice to the party entitled to the disclosure.” Id. at *6 (quoting Nguyen, 162 F.R.D. at 680). The burden to prove substantial justification or harmlessness

¹³Rule 26(e)(2) of the Federal Rules of Civil Procedure provides that “a party is under a duty seasonably to amend a prior response to an interrogatory, request for production, or request for admission if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.”

¹⁴Notwithstanding Rule 37(c)(1)’s self-executing nature, “courts in this circuit have recognized that the imposition of sanctions is under Rule 37(c)(1) is a matter for within the trial court’s discretion.” Ward v. The Nat’l Geographic Soc’y, 2002 WL 27777, at *2 (S.D.N.Y. Jan. 11, 2002) (internal quotation and citation omitted).

rests with the party who failed to comply with Rule 26. See Mopex, Inc., 215 F.R.D. at 93 (citing Wright v. Aargo Sec. Servs., Inc., 2001 WL 1035139, at *2 (S.D.N.Y. Sept. 7, 2001)).

During discovery, Norbrook requested “[a]ll documents concerning any market studies, projected sales volume, product development, competitive advantage and profitability forecasts concerning . . . Hanford’s Amended Process [the *in situ* method] or Hanford’s PGP injections.” Dkt. No. 60, Pl.’s Mot. To Strike Test. and Compel Produc. of Docs. at Ex. A, Norbrook’s Doc. Request No. 29; Dkt. No. 71, Trial Tr. at 668. Hanford did not produce any such materials, instead responding that “no documents [pertaining] to this request are known to be in Hanford’s possession, custody or control.” Id. at Ex. B, Hanford’s Resps. Norbrook’s counsel was surprised by Hanford’s response and sent Hanford’s counsel a letter to this effect. Id. at Ex. C, Pl.’s Letter to Def., dated April 8, 2003. [REDACTED]

[REDACTED]. Norbrook’s counsel asked Mr. Ward when Hanford prepared the documents that served as the basis for this figure, and he testified that Hanford prepared sales estimates concerning PGP injections manufactured using the *in situ* method in April or May of 2003. Dkt. No. 68, Trial Tr. at 349-50. Norbrook’s counsel immediately moved to strike the testimony. Id. at 350. In opposing Norbrook’s motion, Hanford’s counsel argued that the sales estimate document was attorney work product, that the attorney–client privilege governed it, and that Mr. Ward made a simple calculation to arrive at the [REDACTED] figure. Hanford’s counsel, however, conceded that he believed Hanford prepared the sales estimate document during the last week of April or early May 2003. Dkt. No. 71, Trial Tr. at 669-71

Here, the court cannot say that Hanford’s failure to disclose the sales estimates document was

either substantially justified or harmless. The failure to disclose was not substantially justified: Norbrook plainly requested sales projections, which, as was revealed at the hearing, Hanford had in fact possessed but failed to produce. The failure to disclose was not harmless: Norbrook was unable to effectively cross-examine Mr. Ward on the relevant testimony. Accordingly, the court strikes from the record Mr. Ward's testimony concerning projected sales.

B. Motion to Compel Production of Documents

During discovery, Norbrook requested that Hanford produce "all documents concerning the sale or marketing of any products manufactured, or intended to be manufactured, using Hanford's Amended Process." Dkt. No. 60, Pl.'s Mot. To Strike Test. and Compel Produc. of Docs. at Ex. A, Norbrook's Doc. Request No. 21. Hanford objected to the request as being "vague, ambiguous, overly broad, [and] unduly burdensome," but nevertheless replied that it had no documents responsive to Norbrook's request. Dkt. No. 60, Pl.'s Mot to Strike Test. and Compel Produc. of Docs. at Ex. B, Hanford's Resps. Mr. Ward testified that Hanford planned "an extensive launch campaign" whereby Hanford would show thirty sales representatives how to market and sell its product, and that the campaign's materials were "ready to go." Dkt. No. 68, Trial Tr. at 334. Hanford introduced an advertisement of its product manufactured using the *in situ* method. *Id.* at 335. At the hearing in response to Norbrook's motion to compel, Hanford's counsel argued that the production of advertising and marketing materials was irrelevant and "not probative of the facts the court is trying to determine." Dkt. No. 71, Trial Tr. at 669, 673. If this were truly the case, however, the court suspects that Hanford would not have bothered to introduce the advertisement. Although the court expresses no opinion on the materials' continued relevance, it orders Hanford to produce *all* documents that are responsive to Norbrook's document request number twenty-one.

II. Conclusions of Law

A. *Preliminary Injunction Standard*

To obtain a preliminary injunction, respondent must demonstrate: (a) that it will suffer irreparable harm in the absence of the requested relief; and, (b) either (1) that it is likely to succeed on the merits or (2) there are sufficiently serious questions going to the merits and the balance of hardships tips decidedly in the movant's favor. See Federal Express Corp. v. Federal Espresso, Inc., 201 F.3d 168, 173 (2d Cir. 2000); Latino Officers Ass'n. v. Safir, 170 F.3d 167, 171 (2d Cir. 1999) (citations and internal quotation marks omitted); Landscape Forms, Inc. v. Columbia Cascade Co., 113 F.3d 373, 376 (2d Cir.1997). Issuing a preliminary injunction is regarded as a drastic measure. See Borey v. National Union Fire Ins. Co., 934 F.2d 30, 33 (2d Cir.1991). Moreover, the "loss of trade secrets cannot be measured in money damages" because "[a] trade secret once lost is, of course, lost forever." N. Atlantic Instruments, 188 F.3d at 49 (quoting FMC Corp. v. Taiwan Tainan Giant Indus. Co., 730 F.2d 61, 63 (2d Cir. 1984)). Norbrook has demonstrated that it is entitled to a preliminary injunction.

B. *Likelihood of Success on the Merits*

Under New York law, to succeed on a claim for the misappropriation of trade secrets, a plaintiff must demonstrate: (1) that it possessed a trade secret, and (2) that the defendant used that trade secret in breach of an agreement, confidential relationship or duty, or as a result of discovery by improper means. N. Atl. Instruments, Inc. v. Haber, 188 F.3d 38, 43-44 (2d Cir. 1999) (citing Hudson Hotels Corp. v. Choice Hotels Int'l, 995 F.2d 1173, 1176 (2d Cir. 1993) (*abrogated on other grounds*)). Norbrook has established a claim under New York State law for misappropriation of trade secrets because Norbrook has shown that (1) it owns a trade secret, and (2) Hanford has used

the trade secret in breach of an agreement, confidential relationship or duty, or as a result of discovery by improper means. N. Atlantic Instruments, 188 F.3d at 49 (applying New York law); Integrated Cash Mgmt. Servs., Inc. v. Digital Transactions, Inc., 920 F.2d 171, 173 (2d Cir. 1990) (applying New York law).

1. Trade Secret Defined

New York courts generally look to Section 757 of the first Restatement of Torts for its definition of a trade secret. “[A] trade secret is ‘any formula, pattern, device or compilation of information which is used in one’s business, and which gives [the owner] an opportunity to obtain an advantage over competitors who do not know or use it.’” Softel, Inc. v. Dragon Med. & Scientific Communications, Inc., 118 F.3d 955, 968 (2d Cir. 1997) (quoting RESTATEMENT OF TORTS § 757 cmt. b (1939)). A trade secret “is not simply information as to single or ephemeral events in the conduct of the business”; rather, it “is a *process* or device for continuous use in the operation of the business.” Softel, Inc., 118 F.3d at 968 (quoting Ashland Mgmt. Inc. v. Janien, 82 N.Y.2d 395, 407, 624 N.E.2d 1007, 1013, 604 N.Y.S.2d 912, 918 (1993)) (emphasis added). Under New York law, “a trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage.” Integrated Cash Mgmt. Serv., Inc., 920 F.2d at 174.

Similarly, as the Seventh Circuit has explained, “in order to be considered a trade secret, a . . . process need not reach the level of invention necessary to warrant patent protection. A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret.” Minnesota Mining & Mfg. Co. v.

Pribyl, 259 F.3d 587, 595-96 (7th Cir. 2001). As such, 3M did not need to identify specific items within its 500 pages of materials to claim a trade secret. Id. at 595; *cf.* Harbor Software, Inc. v. Applied Systems, Inc., 887 F.Supp 86, 90 (S.D.N.Y. 1995) (explaining that the overall design of a software program may be protectable as a trade secret, even if the individual components of that program are common knowledge in the programming industry); Monovis, Inc. v. Aquino, 905 F. Supp. 1205, 1231 (W.D.N.Y. 1994) (stating that “[e]ven had the defendants succeeded in proving that all of the individual elements of information relating to [the process] were ‘out there’ in the public domain, they would still have had to explain why the synergistic combination of such elements into a unified whole, capable of producing working and commercially feasible single-screw compressors, should not be afforded trade secret protection”); Uncle B’s Bakery, Inc. v. O’Rourke, 920 F. Supp. 1405, 1428 (N.D. Iowa 1996) (rejecting defendant’s argument that “almost all the individual segments of Uncle B’s Bakery’s production system were generally known to the baking industry” and finding that, “on the basis of the preliminary injunction record, the entirety of Uncle B’s Bakery’s manufacturing process, from ingredients through bagging, is sufficiently unique to constitute a trade secret”); Integrated Cash Mgmt. Serv., Inc. v. Digital Transactions, Inc., 732 F.Supp. 370, 376 (S.D.N.Y. 1989) (explaining that while general concepts are not afforded trade secret protection, the specific implementation involving a particular combination of general concepts may well amount to a trade secret).

2. Norbrook’s *In Situ* Method Constitutes A Trade Secret

Section 757, Comment b of the first Restatement of Torts sets forth the following non-exclusive factors as relevant to a determination of whether information constitutes a trade secret:

- (1) the extent to which the information is known outside of [the] business, (2) the extent to which it is known by employees and others involved in [the] business; (3)

the extent of measures taken by [the business] to guard the secrecy of the information; (4) the value of the information to [the business] and [its] competitors; (5) the amount of effort or money expended by [the business] in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

See also Hudson Hotels, 995 F.2d at 1176 n.1.

a. Norbrook's *In Situ* Method Is Unknown Outside of Norbrook

The *in situ* process at issue in this case is unknown outside of Norbrook. The trade secret claimed in Norbrook's *in situ* method is the reaction of penicillin G potassium and procaine hydrochloride in the presence of the excipients necessary to make an injectable suspension of PGP in final dosage form. Subsidiary trade secrets include the determination of which commonly-used excipients can be grouped and sterilized in which pre-reaction solutions, and the acceptable size of the resulting PGP particles prior to milling.

Hanford contends that the science behind Norbrook's *in situ* method is not novel, and that between an examination of certain patents, the USP monograph and Norbrook's product label, its secrets are revealed. Hanford, however, misapprehends the level of scientific novelty required for trade secret protection. Furthermore, the publicly available data does not reveal Norbrook's *in situ* method or detract from Norbrook's claim of secrecy.

To secure trade secret protection for its *in situ* method, Norbrook need not demonstrate scientific novelty:

Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require

also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it.

RESTATEMENT OF TORTS § 757 cmt. b (1939). Thus, as stated above, "a trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage." Integrated Cash Mgmt. Serv., Inc., 920 F.2d at 174.

One of Hanford's expert witnesses, Dr. Paul Niebergall, testified that Dr. Quinn's consultancy with Hanford was irrelevant because Hanford would have eventually developed the *in situ* method on its own. Dkt. No. 73, Trial Tr. at 980. Dr. Niebergall's analysis focused not on whether Dr. Quinn had contributed to Hanford's development of the *in situ* method, but rather on whether there was anything secret about Norbrook's *in situ* method. Id. at 946, 958, 965, 967, 969, and 970-74. Under this approach, Dr. Niebergall ignored three of the four *in situ* products that Dr. Quinn developed for Norbrook, the scope and substance of information that Dr. Quinn provided to Hanford, and the extent of Hanford's experimental work in developing the *in situ* method. Dkt. No. 73, Trial Tr. at 944-49, 982-83, and 970-76. Thus, Dr. Niebergall's testimony was not particularly helpful to the court in this regard.

The trial and error work in which Norbrook engaged to develop its *in situ* method is both evidence that the method is a trade secret, and that it is entitled to trade secret protection. See Integrated Cash Mgmt. Servs., Inc., 732 F.Supp at 375-77 (finding that a trade secret existed where a company had expended substantial time and money in trial and error experimentation with different formulations of its computer program, and enjoining its two former employees from using the

information they learned through their familiarity with the trial and error process); InFlight Newspapers, Inc. v. Magazines In-Flight, LLC, 990 F.Supp. 119, 132 (E.D.N.Y. 1997) (finding that the trade secret at issue was “not the finished product” but rather the process, derived from years of trial and error research, by which the finished product resulted). More to the point, in explaining why plaintiff’s technology was afforded trade secret protection, the court in Monovis v. Aquino, noted that plaintiff’s

Know-How¹⁵ serve[d] as a guide, charting the way through the many problems and decisions faced in designing . . . and developing [the particular technology]. At each step along the way, [plaintiff] identify[ed] the problems and possible solutions and endeavor[ed] to explain the best way to proceed. To date, [plaintiff] and his licensees are alone in having successfully maneuvered the entire course and achieved commercially-viable single-screw compressors. Such knowledge is clearly valuable and should be protected from wrongful misappropriation by those exposed to it under a duty of confidence.

905 F.Supp. at 1231. Similarly, in Imperial Chemical Industries Limited v. National Distillers and Chemical Corp., 342 F.2d 737, 743 (2d Cir. 1965), the Second Circuit, in reversing the trial court’s denial of plaintiff’s motion for a preliminary injunction, emphasized the trial court’s finding that

although the components of the [manufacturing process] are available in [literature available to the public], development of the know-how . . . to operate a commercial process using such a [component] based upon information in the public domain would have required vast research, at great expense in money and time, plus considerable trial and error over an extended period of time. In making its agreements with [plaintiff], it was obviously [defendant’s] purpose to avoid the difficulties and the time and expense that would be required to arrive at a commercially feasible process from a synthesis of the information disclosed in the literature.¹⁶

¹⁵“Know-How” was a book that plaintiff licensed that included an extensive compilation of plaintiff’s collected knowledge in the relevant industry.

¹⁶The trial court had denied plaintiff’s motion for a preliminary injunction because of agreements made between the parties. “Were this an ordinary trade secrets case . . . injunction would issue . . . This, however, is not such a case because the rights and obligations of the parties which might otherwise obtain have been altered and defined by the agreements which they made.” Imperial Chem. Indus. Ltd. v. Nat’l

The Second Circuit then noted that “[i]t is no defense in an action of this kind that the process in question *could have* been developed independently, without resort to information gleaned from the confidential relationship . . . ‘Even if resort to the patterns of the plaintiff was more of a convenience than a necessity, still, if there was a secret, it belonged to him, and the defendant had no right to obtain it by unfair means, or to use it after it was thus obtained.’” Imperial Chem. Indus. Ltd. v. Nat’l Distillers and Chem. Corp., 342 F.2d at 743 (emphasis added) (quoting Tabor v. Hoffman, 188 N.Y. 30, 35, 23 N.E. 12 (1889)).

Neither of the two patents introduced at the hearing nor the information available to the general public disclose Norbrook’s *in situ* method. At the hearing, Hanford introduced Patent 2,525,898 (“‘898 patent”) and Patent 2,725,336 (“‘336 patent”) as evidence that Norbrook’s *in situ* method was already in the public domain. Dkt. No. 72, Trial Tr. at 889-95; Def.’s Exs. 37 and 38. These patents relate to the precipitation of PGP but do not contemplate the excipients necessary to form a PGP injection. Dkt. No. 69, Trial Tr. at 503; Dkt. No. 73, Trial Tr. at 937. The stated objective of these patents is to produce PGP as a bulk material in dry powder form. Dkt. No. 69, Trial Tr. at 501-02; Dkt. No. 73, Trial Tr. at 932, 937. Taken together, the ‘898 and ‘336 patents do not reveal how to manufacture a final dosage form of PGP injection using an *in situ* method. Dkt. No. 69, Trial Tr. at 502-03. See Uncle B’s Bakery, 920 F.Supp. at 1428 (defining plaintiff’s bagel bagging process as a trade secret and concluding that “although it may be readily ascertainable that Uncle B’s Bakery’s bagels are packaged in an ‘air tight’ bag, it is not readily ascertainable what equipment or process is involved in so bagging the bagels, nor is it readily ascertainable what part the formulation and preparation of the bagels themselves may have in their freshness without

Distillers and Chem. Corp., 342 F.2d at 740 (quoting the trial court’s conclusions of law).

freezing and long shelf-life”). With regard to the ‘336 patent, Dr. Niebergall testified that he would have ignored many of its instructions if he were formulating an *in situ* method of manufacture for an injectable suspension of PGP. Dkt. No. 73, Trial Tr. at 938-42. Dr. Niebergall asserted that the patents would have set him on the right track to achieving, with relative ease, an *in situ* method of manufacture for an injectable PGP suspension but conceded that achieving a finished product would require further trial and error experimentation. *Id.* at 943 (“[S]o when we formulate this thing, . . . let’s add it a little slower and see what happens.”). For the court this is of small consequence because Hanford failed to demonstrate any reliance on the patents. The patents are merely a *post hoc* explanation for how Hanford might have developed an *in situ* method, but Hanford presented no evidence at the hearing to suggest that its own chemists ever reviewed the patents. *Id.* at 931-32; Dkt. No. 69, Trial Tr. at 504. *See Franke v. Wiltschek*, 209 F.2d 493, 495 (2d Cir. 1953) (“It matters not that defendants could have gained their knowledge from a study of the expired patent and plaintiffs’ publicly marketed product. The fact is that they did not . . . they gained it from plaintiffs via their confidential relationship.”).

Hanford argued that the USP monograph and Norbrook’s United States product label alerted it that “something had changed” with respect to Norbrook’s method of manufacture. Dkt. No. 70, Trial Tr. at 565-66; Dkt. No. 72, Trial Tr. at 882, 885. Hanford also asserts the *in situ* method is revealed by simply testing Norbrook’s PGP injections for KCl. Dkt. No 70, Trial Tr. at 566-67; Dkt. No. 72, Trial Tr. at 885-86. Biochemie performed such a test as requested by Hanford and confirmed the presence of KCl. Dkt. No. 71, Trial Tr. at 716-18. Although the monograph, product label and KCl testing effectively disclosed that Norbrook was using an *in situ* method of manufacture to produce its PGP injections, they did not disclose how Norbrook accomplished this feat. The

documentation and testing simply indicated that Norbrook had eliminated the drying step in its manufacture of PGP and therefore must have been using an *in situ* method. Dkt. No. 73, Trial Tr. at 926-28, 1040-42.

b. Norbrook's *In Situ* Method Is Not Easily Acquired or Duplicated

Hanford's efforts prior to its employ of Dr. Quinn demonstrate that Norbrook's *in situ* method is neither easily acquired nor duplicated. As discussed above, Hanford's attempts to learn about Norbrook's new method of manufactures were unsuccessful: citing the huge investment and the anticipated regulatory change, Biochemie declined to pursue an *in situ* method that removed the dry powder step on Hanford's behalf; in his letter to Senator Schumer, Mr. Ward noted that Hanford had sought "in vain" to learn the details of Norbrook's "streamlined" process; and, the FDA apparently refused to provide Hanford with information about Norbrook's *in situ* method under FOIA. Pl.'s Exs. 58 and 59.

In order to create an *in situ* method of manufacture for PGP injections from scratch, one would need to conduct significant experimentation. Dkt. No. 69, Trial Tr. at 504-10; Dkt. No. 73, Trial Tr. at 959-62. Mr. Lauback, testified that Hanford did not have a formulations chemist on staff and that he had no relevant experience with a manufacturing process similar to Norbrook's *in situ* method. Dkt. No. 71, Trial Tr. at 678, 697; Dkt. No. 72, Trial Tr. at 813-14. Mr. Lemanczyk, also testified that he had no background in chemistry and relied on Dr. Quinn to show him how to produce PGP injections via the *in situ* method. Dkt. No. 68, Trial Tr. at 358, 401. The court also credits the expert testimony that, normally, a pharmaceutical manufacturer will conduct lab-scale experimentation before developing a new product or manufacturing process on a commercial scale. Dkt. No. 73, Trial Tr. at 1052. The absence of such work by Hanford prior to its authorization of

the expenditure of hundreds of thousands of dollars on the *in situ* method is highly relevant to the issue of misappropriation of a trade secret, which is discussed below.¹⁷

Without Dr. Quinn, Hanford would not have developed an *in situ* method as readily as it did.¹⁸ As a result of his work for Norbrook, Dr. Quinn developed a significant body of knowledge concerning the *in situ* method for manufacturing PGP injections, including how various excipients interact, and how the parameters may change depending upon the specific excipients used in a particular product's formulation. During his consultancy with Hanford, Dr. Quinn applied this body of knowledge for Hanford's benefit. Dkt. No. 67, Trial Tr. at 139-40, 142-43; Dkt. No. 69, Trial Tr. at 521-23, 526-29; Dkt. No. 73, Trial Tr. at 979-80.

c. Norbrook's *In Situ* Method of Manufacture for PGP Injections Meets the Four Remaining Trade Secret Factors

The four remaining factors the Restatement directed the court to consider, (1) the extent to which the information is known by employees and others involved in [the] business; (2) the extent of measures taken by [the business] to guard the secrecy of the information; (3) the value of the information to [the business] and [its] competitors; and, (4) the amount of effort or money expended by [the business] in developing the information, tip in favor of according Norbrook's *in situ* method of manufacturing PGP injections trade secret protection. The court concludes that Norbrook limited

¹⁷Conversely, the fact that Norbrook conducted a considerable amount of lab scale and development work demonstrates that its *in situ* method is a trade secret within the meaning of New York law. Dkt. No. 69, Trial Tr. at 510.

¹⁸The court does not mean to imply that Hanford's achievement of an *in situ* method of manufacture for PGP injections would have been a foregone conclusion, albeit one requiring a greater investment of time and money, had Hanford not consulted with Dr. Quinn. Nor can the court conclude that Hanford would never have developed the *in situ* method had it not consulted with Dr. Quinn. Therein lies the problem: because Hanford consulted with Dr. Quinn to the extent that it did, it is all but impossible to determine what Hanford might have accomplished on its own. The record, however, demonstrates that Dr. Quinn's consultancy with Hanford allowed it to develop the *in situ* method.

access to its *in situ* method to only those employees with a “need to know” and required its employees to sign confidentiality agreements.¹⁹ Dkt. No. 67, Trial Tr. at 165-71; Pl.’s Exs. 10, 11, 12, and 14. Moreover, Norbrook’s security personnel maintained constant surveillance over its facilities. Dkt. No. 67, Trial Tr. at 165. The protective measures Norbrook employed to guard the secrecy of its *in situ* method support according it trade secret protection. *See, e.g. Integrated Cash Mgmt.*, 920 F.2d at 174 (finding plaintiff took effective protective measures by keeping its doors locked and requiring employees to sign non-disclosure agreements).

The monetary value of Norbrook’s *in situ* method to Norbrook and its competitors need not detain the court long. It is the significant cost savings afforded by the *in situ* method over the conventional method that gave Norbrook a leg-up on the competition and thereby forced Hanford to reconsider its method of manufacture. Norbrook’s sales of PGP manufactured using the *in situ* method accounted for ██████████ of Norbrook’s total sales in the United States, or ██████████. Norbrook invested more than ██████████ and years of labor into the development of its *in situ* method. In conclusion, Norbrook’s *in situ* method satisfies all the elements of a trade secret under New York law.

3. Hanford Misappropriated Norbrook’s *In Situ* Method of Manufacture for PGP Injections²⁰

¹⁹ Although not specified as a factor by the Restatement, the extent to which Norbrook’s *in situ* method was known by others in the veterinary pharmaceutical industry was limited to general theories as opposed to the application, confirmation or refinement of those theories to a practicable and detailed method of manufacture.

²⁰ Although neither party raised the issue, Norbrook’s claim against Hanford for misappropriation of its trade secret is timely. New York trade secret misappropriation claims are governed by a three-year statute of limitations for suits based on injury to property. N.Y. C.P.L.R. § 214(4) (McKinney 2003). “Accrual of a claim for trade secret misappropriation occurs as follows: If a defendant misappropriates and discloses a trade secret, he becomes liable to plaintiff upon disclosure. On the other hand, if the defendant [misappropriates and] keeps the secret confidential yet makes use of it to his own commercial advantage, each successive use

Norbrook is also likely to prevail on its misappropriation of trade secrets claim. Use of a trade secret is unlawful if “the defendant used that trade secret in breach of an agreement, confidential relationship or duty, or as a result of discovery by improper means.” N. Atlantic Instruments, 188 F.3d at 49. Here, Hanford improperly obtained Norbrook’s trade secret from Dr. Quinn in breach of his specific contractual obligations with, and fiduciary duties to, Norbrook, and despite a court order entered in Northern Ireland, which bars Dr. Quinn from disclosing any of Norbrook’s confidential information. N. Atlantic Instruments, 188 F.3d at 47-48 (applying New York law and finding that a former employee cannot disclose confidential information obtained from his former employer even after termination of that employment).

Hanford advances two primary defenses, neither of which the court finds persuasive. First, Hanford claims that Dr. Quinn was free to apply “the skills and knowledge acquired by the overall experience of his previous employment . . . [including] those techniques which are but ‘skillful variations of general processes known to the particular trade.’” Dkt. No. 76, Def.’s Proposed Findings of Fact and Conclusions of Law at 68 (quoting PSC, Inc. v. Reiss, 111 F.Supp.2d 252, 257 (W.D.N.Y. 2000) (citation and internal quotations omitted)). Second, Hanford contends that it independently developed the *in situ* method, as allegedly evidenced by the facts that (1) the excipients in the Hanford formulation for PGP injections are different from those used in Norbrook’s United States formulation; (2) many of the specific manufacturing parameters—temperature, pH, mixing time, mixing rate, the order in which ingredients are added, and rate of addition are different

constitutes a new actionable tort for purposes of the Statute of Limitations.” Architectronics, Inc. v. Control Systems, Inc., 935 F.Supp. 425, 433 (S.D.N.Y. 1996) (citing Lemelson v. Carolina Enterprises, Inc., 541 F.Supp. 645, 659 (S.D.N.Y. 1982)). Here, Hanford continued to use Norbrook’s trade secrets until the court’s previous order granting Norbrook’s motion for a preliminary injunction, having applied to the FDA to amend its commercial manufacturing process for PGP injections on January 24, 2002.

from those contained in Norbrook's PCR's; and, (3) Hanford conducted its own, i.e. without Dr. Quinn's tutelage, engineering and validation batch experiments and continues to further define the parameters to this day. *Id.* at 67-68. The court will address these two arguments *seriatim*.

The information and services Hanford wanted and that Dr. Quinn provided were not mere skillful variations of general processes known throughout the veterinary pharmaceutical industry. Instead, Hanford sought, and Dr. Quinn provided, the same kind of *in situ* method for manufacturing PGP injections used by Norbrook, or in other words, Norbrook's proprietary information. In hiring Dr. Quinn, Hanford was interested only in the fact that he had worked on Norbrook's *in situ* method.²¹ The fact that Hanford required Dr. Quinn to sign a confidentiality agreement and Mr. Lemanczyk's testimony that he viewed the information provided by Dr. Quinn during his consultancy as Hanford's information that could not be shared outside of Hanford suggest that Dr. Quinn was not providing general knowledge. Hanford initially emphasized to Dr. Quinn that it wanted him to simply improve the efficiency of its existing conventional method and did not seek any of Norbrook's proprietary information. Dkt. No. 67, Trial Tr. at 238-40. This initial directive and admonishment, however, might as well have been said with an accompanying and telling wink, for they are wholly inconsistent with what Dr. Quinn's consultancy entailed thereafter. Dr. Quinn did not merely fine-tune Hanford's conventional method in order to improve its efficiency; rather, he took Hanford's existing formulation, determined that it was suitable for an *in situ* method of manufacture and then showed Hanford how to accomplish this feat. As Mr. Ward testified, what Dr. Quinn "talked to Steve Lemanczyk about, I can't tell you," *Id.* at 240, but Mr. Lemanczyk testified

²¹Bearing this in mind, some of Hanford's employees testified that they were not comfortable with Dr. Quinn's involvement on the project. Dkt. No. 71, Trial Tr. at 680-81; Cross Dep. at 67, 82-82, and 129. Similarly, the court finds it somewhat curious that Mr. Ward inquired no further after Dr. Quinn revealed that he had been involved in prior litigation with Norbrook. Dkt. No. 67, Trial Tr. at 244.

that Dr. Quinn was the key to Hanford's efforts in developing the *in situ* method. Dkt. No. 68, Trial Tr. at 401.

Hanford has the burden of proving its defense that it independently developed the *in situ* method. See Integrated Cash Mgmt., 732 F.Supp. at 377-78 ("It is a well-recognized principal that, where a defendant in a trade secret case claims independent development, the burden shifts to the defendant to show that this was in fact the case.") (citing Rapco Foam, Inc. v. Scientific Applications, Inc., 479 F.Supp. 1027, 1030-31 (S.D.N.Y. 1979)). Hanford has not sustained this burden.

Hanford's evidence that its formula for PGP injections contains excipients not found in Norbrook's United States formulation is hardly probative of independent development because (1) the formulations are dictated by the companies' respective NADAs and (2) in any event, through his experience at Norbrook, specifically his work on Norbrook's non-United States formulations of PGP injections, Dr. Quinn was readily familiar with Hanford's own excipients. Dkt. No. 69, Trial Tr. at 523, 526-28; Dkt. No. 70, Trial Tr. at 538.

In comparing Norbrook's and Hanford's *in situ* methods, Hanford points to the fact that many of the specific manufacturing parameters, temperature, mixing time, mixing rate, flow rate, the order in which ingredients are added, rate of addition, and milling device, are different. Dkt. No. 67, Trial Tr. at 150. This argument has been rejected before. In Computer Associates International v. Bryan, the court found trade secret misappropriation where plaintiff's former employee developed for a competitor a "prototype" computer program based upon plaintiff's original technology that the competitor subsequently modified. 784 F.Supp. 982, 1008-1009 (E.D.N.Y. 1992). Here, different equipment and batch sizes require adjustment of the *in situ* method because all of the parameters

interrelate, but the overall process remains the same.

Dr. Quinn's work for Hanford was the prototype for its final manufacturing instructions. When Hanford's Board of Directors approved the expenditures for Hanford's *in situ* method in June of 2000, Hanford relied solely on the Dr. Quinn's work, in particular, his 1,000-litre batch and corresponding manufacturing instructions. Mr. Lemanczyk testified, and his handwritten notes confirm, that when he first sought to create Hanford's manufacturing instructions, he relied on Dr. Quinn's work. Dkt. No. 68, Trial Tr. at 397-400; Pl.'s Exs. 90 and 157. Even more importantly, Mr. Lemanczyk was able to observe Dr. Quinn use the *in situ* method, as outlined in Dr. Quinn's manufacturing instructions, to manufacture a batch of PGP using Hanford's formulation. This is direct evidence of the ancestral link between Dr. Quinn's work at Norbrook and Hanford's *in situ* method, and thus of trade secret misappropriation. See Monovis, 905 F.Supp at 1232 (finding it reasonable to infer that defendant, having been exposed to plaintiff's method of manufacture, understood the particulars of plaintiff's method, and that defendant used this understanding as a springboard to launch his own manufacturing approach).

Hanford has not met its burden to show independent development.

4. Norbrook Has Prevailed On Its Claim of Unfair Competition²²

Under New York law, "the gravamen of a claim of unfair competition is the bad faith misappropriation of a commercial advantage belonging to another by infringement or dilution of a

²²Contrary to Hanford's assertion, the court is not necessarily compelled to consider Norbrook's trade secret misappropriation claim and unfair competition claim as a single cause of action. See Continental Dynamics Corp. v. Kanter, 64 A.D.2d 975, 408 N.Y.S.2d 801, 802 (2d Dep't 1978) (finding that while no trade secret existed in customer lists, "an employee's physical taking or studied copying of such lists may, nevertheless, form the basis for a cause of action for unfair competition") (internal quotation marks omitted). In any event, because the court found that Norbrook possessed a trade secret and that Hanford misappropriated it, no further discussion of this matter is required.

trademark or trade name or by exploitation of proprietary information or trade secrets. Eagle Comtronics, Inc. v. Pico Products, Inc., 256 A.D.2d 1202, 1203, 682 N.Y.S.2d 505, 506 (4th Dep't 1998). The essence of an unfair competition claim is that one may not misappropriate the results of the labor, skills and expenditures of another, LinkCo., Inc. v. Fujitsu Ltd., 230 F.Supp.2d 492, 500 (S.D.N.Y. 2002); the tort functions to protect "property rights of value . . . from *any form of commercial immorality.*" Metro. Opera Ass'n v. Wagner-Nichols Recorder Corp., 199 Misc.786, 101 N.Y.S.2d 483, 492 (Sup. Ct. 1950) (emphasis added), *aff'd*, 279 A.D. 632, 107 N.Y.S.2d 795 (1st Dep't 1951) (per curiam). New York courts broadly construe this tort: "[t]he incalculable variety of illegal practices denominated as unfair competition is proportionate to the unlimited ingenuity that overreaching entrepreneurs and trade pirates put to use." Electrolux Corp. v. Val-Worth, Inc., 6 N.Y.2d 556, 558, 190 N.Y.S.2d 977, 161 N.E.2d 197 (1959) (internal quotation marks and citations omitted); Demtriades v. Kaufman, 698 F.Supp. 521, 525 (S.D.N.Y. 1988) (finding that the confines of the "adaptable and capricious tort of unfair competition . . . are marked only by the conscience, justice and equity of common-law judges") (internal quotation marks and citation omitted). At a minimum, however, a claim for unfair competition "requires allegations of unfairness and an unjustifiable attempt to profit from another's expenditure of time, labor and talent." Greenblatt v. Prescription Plan Services Corp., 783 F.Supp 814, 825 (S.D.N.Y. 1992) (internal quotation marks and citation omitted).

a. Statute of Limitations

Before reaching the merits of Norbrook's unfair competition claim, the court must first address Hanford's argument that it is barred by the applicable statute of limitations. Norbrook's unfair competition claim is governed by the three-year statute of limitations imposed by N.Y.

C.P.L.R. § 214(4). Hanford contends that the alleged misappropriation that forms the basis of Norbrook's unfair competition claim occurred no later than January 2000, the month that Dr. Quinn produced the 1,000-litre Univet batch, and that because Norbrook filed its claim February 7, 2003, it is untimely. The court concludes, however, that Norbrook's unfair competition claim accrued on January 24, 2002, when Hanford applied to the FDA to amend its commercial manufacturing process for PGP injections. *Cf. Mopex, Inc. v. American Stock Exch., LLC*, 2002 WL 342522, at *11 (Mar. 5, 2002) (finding that plaintiff's unfair competition claim accrued at least as early as when defendant applied to the SEC for authority to trade financial products based on plaintiff's trade secrets). Therefore, Norbrook's claim is not time-barred by the statute of limitations.

b. Hanford Exploited Norbrook's Trade Secret

Given the amount of time and money that Norbrook expended in developing and implementing its *in situ* method, it has a protectable property interest in the method. Hanford has endeavored to "reap where it has not sown" and benefit from its misappropriation of Norbrook's confidential information. Although Hanford's unfair competition is perhaps more sophisticated than outright trickery, trespass or piracy in that it secured the services of a third-party no longer associated with its direct competitor, Hanford's conduct in this case amounts to a form of commercial immorality. *See LinkCo., Inc.*, 230 F.Supp.2d at 502 (finding defendant misappropriated plaintiff's confidential information in bad faith and used it for its own benefit where former employee showed defendant plaintiff's confidential information and had secret meetings with defendant). Norbrook has prevailed on its claim of unfair competition.

C. *Irreparable Harm*

Irreparable harm is that injury which is so serious that a monetary award cannot adequately

compensate the injured party. See Citibank N.A. v. Citytrust, 756 F.2d 273, 275 (2d Cir. 1985). The showing of irreparable harm is the “single most important prerequisite for the issuance of a preliminary injunction.” Reuters Ltd. v. United Press Int’l, Inc., 903 F.2d 904, 907 (2d Cir. 1990) (citing Bell & Howell v. Masel Supply Co., 719 F.2d 42, 45 (2d Cir. 1983)). The mere possibility of harm is not sufficient as the harm must be imminent and the movant must show that he is likely to suffer irreparable harm if equitable relief is denied. JSG Trading Corp. v. Tray-Wrap, Inc., 817 F.2d 75, 79 (2d Cir. 1990). Moreover, as stated above, the “loss of trade secrets cannot be measured in money damages” because “[a] trade secret once lost is, of course, lost forever.” FMC Corp., 730 F.2d at 63. Thus, “irreparable harm is presumed where a trade secret has been misappropriated.” Carpetmaster of Latham, Ltd. v. Dupont Flooring Sys., Inc., 12 F.Supp.2d 257, 263 (N.D.N.Y. 1998) (McAvoy, C.J.) (citing FMC Corp., 730 F.2d at 63.); Prod. Res. Group, LLC v. Oberman, 2003 WL 22350939, at *7 (S.D.N.Y. August 27, 2003) (citing FMC Corp., 730 F.2d at 63); Worldwide Sport Nutritional Supplements, Inc. v. Five Star Brands, LLC, 80 F.Supp.2d 25, 33 (N.D.N.Y. 1999) (McAvoy, C.J.) (citing FMC Corp., 730 F.2d at 63); Greek Orthodox Archdiocese of N. and S. America, Inc. v. Greek Orthodox American Leaders, Inc., 1998 WL 832707, at *3 (S.D.N.Y. Nov. 25, 1998) (citing FMC Corp., 730 F.2d at 63); InFlight Newspapers, Inc., 990 F.Supp. at 124-25 (citing FMC Corp., 730 F.2d at 63); Lumex, Inc. v. Highsmith, 919 F.Supp. 624, 628 (E.D.N.Y. 1996) (citing FMC Corp., 730 F.2d at 63); Ivy Mar Co., Inc. v. C.R. Seasons Ltd., 907 F.Supp. 547, 567 (E.D.N.Y. 1995) (citing FMC Corp., 730 F.2d at 63).

Having found that Norbrook’s *in situ* method is a trade secret and that Hanford misappropriated it, the court also finds that Hanford’s use of Norbrook’s *in situ* method will cause Norbrook irreparable harm. The same, however, cannot also be said of Norbrook’s unfair

competition claims. As Hanford correctly points out, Norbrook failed to cite to any cases standing for the proposition that: a likelihood of success on the merits of an unfair competition claim entitles the party moving for a preliminary injunction to a presumption of irreparable harm. The courts own research, however, disclosed that “the potential loss of an industry leader’s present market and loss of the advantage of being the pioneer in the field and the market leader, may constitute irreparable harm.” Computer Associates Int’l, 784 F.Supp. at 986; Anacomp, Inc. v. Shell Knob Services, 1994 WL 9681, at *6 (S.D.N.Y. Jan. 10, 1994); Natural Organics, Inc. v. Protein Plus, Inc., 724 F.Supp. 50, 54 (E.D.N.Y. 1989). Absent preliminary relief, Norbrook has demonstrated that its reputation as an industry leader as the first veterinary pharmaceutical manufacturer to utilize the *in situ* method in its commercial production of PGP injections would suffer. Moreover, Norbrook uses its sales of PGP manufactured using the *in situ* method as a “lever to introduce other products.” Dkt. No. 66, Trial Tr. at 54. On this basis, the court finds a likelihood of irreparable harm in relation to Norbrook’s unfair competition claim.

D. Balance of Hardships

In balancing Norbrook’s harm from the denial of a preliminary injunction against any harm Hanford may suffer from granting the injunction, the court finds that the balance favors the issuance of the injunction. The primary burden on Hanford is the delay of its anticipated cost savings of using the *in situ* method until this matter is resolved. Hanford is of course free to continue to produce PGP injections using the above-described conventional process. On the other hand, the harm to Norbrook if the court did not issue an injunction would be irreparable. Hanford’s commercial use of Norbrook’s *in situ* method would allow it to unfairly compete with Norbrook in the United States market for PGP injections by using a technology that Norbrook spent years in developing,

implementing and gaining its regulatory approval. This the court cannot permit.

CONCLUSION

WHEREFORE, for the foregoing reasons, it is hereby

ORDERED, that Hanford's motion to preclude Norbrook from introducing a new legal theory is DENIED; it is further

ORDERED, that Norbrook's motion to strike the testimony of Mr. Ward concerning Hanford's sales projections for PGP injections manufactured using the *in situ* method and to compel production of documents concerning Hanford's marketing and advertising of products manufactured using the *in situ* method is GRANTED; it is further

ORDERED, that Norbrook's motion for a preliminary injunction is GRANTED; it is further

ORDERED, that Hanford's motion for judgment as a matter of law is DENIED; it is further

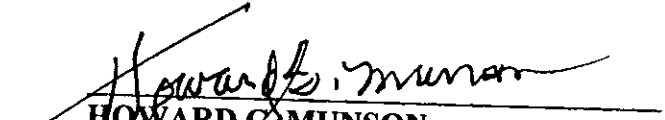
ORDERED, that Hanford, its officers, agents, servants, employees, attorneys, and anyone in privity with it, including all those in active concert or participation with it, are preliminarily enjoined from: (1) manufacturing, marketing, selling, advertising for sale or in any other way dealing in injectable antibiotics comprising the suspension of PGP where the product is manufactured using any part of Norbrook's exclusive *in situ* method of manufacturing PGP injections or confidential information; (2) using, publishing or disclosing writings, drawings, research findings, know-how, or in any other way dealing with information in any form relating to injectable antibiotics containing penicillin G procaine that is or are based on or derived from Norbrook's exclusive *in situ* method of manufacturing PGP injections or confidential information; and, (3) parting with possession, custody, power or control (other than to Norbrook's attorneys) of information relating to injectable antibiotics containing PGP based on or derived from Norbrook's

exclusive *in situ* method of manufacturing PGP injections or confidential information, pending a final decision and judgment or further Order of this court; it is further

ORDERED, that the Clerk of the Court serve a copy of this Decision and Order upon the parties by regular mail.

IT IS SO ORDERED.

Dated: December 18, 2003
Syracuse, New York


HOWARD C. MUNSON
SENIOR U.S. DISTRICT JUDGE