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Jurisdiction	USA
Tribunal	U.S. District Court for the Southern District of New York
Date of the decision	10 May 2002
Case no./docket no.	99CIV3607(RWS)
Case name	*Geneva Pharmaceuticals Technology Corp. v. Barr Laboratories, Inc.*

Opinion

Sweet, District Judge

Defendants Barr Laboratories, Inc.; Brantford Chemicals, Inc.; Bernard C. Sherman; Apotex Holdings, Inc.; Apotex Inc.; and Sherman Delaware Inc. have moved for summary judgment to dismiss the complaint of plaintiffs Geneva Pharmaceuticals Technology Corp. (as successor in interest to Invamed, Inc.) and Apothecon Inc. alleging violations of the federal antitrust laws, the New York antitrust laws, and numerous related state law claims. 1

For the foregoing reasons, that motion is granted in part and denied in part.

The Parties

A. The Plaintiffs

Plaintiff Geneva Pharmaceuticals Technology Corp. («GPTC») is a New Jersey corporation with its principal place of business in New Jersey. GPTC is in the business of developing, manufacturing and marketing generic pharmaceuticals. GPTC is a wholly owned subsidiary of Geneva Pharmaceuticals, Inc. («Geneva»), which itself is a member of the generics sector of Novartis AG, the Austrian pharmaceutical company. Until its purchase by Geneva in December 1999, GPTC was known as Invamed, Inc. («Invamed»). 2

Plaintiff Apothecon, Inc. («Apothecon») is a Delaware corporation with its principal place of business in New Jersey. Apothecon is a wholly-owned subsidiary of the Bristol-Myers Squibb Company («BMS»), one of the world's leading pharmaceutical companies, and is engaged in the business of developing, manufacturing and marketing generic pharmaceuticals. Apothecon's approximate annual sales are $600 million. 3

B. The Plaintiffs' Relationships

On June 28, 1996, Invamed and Apothecon entered into an exclusive five-year Development and Supply Agreement in connection with manufacturing and marketing a number of generic pharmaceuticals, including warfarin sodium, a generic version of the drug Coumadin made by 4

DuPont Pharmaceuticals Company («DuPont»). Plaintiffs allege that this arrangement constituted a joint venture, in that the parties agreed to share profits and loss and referred to each other as «partners» and to the agreement as a «joint venture.»

On December 15, 2000, Geneva's affiliate Biochemie U.S. acquired Apothecon's portfolio of commodity generic pharmaceutical products, and Geneva gained the right to sell (under the Geneva or Apothecon label) all of the products, including warfarin sodium, that had been previously supplied to Apothecon by Invamed. On June 7, 2001 BMS agreed to acquire the drug business of DuPont, including Coumadin, for $7.8 billion in cash. 5

C. The Defendants

Defendant Barr Laboratories, Inc. («Barr») is a New York corporation with its principal place of business in New York. Barr is engaged in the business of developing, manufacturing and marketing generic pharmaceuticals. 6

Defendant Brantford Chemicals, Inc. («Brantford») is a Canadian corporation with its principal place of business in Brantford, Ontario. Brantford is engaged in the business of manufacturing and marketing active pharmaceutical ingredients («API»), chemical compounds used in the manufacture of pharmaceuticals. Brantford was known as ACIC (Canada) («ACIC») until 1996.

Defendant Apotex Inc. («Apotex») is a Canadian corporation with its principal place of business in Weston, Ontario. Apotex is engaged in the business of researching, manufacturing and marketing both generic and branded pharmaceuticals. Apotex does not currently manufacture or market pharmaceuticals for sale in the United States.

Defendant Apotex Holdings, Inc. («Apotex Holdings») is a Canadian holding company with its principal place of business in Weston, Ontario.

Defendant Dr. Bernard C. Sherman («Sherman») is an individual residing in Canada. Sherman founded Apotex in 1974 and is the chairman of its board of directors. Sherman is also a member of the board of directors of Barr[1] and the president of Apotex Holdings.

Defendant Sherman Delaware, Inc. («Sherman Delaware») is a Delaware holding company with its principal place of business in Delaware.

D. The Defendants' Common Ownership

Sherman owns 99% of the voting shares of Sherman Holdings Inc. («Sherman Holdings»). Sherman and members of his family are also the beneficiaries of the Bernard and Honey 7

[1] Sherman first acquired a majority ownership interest in Barr in the early 1980's, when he obtained more than 80% of Barr's stock. Sherman claims to be a «portfolio investor» in Barr and noted that he refrained from any «active role» in decisions at Barr to avoid any conflict with his other pharmaceutical interests. Barr's general counsel confirmed that Sherman is a «passive investor» in Barr and does not have «effective control» over the board of directors.

Sherman Trust («Sherman Trust»). Sherman Holdings and the Sherman Trust together own approximately 100% of the voting shares of Shermco Inc.

Shermco Inc. owns 100% of Shermfam Inc., which owns 100% of the outstanding shares of Apotex Holdings. Apotex Holdings owns 100% of Apotex Pharmaceutical Holdings Inc., which owns 100% of the outstanding shares of both Apotex and Brantford.

Apotex Pharmaceutical Holdings Inc. and its affiliates have owned 75% of Brantford (then ACIC) since March 1990. The family of Luciano Calenti, ACIC's president, owned the minority interest, along with institutional investors. Apotex Pharmaceutical Holdings Inc. acquired the remaining 25% of ACIC in 1996. In 1990 ACIC was experiencing financial difficulties and Calenti turned to Sherman, a longtime client of ACIC. Sherman pursued the acquisition of ACIC as an opportunity to integrate a supplier with his operations and increase their capacity to develop chemicals. Plaintiffs claim that Sherman did not take an active interest in ACIC until 1996, when he bought out Calenti. Calenti «ran the company» himself until the buy out in July 1996.

Apotex Holdings also owns 100% of Shermfin, Inc., which owns 100% of both Sherman Delaware and Glastex Investments, Inc. From 1993 to 1997, Sherman Delaware and Glastex Investments owned outstanding shares of Barr. In mid-1993, they owned approximately 66%. As of December 31, 1997, Sherman Delaware and Glastex Investments owned approximately 63% of Barr. After a Barr secondary offering in March 1998, Sherman Delaware and Glastex Investments owned approximately 48.6% of Barr.

Prior Proceedings

Invamed filed its complaint on February 6, 1998, alleging violations of the antitrust laws of the United States and various state law claims arising out of defendants' alleged efforts to monopolize and restrain trade in the markets for an oral anti-coagulant medication known as warfarin sodium. The complaint alleged eleven causes of action against the defendants. 8

On April 9, 1998, Sherman, Apotex Holdings, Apotex, and Sherman Delaware moved under Fed.R.Civ.P. 12(b)(6) to dismiss Invamed's First, Second, Third, Fourth, Eighth, and Ninth Causes of Action, claiming that there are no allegations in the complaint which would establish the basis for those claims. The Court granted this motion to dismiss with leave to replead. Invamed did not replead.

Therefore, Invamed's eleven causes of action are as follows. Count I and II allege monopolization and attempted monopolization against Barr and ACIC/Brantford in both the relevant warfarin sodium market and the market for clathrate, the bulk material used to make the drug. Counts III and IV allege conspiracy to monopolize against Barr and ACIC/Brantford. Count V alleges against all defendants that the acquisition of ACIC/Brantford by Apotex and, through Apotex, by Apotex Holdings, Sherman, Sherman Delaware, and Barr, violates Section 7 of the Clayton Act. Counts VI and VII allege breach of contract and promissory estoppel against ACIC/Brantford. Counts VIII and IX allege tortious interference with contract and with business relations against Barr. Counts X and XI allege negligence and negligent misrepresentation against ACIC/Brantford.

Apothecon filed a separate suit on May 19, 1999, and the cases were consolidated on July 29, 1999. Apothecon included the same causes of action discussed above as well as a few additional ones. Against Barr and ACIC/Brantford, it alleged violation of the Donnelly Act, New York's antitrust law (Count VI) and fraud (Count VIII). Further, it alleged breach of fiduciary obligation (Count XIV) against ACIC/Brantford and unfair competition against Barr (Count XV).

The defendants moved for summary judgment on August 6, 2001. They filed a joint motion on plaintiffs' antitrust claims, and ACIC/Brantford and Barr each submitted a separate motion addressing the state law claims against them. Oral argument was heard on February 13, 2002, and submissions were considered fully complete at that time.

Facts

The following facts are taken from the parties' Rule 56.1 statements and, as required, are construed in the light most favorable to the non-movant, as applicable.[2] 9

I. Background

A. Warfarin Sodium

Warfarin sodium is an oral anti-coagulant medication that, in tablet form, is prescribed for the treatment of venous thrombosis and pulmonary embolism, or blood clots, particularly in patients over the age of 60. In its simplest terms, warfarin sodium thins the blood, preventing harmful clots that can cause strokes and heart attacks. 10

A pharmaceutical product that has a narrow range between its therapeutic dose and its toxic dose is considered a narrow therapeutic index («NTI») product. Warfarin sodium is an NTI drug. Patients for whom warfarin sodium is indicated are often high-risk patients for whom changes in their medication are viewed with great concern. Warfarin sodium possesses 11

[2] Defendants ask that some of their proposed facts which plaintiffs dispute be admitted, arguing that plaintiffs failed to properly respond to them. As defendants note, «a proper 56.1 statement submitted by a non-movant should consist of a paragraph-by-paragraph response to the movant's 56.1 statement, much like an answer to a complaint.» *Rodriguez v. Schneider,* 1999 WL 459813, at *1 n. 3 (S.D.N.Y. June 29, 1999). Plaintiffs did provide a paragraph-by-paragraph response to defendants' 56.1 statement. However, some of those responses referred generally to an «affirmative statement» for the grounds of dispute. In particular, plaintiffs assert no less than sixteen times, without any citation to specific facts, that «in light of the material facts discussed [in Plaintiffs' affirmative statement] there exists a genuine issue to be tried as to whether Coumadin competes in the same market as generic warfarin sodium.» The Court did not impermissibly have «to scour the record on its own in a search for evidence which may support that party's contention that a certain fact is in dispute.» Id. However, plaintiffs' statement did require scouring the affirmative statement to determine which parts of it supported plaintiffs' contention that a triable issue exists as to whether Coumadin competes in the same market as generic warfarin sodium. Because of this, the Court will accept the facts submitted by the defendants to which plaintiffs responded by referring generally to its later affirmative statement. This does not mean that the Court ignored the affirmative statement, and facts from the affirmative statement are included in the statement of facts below. It does mean that the Court will not sift through an affirmative statement to make a party's arguments for it – particularly in a complex case such as this one where both parties are ably represented and have demonstrated the ability to brief, in hundreds of pages, the issues. In any case, plaintiffs fail to present a genuine issue to be tried as to whether Coumadin competes in the same market as generic warfarin sodium.

potential side effects that include increased bleeding. Patients taking warfarin sodium are supposed to be monitored in order to ensure that the appropriate amount of the drug is present. The active pharmaceutical ingredient («API») for warfarin sodium is known as «bulk» warfarin sodium or warfarin sodium clathrate («clathrate»). Clathrate and its related compounds are also used in one form of rat poison.

The United States Pharmacopoeia («USP») contains a list of minimum standards for the purity and composition of drugs and pharmaceuticals that are manufactured, prescribed, or sold in the United States. A drug's strength, quality and purity are assessed in accordance with the tests and standards defined in the USP. Raw materials that meet USP standards and meet Good Manufacturing Practices guidelines are suitable for use in manufacturing finished dosage form pharmaceuticals. 12

Clathrate itself consists of two key chemicals, 4-hydroxycoumarin and benzalacetone (or benzylidene acetone). Both chemicals were readily available in the chemical marketplace throughout the 1990's. It is disputed whether the process of making clathrate is simple or complex. Plaintiffs claim that it can take a supplier several years to develop a procedure for the production of clathrate. Clathrate has a shelf life of 22 months. 13

Warfarin sodium was first introduced for human use under the brand name of Coumadin in 1956 by Endo Laboratories, which was purchased by DuPont. DuPont lost patent protection for Coumadin in 1962. DuPont made Coumadin using clathrate purchased from Chemoswed A.B. («Chemoswed»), a Swedish manufacturer. In 1995, DuPont purchased Chemoswed. 14

Even though DuPont's patent protection for Coumadin expired in 1962, for the next 35 years DuPont and Coumadin enjoyed a virtual monopoly in the market for oral anticoagulants. As a result of that position in the market, DuPont's Coumadin eventually achieved annual sales exceeding $400–500 million. 15

In the 1980's, several companies received approval to market warfarin-related products, including Purdue Frederick, Abbott Laboratories, Rosemont Pharmaceuticals, and Circa/Watson Pharmaceuticals. The FDA publishes an official directory of generic drugs known as the Orange Book. These products were not successful, and the Orange Book now lists them as discontinued. 16

In 1990, the New England Journal of Medicine published the results of two new studies indicating that warfarin sodium was effective in preventing strokes in patients suffering from arterial fibrillation (irregular heartbeat), and in reducing strokes and subsequent heart attacks in patients who had survived a heart attack. These and similar articles spurred renewed interest in warfarin sodium by physicians and pharmaceutical companies. 17

Four companies sell warfarin sodium in the United States today: (1) DuPont, which has marketed Coumadin since 1956; (2) Barr, which has marketed generic warfarin sodium since July 1997; (3) Geneva (as successor to plaintiffs), which has marketed generic warfarin sodium since October 1998; and (4) Taro Pharmaceutical Industries Ltd. («Taro»), which has marketed generic warfarin sodium since September 1999. All generic warfarin sodium available in the 18

market today is therapeutically equivalent to Coumadin and bears the FDA's equivalence rating «AB.» The process of achieving this rating is described below.

Invamed/Apothecon and Barr have been and continue to be competitors with respect to warfarin sodium and finished dosage form pharmaceutical products in general. 19

B. Generic Pharmaceutical Drugs

1. Development

To develop any generic drug, a pharmaceutical company must first procure the raw materials necessary to make the drug, including its API. Numerous companies manufacture APIs for sale to the pharmaceutical industry. In the developmental stage, pharmaceutical companies typically obtain small quantities of API (generally less than 1 kg) and technical product information from API suppliers for initial analysis and testing. A sample is typically a small quantity measured in grams and is usually provided free of charge. 20

Following evaluation of the initial samples, pharmaceutical companies typically obtain developmental or «R & D» quantities of the API to begin dosage form development and initial formulation analysis. An R & D quantity is smaller in size (e.g., 1–25 kg) than larger «commercial» quantities (e.g., more than 50 kg) that are later used to put the finished-dosage product into commercial production. R & D quantities and commercial quantities frequently differ in price. 21

Generic drug manufacturers obtain FDA approval for generic forms of innovator or branded drugs by filing an Abbreviated New Drug Application («ANDA»), which includes information demonstrating that the subject drug is bioequivalent to the branded drug. An ANDA must contain information to show that the generic product has the same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling as the branded drug. 22

The FDA requires pharmaceutical companies to identify in the ANDA the API supplier or suppliers they intend to use in manufacturing the product. Plaintiffs claim that applicants tend to specify only one supplier of its pharmaceutical ingredients so as to minimize the time taken by the FDA for its review and approval.[3] API from a different source can be substituted only upon FDA approval of a supplement or amendment to the ANDA. 23

The FDA classifies as «therapeutically equivalent» those products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents; (3) they are bioequivalent; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations. The FDA rates a generic product «AB» equivalent to its branded counterpart if a study is submitted demonstrating bioequivalence to the branded product. Despite this, there may be physical differences between branded and generic drugs, such as the particle size of the active 24

[3] Invamed, however, has a longstanding policy of including two sources if possible.

pharmaceutical ingredient, water content, and crystalline structure. A different process is used to manufacture generic products and that process may lead to other differences.[4]

API suppliers submit Drug Master Files («DMFs») to the FDA, which summarize the equipment, manufacturing steps, raw materials and laboratory controls used to prepare the particular API. In a DMF «reference letter,» the API supplier commits to the FDA that it will manufacture its material as set forth in its DMF. In the letter (which is sent by the supplier to the FDA), the supplier authorizes the FDA to refer to its DMF in connection with an ANDA filed by the drug manufacturer. The FDA reviews a supplier's DMF in conjunction with its review of the pending ANDA. If both are in order, the drug will be approved for marketing. 25

Because of the need for approval to change suppliers after approval, plaintiffs allege that it is a widespread practice throughout the industry that a supplier providing a reference letter commits itself to providing commercial quantities of the raw material. Plaintiffs also allege that throughout the 1990's it was also practice to rely on informal oral arrangements, rather than written supply contracts. For example, more than 90% of the bulk pharmaceutical ingredients purchased by Barr, and the majority of bulk pharmaceuticals sold by ACIC/Brantford, do not involve written supply agreements. 26

2. Equivalence of Branded and Generic Warfarin Sodium

Generic warfarin sodium products that are rated AB by the FDA are therapeutically equivalent to the brand product and by approving the products for marketing, the FDA has certified both Barr's and plaintiffs' product as chemically and therapeutically equivalent to the innovator's product, Coumadin. 27

Plaintiffs' and Barr's generic warfarin sodium products are, therefore, fully interchangeable with each other and with Coumadin. In its interrogatory responses, Invamed stated that it is not aware of any reason why any of the three warfarin sodium products «should not be substituted for any of the others.» Apothecon, in response to interrogatories asking whether plaintiffs' product, Barr's product, and Coumadin may be substituted or are interchangeable, stated that it is not «aware of any reason why any of the three ... warfarin sodium products should not be substituted for any of the others.» 28

In Invamed's ANDA, Section II, captioned «BASIS FOR ANDA SUBMISSION» Invamed stated that its «WARFARIN SODIUM TABLETS USP ... are the same as the listed drug COUMADIN TABLETS ... manufactured by DuPont. ... » 29

Both Barr and Apothecon conducted clinical studies demonstrating that their products were clinically interchangeable with Coumadin. In addition, both Apothecon/Invamed's warfarin sodium product and Barr's warfarin sodium product contain the same labeling and identical 30

[4] Plaintiffs state that other differences exist between branded and generic drugs, but do not allege that this differences necessarily exist between generic and branded warfarin sodium. These differences are: (1) consumers and doctors may not view the generic product as interchangeable with the branded product; (2) lower price; and (3) the principal customers for pharmaceutical drugs – large chain drug stores and distributors – tend to stock the branded product and only one generic product for any particular pharmaceutical.

prescribing information as that used with Coumadin. Coumadin uses different tablet colors to correspond with and signify different dosage sizes. Barr and Apothecon/Invamed use the same colors as Coumadin.

Generic warfarin sodium and Coumadin are sold to the same customers: wholesalers, hospitals, retail pharmacy chains, mail order houses, clinics, and managed care organizations. 31

II. Barr's Generic Warfarin Sodium

A. Barr's Development

Barr's business strategy is to be the first or second manufacturer to enter the market for a particular generic product. To accomplish this goal, Barr chooses products with high barriers to entry so that the company will face limited competition. 32

In the early 1990's, Barr identified warfarin sodium as a product where there were barriers to entry because of the difficulty of obtaining a supply of the raw material necessary to produce the product. Barr researched potential API suppliers at that time. 33

In January 1991, Ed Cohen, Barr's president, and Luciano Calenti, ACIC's founder and president, discussed a potential 20 kg order of clathrate. Calenti confirmed that ACIC could produce commercial quantities of clathrate for $2,000 per kilogram, and the initial 20 kg for $2,500 per kilogram. Calenti said a 50% advance payment would be required to ensure that Barr would not rescind the order. 34

On February 5, 1991, Cohen confirmed Barr's interest to Calenti, sent ACIC its purchase order for 20 kg of clathrate, and offered to lend any analytical support needed in developing purity specifications for the product. The day after Barr's order, ACIC began process development work on warfarin sodium. ACIC developed an acceptable process for synthesizing warfarin sodium by the spring of 1991. 35

Barr next ordered 7 kg of clathrate from ACIC in June 1993, and another 10 kg in May 1994. 36

ACIC filed a DMF for clathrate with the FDA on March 15, 1995. On April 3, 1995, ACIC provided a DMF reference letter for clathrate to the FDA in support of Barr's warfarin sodium ANDA. On May 10, 1995, Barr filed its ANDA, listing ACIC as its clathrate supplier and including its DMF reference letter.

In September 1995, Barr entered into an agreement with ACIC for the supply of clathrate. Barr ordered 900 kg of clathrate from ACIC on September 29, 1995. ACIC shipped that quantity to Barr in December 1995. In September 1996, Barr ordered an additional 900 kg of clathrate from ACIC (by that time known as Brantford). This quantity was shipped to Barr in separate lots in February 1997. 37

On March 26, 1997, the FDA approved Barr's ANDA and authorized the company to begin marketing, which it did beginning July 28, 1997. The FDA's approval of Barr's product was premised on the determination of the FDA's Division of Bioequivalence that Barr's «Warfarin 38

Sodium Tablets» were «bioequivalent and, therefore, therapeutically equivalent to the listed drug» Coumadin. Consequently, Barr announced in an early advertisement that its warfarin sodium tablets were «[t]herapeutically equivalent to Coumadin» and that «[t]he only difference is cost.»

On August 8, 1997, Barr submitted a purchase order for another 900 kg of clathrate. ACIC/Brantford shipped this quantity to Barr in separate lots in January and April 1998. 39

In a document dated September 1997, Barr referred to ACIC/Brantford as the «only source [of clathrate] available to the generic industry.» Barr also attempted to locate a back-up producer of clathrate. As of March 1998, Barr had been unable to locate an FDA-approved supplier. 40

B. The Supply and Confidentiality Agreements

In the summer of 1995, Barr and ACIC began discussions regarding a supply agreement for commercial quantities of clathrate. ACIC demanded an arrangement in which a pharmaceutical company would pay for a substantial amount of clathrate prior to receiving FDA approval. Calenti told Barr that if Barr did not strike an agreement with ACIC, Calenti would try to make one with another company.[5] 41

1. The Supply Agreement

By letter agreement dated September 19, 1995 (the «Supply Agreement»), Barr and ACIC contracted for ACIC to supply Barr with clathrate. The Agreement obligated Barr to purchase 900 kilograms of clathrate from ACIC for $1.8 million regardless of whether it could use the product or not. The Supply Agreement was negotiated as an arm's length transaction, and at the time it was signed, Barr's President, Bruce Downey, was unaware of any relationship between ACIC/Brantford and Apotex or Sherman. 42

The Supply Agreement provided that ACIC would exclusively supply Barr with commercial quantities of clathrate in the U.S. until another manufacturer began selling generic warfarin sodium. Barr agreed to purchase 100% of its commercial requirements from ACIC during the exclusivity period. 43

As to delivery requirements, the Supply Agreement provided that «ACIC will supply the [clathrate] in quantities requested by Barr, provided that Barr provides ACIC with lead times consistent with its normal operations.» 44

Because the Supply Agreement applied only to commercial quantities of clathrate, it did not prohibit ACIC from selling sample or developmental quantities to other generic manufacturers seeking FDA approval of their products. In addition, because the Supply Agreement applied only to clathrate manufactured in ACIC's facilities, it did not prevent ACIC from brokering clathrate manufactured by other suppliers. The Supply Agreement also permitted ACIC to supply commercial quantities to DuPont. Finally, the Supply Agreement permitted Barr, at its 45

[5] By the time these discussions took place, ACIC had supplied samples and/or a DMF reference letter to Diosynth, Invamed, Mylan, Par Pharmaceutical Inc., and Taro.

option, to purchase sufficient quantities of clathrate from another supplier in order to qualify that supplier as an alternate source.

2. The Confidentiality Agreement

On October 5, 1995, approximately seven days after the Supply Agreement was signed, Barr and ACIC executed a Confidentiality Agreement restricting disclosure of «valuable, proprietary, technical, commercial and other confidential information» for five years. This agreement precluded ACIC/Brantford from disclosing to Invamed or any other entity the existence of the exclusive supply contract. It was also ACIC's practice to keep all of its contracts and commercial transactions with its customers confidential. 46

Soon after these agreements were signed, ACIC removed clathrate from its internal products list, and Calenti advised his sales representatives to stop promoting it to new clients.

Plaintiffs claim that if they had known about the exclusive arrangement, they could have sought another supplier in 1995 and entered the market in a timely fashion.

III. Invamed's Attempts to Secure a Supply of Clathrate

Between 1993 and 1996, Invamed explored the possibility of obtaining clathrate from a number of different sources. Invamed's vice president, Dr. Mahendra Patel («Patel»), was responsible for the company's research and development efforts for new drugs, including warfarin sodium. Patel co-founded Invamed in 1983 after several years in the pharmaceutical industry, including six years at BMS. It was Patel's responsibility to identify and select potential API suppliers. Plaintiffs claim that Invamed concluded that ACIC/Brantford was the only viable supplier. 47

A. Chemoswed A.B.

In December 1994, Invamed received a 10-gram sample of clathrate made by Chemoswed, together with technical product information. The supporting technical information indicated that the Chemoswed clathrate was USP grade material and suitable for testing in an Invamed finished product. In early 1994, Invamed performed one product development trial using the Chemoswed clathrate 48

At the time, Chemoswed supplied clathrate to DuPont for use in its manufacture of Coumadin. In 1995 DuPont purchased Chemoswed. Plaintiffs claim that it was widely understood throughout the industry that Chemoswed would not be willing to sell commercial quantities to a generic manufacturer.

During 1995 to 1998, defendants claim that Chemoswed/DuPont received inquiries from at least two pharmaceutical companies, JLM and Rosemont, regarding clathrate. The price quoted to these entities was $30,000 per kilogram. Patel did not request material from Chemoswed/DuPont, stating that «it was not worthwhile» because «[w]e won't get the material.»

B. Medea Research Laboratories

Medea Research Laboratories, Inc. («Medea») provided 5 kilograms of clathrate to Invamed on January 11, 1994, and provided Invamed with a DMF reference letter on February 16, 1994. Medea's DMF for clathrate had been filed with FDA in August 1993. Although Invamed found Medea's clathrate suitable for use in its warfarin sodium tablets, Invamed returned the 5 kg order for credit in September 1994. Sometime after Invamed received Medea's material, Medea's plant was destroyed by fire. 49

C. Hoechst Celanese

On September 30, 1994, the API manufacturer Hoechst Celanese («Hoechst»), a unit of Hoechst A.G., shipped Invamed a 100-gram sample of clathrate together with technical information. Hoechst manufactured clathrate at its facility in Coventry, Rhode Island. Invamed had previously dealt with Hoechst for ibuprofen API. Invamed's discussions with Hoechst continued in late 1995 and early 1996, as discussed below. 50

D. ACIC

1. Invamed's Relationship with ACIC

Invamed first became a customer of ACIC in the late 1980's or early 1990's. Sergio Getrajdman, ACIC's U.S. sales representative, («Getrajdman») was responsible for sales to Invamed and reported to Calenti. Getrajdman, who operated out of an office in New Jersey, where Invamed was located, sold Invamed a variety of products, including atenolol, cimetidine, and nadolol, which ACIC either brokered for others or manufactured itself. 51

a. Atenolol

ACIC sold Invamed atenolol acting as broker for the manufacturer ICI, which was located in Italy. Dr. Pankaj Dave, Invamed's regulatory manager who joined the company in 1983 («Dave»), contacted Getrajdman in advance of his purchase orders to discuss price, quantity and delivery dates for the material, and kept ACIC informed of the status of its ANDA approval. 52

In March 1994, after discussing with ACIC Invamed's requirements for the remainder of the year and negotiating price and payment terms, Dave submitted a purchase order for 10,000 kg of atenolol. ACIC confirmed the purchase order with its supplier and arranged for shipment of the first 500 kg. After receiving several shipments through the next year, Invamed cancelled the purchase order in June 1996 with an undelivered balance of more than 7,000 kg

b. Nadolol

On January 3, 1995, after discussing Invamed's commercial requirements with Getrajdman, Dave submitted a $1.8 million purchase order for 2,500 kg of nadolol, the first 500 kg to be delivered in mid-March 1995. Although multiple shipments were made through the next year, the product was often unavailable. In June 1996, Invamed cancelled the purchase order with an undelivered balance of more than 1,500 kg. 53

c. Cimetidine

ACIC sold Invamed cimetidine acting as broker for the manufacturer, Signa, in Mexico. In June 1993, Dave requested prices, technical information and samples. On October 7, 1993, Dave requested a price for 100 kg, was quoted $65 per kilogram, and followed up with a purchase order the next day. In February 1994, ACIC provided Invamed a DMF reference letter for the product. In May 1994, Invamed advised ACIC it had submitted its cimetidine ANDA and to prepare for an FDA inspection. In February 1995, Dave advised Getrajdman that Invamed would require 5,000 kg for its product launch, tentatively scheduled for July, and the parties discussed pricing on a target quantity of 45,000 kg per year. In April, Dave submitted a purchase order for 4,000 kg of cimetidine and advised Getrajdman that Invamed expected FDA approval within the next two weeks. 54

On May 13, 1995, Dave wrote Getrajdman requesting a cimetidine delivery schedule for June, and discussed projections for future deliveries. In light of product quality problems at the Signa plant, by September 1995 Invamed had refused delivery of cimetidine and held back payment for nadolol. On September 28, 1995, Getrajdman wrote Dave insisting on payment for nadolol and that Invamed accept and pay for shipments of cimetidine

In December Invamed submitted a purchase order for 5,000 kg of cimetidine, and in January 1996 sought an agreement from ACIC to supply 75,000 kg for the next two years. By letter dated January 4, Patel sought a fixed price of $100 per kilogram for the first year, and, the same price for the second year for the first 75 tons and afterward a price of $90 per kilogram. Days later, however, after Getrajdman sent a draft agreement to Dave, Invamed issued a purchase order to ACIC for only 20,000 kilogram. Ultimately, Invamed stopped making the product.

2. Clathrate

On September 20, 1994, Dave discussed the availability of clathrate with Getrajdman, who told him there was no exclusive on the material and that ACIC could provide it to Invamed. 55

The next day, Dave telephoned ACIC for a price on 5–10 kilograms of clathrate and was quoted an approximate price of $2,500 per kilogram. On September 26, 1994, ACIC sent Invamed clathrate samples of 1g and 10g, and technical information, free of charge.[6] Invamed also received research and development quantities of clathrate in February 1995 and March 1995, free of charge. ACIC/Brantford provided the samples free of charge in anticipation of selling Invamed substantial quantities of clathrate if Invamed successfully developed warfarin sodium.

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[6] It was ACIC's practice to supply samples and technical information packages free of charge to any customer that asked for one. These packages included samples, certificates of analysis, impurities data, stability data, specifications, test methods and safety information, and a schematic flowchart of the synthetic process. At times, the packages included a DMF reference letter. It was Invamed's practice to request a full technical package from numerous API suppliers.

Invamed also purchased 15 kilograms of clathrate from ACIC/Brantford in February 1995 and an additional 5 kilograms in July 1995, at a price of $2500 per kilogram. The February 1995 purchase order contained an attachment requesting a variety of other information and materials in addition to the requested quantity of clathrate.[7]

On March 7, ACIC shipped the 15 kg clathrate order, and on March 21 it shipped the three additional 50-gram samples with requested information.

On April 3, 1995, ACIC sent the FDA a DMF reference letter as requested in the purchase order and attachment. The same day, ACIC sent a copy of the letter to Invamed. It stated: 57

> «Dear Sir,
>
> Re: WARFARIN SODIUM DMF # 11387
>
> Authorization is hereby given to the Food and Drug Administration to refer to our Master File for WARFARIN SODIUM on behalf of:
>
> INVAMED, INC.
>
> 2400 Route 130 North
>
> Dayton, NJ 088100 – U.S.A
>
> In support of any new drug application they may file on pharmaceutical preparation containing the drug manufactured by us.
>
> ACIC (CANADA) INC. herewith commits itself to manufacture all of their pharmaceutical products in accordance with the current good manufacturing practices and by the methods described in this specific Drug Master File, and to issue a new DMF reference letter after each amendment on the above Drug Master File.»

The letter constitutes a commitment to the FDA to manufacture clathrate in accordance with the requirements outlined in the DMF and the industry requirements if ACIC manufactures the product. 58

Plaintiffs claim that the sending of this letter also constituted a commitment that ACIC/Brantford would supply commercial quantities of clathrate to Invamed. However, the letter contains no language by which the manufacturer commits to supply the purchaser with the subject materials, although manufacturers can include such language in DMF letters. Further, Invamed did not consider itself obligated to purchase clathrate from all of the companies from which it obtained samples and DMF referral letters such as the one above. 59

On July 21, 1995, Dave submitted a second standard purchase order and attachment to Getrajdman for 5 kg of clathrate, and requested ACIC's safety and handling procedures for the 60

[7] These included: (1) a DMF referralletter (in triplicate) and any amendments to the original DMF referral letter from ACIC; (2) three additional lots of samples (minimum 50g each) with corresponding certificates of analysis; (3) a complete technical package including a synthesis flow chart, identification of major impurities and synthesis precursors and an impurity standard sample with a certificate of analysis; and (4) Certificate of Analysis, impurities data and particle size for the 15 kilogram shipment.

product. ACIC faxed the requested information to Invamed on July 24, and Invamed received the shipment early in August.

On or about August 23, 1995, Getrajdman allegedly tried to discourage Invamed from pursuing its ANDA submission for warfarin sodium «on the pretext that others were ahead of him and his market share would thus be proportionally smaller.» 61

In January 1996, Dave placed an order for an additional 12 to 14 kilograms of clathrate from ACIC/Brantford to perform tests on a particular machine. Getrajdman advised Invamed that he did not know when availability would allow ACIC to accept an order for clathrate, and that he would have to check with Calenti. In a fax sent the next week, Dave asked Getrajdman to «let him know» so he could submit a confirming purchase order. 62

The January 1996 order was never fulfilled, and Invamed concluded that the failure to deliver was a result of «poor communication» between the two companies or that ACIC/Brantford was «too busy» to fill a small order. The principals of Invamed did not consider the failure to be serious. In place of ACIC/Brantford's clathrate, Invamed used non-FDA approved material it received from Hoechst.

Before 1996 and in 1996, Patel told Getrajdman that Invamed was working with ACIC/Brantford's material and would be filing its ANDA with it. Plaintiffs claim that Invamed also specifically advised ACIC/Brantford that it would be obligated to supply commercial quantities of clathrate when Invamed's ANDA was approved. Sometime in 1995, Getrajdman told Patel that ACIC/Brantford was one of the suppliers that had clathrate available and that when Invamed placed its order ACIC/Brantford would provide the material. Plaintiffs also claim that ACIC/Brantford «repeatedly assured» Invamed that it would supply commercial quantities of clathrate to it on numerous occasions in 1996. Plaintiffs claim that as part of this implied-in-fact contract, Invamed and ACIC agreed on the price and on a «commercial quantity.» Further, Patel testified that as part of the agreement, Invamed had to give commercially reasonable notice of its orders. They did not agree on delivery dates. 63

By January 1996, ACIC/Brantford advised Invamed that it was looking to other API suppliers as possible replacement sources of clathrate for Invamed. At that time, Getrajdman told Dave about a possible switching of the manufacturing to Signa in Mexico to obtain clathrate for Invamed. On May 29, 1997, Getrajdman also advised Patel about a possible clathrate source in Italy, but Patel did not want to pursue that option. 64

On February 14, 1996, Dave sent a fax to Antoniette Walkom, ACIC's manager of regulatory affairs («Walkom»), requesting that she provide «information with reference to Warfarin Sodium as requested by the FDA.» Later the same day, Dave sent another fax to Walkom stating: «I feel that we have not been treated right and it seems to me that you are not dealing in good faith. I have some important questions regarding WARFARIN SODIUM BULK DRUG SUBSTANCE.» Walkom forwarded the technical information to Dave on February 16 and 27, noting her displeasure with the tone and content of his fax. 65

66

In September 1996, after the sale of Calenti's remaining shares of ACIC to Apotex was complete,[8] ACIC/Brantford issued letters to some companies to which it had provided DMF reference letters, advising them of the change. The letter directed commercial inquiries to Brantford's new sales agent, ACIC Fine Chemicals. Invamed received a letter dated September 27, 1996, with regard to the three ACIC APIs on which it held a reference letter, including clathrate. The letter stated that «[w]e would like to emphasize that the facilities, premises, and procedures as described in the respective files remain unchanged.» The letter also asked recipients to inform Brantford of any products that had become inactive in order to update its records.

Invamed responded on October 4, 1996, and advised Brantford that each of these APIs was in active status. Invamed's letter did not inform Brantford that it had filed its ANDA for warfarin sodium or that it had utilized Brantford's DMF reference letter. It did request that the reference letter for clathrate «continue to be maintained.» **67**

In the spring of 1997, Dave asked Getrajdman for 100–150 kilograms of clathrate. Getrajdman explained that ACIC/Brantford would be able to deliver such material as soon as the FDA approved two generic manufacturers' ANDAs for warfarin sodium. He provided no explanation of why there had to be two approvals, but stated that he may be able to provide clathrate before then. In fact, because of the exclusive supply contract with Barr, ACIC/Brantford could not supply a commercial quantity of clathrate until another generic manufacturer besides Barr was selling warfarin sodium. Thus, in effect, the FDA would have approved two generic warfarin sodium manufacturers at the time ACIC/Brantford could supply a commercial quantity of clathrate. **68**

At or about this time, Patel informed Yashvant Patel that Invamed was having clathrate supply problems and that Invamed would have to «play this right» so that it would not be «cut off from the raw material supply.» Patel was worried that if Invamed put too much pressure on ACIC for the material, Invamed's DMF access letter could be withdrawn. According to Patel, withdrawal of the access letter would have a «catastrophic effect on the company versus having the DMF and ANDA maintained» because «the ANDA would be kicked out and we'd be starting from ground zero.» Patel elected to wait until after the FDA approved Invamed's ANDA to pressure ACIC. **69**

[8] On July 31, 1996, Calenti sold the remaining 25% of ACIC company to Apotex Pharmaceutical Holdings Inc. In connection with the transaction, ACIC changed its name to Brantford Chemicals Inc. («Brantford») and continued the manufacturing and research side of the business under Apotex's management. Calenti formed a new company, ACIC Fine Chemicals, Inc. («ACIC Fine Chemicals») which, under Calenti's leadership, pursued the sales and agency side of the business. ACIC Fine Chemicals served as an exclusive sales representative for certain Brantford products.

E. Banyan Chemicals

By May 1995, Invamed had decided to develop a process to produce clathrate internally and to transfer that knowledge to Banyan Chemicals (Private) Ltd. («Banyan»), an Indian API manufacturer located in Baroda, India and formed in the early 1990's.[9] 70

1. The 1992 MOU

On February 4, 1992, Invamed and Banyan executed a Memorandum of Understanding («Memorandum») regarding the development and supply of APIs by Banyan for Invamed. The Memorandum included provisions regarding product development, transfer of technology, training of personnel and the manufacturing and marketing of several bulk active drug substances. Under the Memorandum, which was to run seven years, Banyan agreed to manufacture three APIs for Invamed, supply Invamed's requirements of these APIs on an exclusive basis in the U.S., and develop such other drug substances that Invamed requested. The Memorandum further provided that all information transferred between Invamed and Banyan pursuant to the agreement would not be disclosed to third parties and would be kept «secret.» 71

2. The May 1995 Addendum

On May 16, 1995, Invamed and Banyan executed an Addendum to the Memorandum of Understanding («Addendum») that expanded the list of products covered by the original 1992 agreement to include clathrate. Invamed included warfarin sodium as one of the products covered by the Addendum because it had begun the product development process for warfarin sodium, wanted to pursue the product for eventual commercialization, and because it was «good business practice» to have a second source for clathrate. Invamed had a policy of having two raw material suppliers for every approved drug if possible. 72

To compensate Banyan for expenses incurred in modifying its plant to facilitate the manufacture of clathrate, Invamed agreed to «purchase [clathrate] from Banyan ... at a premium to the prevailing world market prices ... until such time as the additional costs are recouped by Banyan. ... » 73

The Addendum also provided that Invamed «shall be required to purchase 80% of its annual requirements for [clathrate] from Banyan after receiving formal approval from the U.S. Food and Drug Administration,» and gave Invamed «the option to purchase 100% of the annual requirements for [clathrate] from Banyan.» It also provided that «Banyan shall not sell any quantity of the Products directly to the U.S. market, nor shall they enter into any agreements to supply the Products to any third party for sale into the U.S. market for the duration of [the] Agreement.» The advantage to Invamed of entering into an exclusive relationship with Banyan was that Invamed would have a guaranteed supply of raw material, and would be guaranteed 74

[9] Defendants allege that Patel and other principals in Invamed personally invested in Banyan, but plaintiffs deny this connection. Invamed did state that Banyan was vertically integrated with it.

the quantity of raw material it required without having to share Banyan's production capacity with other customers and risk the non-availability of raw materials.

At the time, Invamed did not tell ACIC of the Banyan contract, as was consistent with Invamed's business practice. In addition, Invamed's rights and obligations relating to clathrate would come into existence only if and when Banyan produced clathrate and supplemental ANDA approval. In 1995, Banyan had not produced clathrate and did not know how to do so. Invamed did not consider Banyan to be a viable supplier because it was not capable of producing warfarin sodium so as to permit Invamed to obtain FDA approval and enter the market in a timely fashion. Banyan's factory was completed in the first quarter of 1997, and Banyan filed a DMF for clathrate in mid-1998. 75

F. Other Potential Suppliers

Defendants claim that other suppliers were able to supply clathrate or could have gained the competence to supply clathrate besides the ones mentioned above. 76

1. Taro Pharmaceuticals

Since 1996, Taro Pharmaceuticals Industries Ltd. has manufactured clathrate that conforms to USP standards. During each year from 1996–1998, Taro manufactured between 25–50 kilograms of clathrate for sampling purposes and for research and development. On November 18, 1997, Taro submitted a DMF to the FDA for clathrate. 77

Taro has had no dealings with Invamed with respect to clathrate. Invamed was aware of Taro at least by 1997, when Taro attempted to contact Invamed. Patel did not return Taro's telephone calls because he did not want to divulge any information on warfarin to Taro.

Taro launched its own finished-dosage generic warfarin sodium tablets in the United States in September 1999, using its own internally developed source of clathrate. Plaintiffs dispute whether Taro had the capacity to manufacture 400 kilograms of clathrate for other customers and whether Taro has offered to sell clathrate to other pharmaceutical companies.

2. API Manufacturers Willing to Produce Clathrate

a. Diosynth/Rosemont

Since 1996, Diosynth has been capable of manufacturing commercial quantities of clathrate if provided with a non-infringing process, synthesis or formulation by a pharmaceutical company. Since 1997, through its own internally developed process, Diosynth has been capable of supplying pharmaceutical manufacturers with sufficient quantities of clathrate so that they could engage in the commercial development and manufacture of warfarin sodium tablets. In September 1999, Diosynth filed a DMF for clathrate. 78

Diosynth has had no dealings with Invamed or Apothecon with respect to clathrate. Invamed did not pursue Diosynth as a source for clathrate because of «the ownership between

Rosemont and Akzo [-Nobel].» Patel also testified that before February 1998 he did not know that Diosynth was a potential supplier

b. Chemagis

Chemagis offered to manufacture clathrate for Invamed. Plaintiffs dispute whether it was capable of timely doing so. 79

c. Lachema

In December 1997, Invamed received samples of clathrate from Lachema, which filed in December 1996 for a DMF for clathrate. Invamed tested the samples and determined them to be suitable for use. On February 26, 1998, Invamed placed an order with Lachema's agent Chemapol for 15 kilograms of clathrate for research and development. 80

Invamed revised the terms and conditions attached to a purchase order for Lachema. The revised attachment included several new provisions: 81

> «In an event, LACHEMA a.s. decides to discontinue the manufacturing of WARFARIN SODIUM CRYSTALLINE CLATHRATE USP, LACHEMA a.s. guarantees to supply this material for a period of not less than eighteen (18) months, or until an alternate source is qualified by Invamed and approved by U.S. FDA, whichever is longer.»
>
> * * *
>
> LACHEMA a.s. agrees to maintain a continuous supply of [the API] to satisfy the future requirements of Invamed Inc. except for:
>
> a) Causes beyond its reasonable control
>
> b) acts of God
>
> «The supply of WARFARIN SODIUM CRYSTALLINE CLATHRATE USP by Lachema a.s. to Invamed shall be construed as an acceptance by Lachema a.s. of all terms and conditions of this agreement.»

At the advice of counsel, Invamed included this language because it wanted to ensure continuity of supply.

Lachema issued a DMF reference letter to Invamed in March 1998. At least one internal Lachema document states that, as of March 1998, Invamed was «prepared to enter into a 3 to 5 year Contract for supplies of Warfarin Sodium Clathrate.» The document further states that Lachema agreed to «maintain a continuous supply of [clathrate]» (200–300 kg per month) «to satisfy the future requirements of Invamed.» 82

Invamed never received the 15–20 kilograms of clathrate it ordered from Lachema. When the material was not delivered for 6–9 months, Invamed learned from Lachema that the «Eastern

Europe block bureaucracy» had accounted for the delay. Invamed then rejected the offer to take the material.

d. Arenol

During the 1995–97 time-frame, Arenol manufactured APIs including amphetamines and methamphetamines. Based upon one eight hour shift per day, five days per week, Arenol's plant was capable of producing 5,000 kilograms of any API in a given year. Arenol could have increased this capacity by adding shifts, if it so desired. However, Arenol never filed a DMF for clathrate and plaintiffs dispute that Arenol had the ability to produce clathrate in 1995. 83

Arenol engaged a consulting chemist to develop the process for producing clathrate in 1997. The chemist developed a procedure for the commercial manufacture of clathrate in mid-1998. Using the chemist's process, Arenol manufactured three 15 kg pilot batches of clathrate. The batches that were manufactured were USP compliant.

In 1997, Apothecon's Doug Hamilton learned that Medea had transferred its warfarin sodium technology to Arenol and that Arenol had manufactured USP-grade batches of clathrate and had 10 to 12 DMFs on file for other products. Arenol informed Hamilton that Arenol could produce USP-grade clathrate batches by the first quarter of 1998. In August 1998, a fire destroyed Arenol.

e. Vinchem

In December 1997, Vinchem, a broker of raw materials, offered Invamed an exclusive clathrate supply contract in November 1997, and offered to supply 15 kg of clathrate in three shipments of 5 kg each, beginning in March 1998. Invamed ultimately decided not to pursue Vinchem because Patel believed Vinchem would not be a viable supplier of clathrate. Invamed did not investigate to determine whether Vinchem had access to a viable source of clathrate. Prior to this time, Invamed had purchased other APIs from Vinchem. 84

IV. Invamed Turns to Hoechst for Additional Clathrate to Complete Its Product Development

Beginning in December 1995, Invamed began discussions with Hoechst, which had by then developed an acceptable process for manufacturing clathrate. In early 1996, Hoechst completed product development work at its Coventry, Rhode Island facility. Hoechst then determined it would be able to manufacture approximately 1,000 kilograms of clathrate per year. 85

At the time, Hoechst was willing and able to enter into a long-term supply contract with Invamed for clathrate. Hoechst, however, wanted an exclusive supply agreement, to which Invamed would not agree. The parties also could not agree on a firm price. As a result, Hoechst would only sell Invamed clathrate on a «spot» basis, from purchase order to purchase order. 86

On January 12, 1996, Invamed submitted a purchase order to Hoechst for 14 kg of clathrate Invamed needed for its warfarin sodium development work. Unlike its standard purchase order, however, and despite the lack of any prior agreement, Invamed included a handwritten 87

notation on the face of the purchase order that read: «It shall be obligatory on the part of Hoechst Celanese Corporation to supply the material as of now and for a period of three years after the approval of the ANDA and in case Hoechst Celanese decides to discontinue product a period until an alternate source is qualified and approved by the FDA.» The attachment also required Hoechst to supply a DMF referral letter.

On January 17, 1996, Hoechst's sales representative, Gary Moss («Moss»), advised Dave and Patel that the additional «obligation» language in the purchase order was unacceptable. Moss further advised that Invamed's order would be put on hold until some «significant items» were resolved, including the state of Hoechst's production, the progress on its DMF and technical materials (which were months away), and the price of the product. Ultimately, Hoechst returned the revised purchase order to Invamed with the language regarding the supply obligation stricken, and shipped the product. **88**

On March 29, 1996, Invamed submitted a purchase order to Hoechst for 8 additional kilograms of clathrate. The purchase order contained no commitment language. Invamed submitted the purchase order to Hoechst because ACIC/Brantford had not responded to its earlier request and because Patel believed ACIC would not supply that amount to Invamed. **89**

Invamed used this Hoechst material for its warfarin sodium development, and in April began manufacturing warfarin sodium tablets using Hoechst's clathrate to complete its product development work and its ANDA. Patel stated that «Hoechst was a suitable alternative to ACIC.»[10] **90**

V. Invamed Files Its Warfarin Sodium ANDA

On June 14, 1996, Invamed submitted its ANDA for warfarin sodium to the FDA. Invamed listed ACIC as its source for raw material and included the DMF reference letter ACIC had sent in April 1995. Plaintiffs relied on the alleged repeated representations by ACIC/Brantford that it would supply commercial quantities of clathrate to Invamed and the purported industry practice that it would do so. **91**

On June 28, 1996, Invamed and Apothecon entered into an exclusive five-year Development and Supply Agreement in connection with the manufacture and marketing of a number of generic pharmaceuticals, including warfarin sodium. In that agreement, Invamed contracted to manufacture warfarin sodium for Apothecon, which Apothecon would then market to its customers. Invamed received $2.1 million up front and was to be paid a transfer price for the tablets it made for Apothecon plus a percentage of the profits.[11] The timetable attached to the agreement targeted June 1997 as the date for FDA approval of Invamed's ANDA for warfarin sodium, and listed August 1995 as the date the «drug substance vendor» had been **92**

[10] Hoechst sold its Coventry facility and its clathrate business to Napp Technologies, Inc. («Napp») in 1998. Napp provided clathrate to Invamed in June 1998.

[11] Plaintiffs claim that this agreement constituted a joint venture. They note that they referred to the agreement as a «joint venture» and «partnership,» and they shared losses. Plaintiffs do not allege that they shared any joint ownership, however.

«contracted.» As of August 1995, Invamed had executed a written contract with only Banyan, which did not have the capability of producing clathrate at the time.

On July 29, 1997, Getrajdman e-mailed a press release to Dave regarding Barr's launch of warfarin sodium. In his e-mail, Getrajdman indicated that he would «commence [his] pressuring of the manufacturer again, as they promised to review the possibilities after launch.» 93

Also on July 29, 1997, after Invamed and Apothecon held a warfarin marketing meeting, raw material sourcing remained as an item requiring action from Invamed. A subsequent Apothecon warfarin launch proposal similarly noted «Raw Materials Still Not Secured» and further listed «Secure Raw Materials!» as the first of many items on a list entitled «What We Need To Do.» 94

In late September, Dave and Patel informed Doug Hamilton, Apothecon's Director of Sourcing («Hamilton»), that they expected ANDA approval any day, but that Invamed had no contract in writing with ACIC/Brantford. Hamilton was also informed that pricing on clathrate was «[approximately] $3500/kg ... Invamed even fuzzy here.» Invamed also identified its plan to obtain clathrate: «get approval then place order with ACIC. Take things from there.» 95

By this time, Apothecon had forecasted 1997–1999 warfarin sodium sales of between $87 million and $112 million. 96

VI. Invamed Arranges for Other Clathrate Suppliers after the Submission of Its ANDA

A. Invamed Requests Additional Clathrate from Hoechst

In July 1996, Invamed provided information about its ANDA filing and relayed its clathrate needs and timing to Gary Moss of Hoechst. As Moss reported in a memorandum to his supervisor, Invamed's original plan «was to submit their ANDA based on» other clathrate and substitute Hoechst's material «at the appropriate time to the FDA without losing time on the ANDA/SNDA approval.» Moss wrote that Invamed never communicated the exact need of volume and time when asked on two separate occasions until July. He also stated that Patel threatened to go to ACIC if Hoechst could not supply clathrate by November. Hoechst submitted its DMF for clathrate in August 1996. 97

B. Invamed Develops a Manufacturing Process for Clathrate

In July 1996, Patel asked Dr. Chandra Kasireddy, one of Invamed's senior research scientists («Kasireddy»), to develop a process for manufacturing clathrate. Patel intended to provide this process to another supplier that would manufacture the product for Invamed. By November 1996, Dr. Kasireddy had performed several tests and found it a «simple process» to prepare clathrate in conformance with Invamed's specifications. Kasireddy prepared a document that summarized his process. 98

C. Invamed Hires a Broker to Locate Manufacturers

Invamed hired Ceres Chemical, a chemicals broker, to find potential clathrate manufacturers. 99

1. Invamed's Negotiations with Pharmeco

In the summer of 1996, Ceres put Invamed in touch with Pharmeco, a Boston area chemical manufacturer, about manufacturing clathrate for Invamed using Kasireddy's process. In September 1996, Invamed entered into a Non-Disclosure Agreement with Ceres and Pharmeco concerning their warfarin sodium discussions. Pharmeco, however, ultimately declined to enter into an agreement to manufacture clathrate for Invamed based on environmental and safety issues relating to the product. 100

2. Invamed's Negotiations with Chemagis

Ceres also brought Chemagis, an Israel-based manufacturer of raw materials, to Invamed's attention. In the fall of 1996, Patel and Yashvant Patel met with Chemagis to discuss the possibility of Chemagis's manufacturing clathrate for Invamed and entered into a Non-Disclosure Agreement with Ceres and Chemagis regarding their warfarin sodium discussions. Patel provided Chemagis with a flowchart of the process involved. 101

In or around November 1996, Chemagis offered to enter into an agreement with Invamed for the supply of clathrate. Chemagis offered to manufacture clathrate for Invamed if Invamed would pay for certain costs associated with setting up a separate manufacturing facility, which Chemagis estimated would take approximately eight months, and bear some of the expenses involved in obtaining a DMF approval. Invamed rejected this proposal because it did not want to pay for the up-front costs and because it was concerned that Chemagis's time-frame to set up the manufacturing process was too long. Invamed had no further communication with Chemagis regarding warfarin sodium.

D. Banyan Begins Manufacturing Clathrate

In March 1997, Kasireddy went to India to train Banyan personnel in the process he had developed for synthesizing clathrate. By the end of May 1997, Kasireddy had produced acceptable pilot-plant scale batches in the Banyan facility. 102

On September 24, 1997, when Invamed knew its ANDA approval was imminent, Invamed ordered 29.5 kilograms of clathrate from Banyan at $4,000 per kg. Invamed planned to supplement its ANDA with Banyan's clathrate. The next day, the idea to present a «hardship case» to the FDA for expedited approval was raised in a meeting with Apothecon.

The FDA inspected Banyan's plant in connection with the manufacture of clathrate in September 1998.

E. Invamed Enters a Supply Agreement with Shanghai Shenxing

In July or August 1996, Invamed had requested that ChemWerth, a pharmaceutical manufacturers' representative and consultant, develop an FDA-approved source of clathrate 103

for Invamed. ChemWerth advised Invamed that a Chinese manufacturer known as Shanghai Shenxing (also known as Shanghai # 16) («Shanghai») was capable of producing clathrate that complied with USP, and offered Invamed an exclusive supply arrangement. On December 5, 1996, ChemWerth received its first sample of USP clathrate from Shanghai.

On April 8, 1997, Invamed received from ChemWerth samples of Shanghai clathrate, that were tested and found to be of very good quality. ChemWerth also sent a written proposal to Invamed for a three-year supply of clathrate from Shanghai. ChemWerth sent a letter to Invamed confirming Invamed's verbal commitment to use Shanghai as a source for clathrate on May 1, 1997. However, later in 1997, Patel told ChemWerth to put its development of the Shanghai source «on hold» when Banyan began producing clathrate.

VII. Invamed's ANDA Is Approved and It Submits a Purchase Order to Brantford for 750 kg of Clathrate

A. Invamed Submits a Purchase Order to Brantford

On September 30, 1997, Invamed received approval from the FDA for its warfarin sodium ANDA. The next day, October 1, 1997, Invamed submitted a $1,875,000 purchase order to ACIC Fine Chemicals for 750 kilograms of clathrate in three shipments of 250 kilograms each, at a price of $2,500 per kilogram.[12] The purchase order requested that the first shipment be delivered «as soon as possible (rush order)» and that the second and third shipments be delivered on January 1, 1998 and April 1, 1998, respectively. 104

Invamed's purchase order was accompanied by a cover letter to Getrajdman in which Invamed informed Getrajdman that it had received FDA approval to manufacture and distribute warfarin sodium tablets. The letter requested that ACIC Fine Chemicals, Inc. supply Invamed with clathrate pursuant to the purchase order enclosed and made reference to an «agreement» for the supply of clathrate. 105

No one at Invamed advised Getrajdman in advance of the purchase order. Prior to submission of the purchase order, Invamed made no inquiries regarding Brantford's availability or capacity to manufacture clathrate, its campaign schedule,[13] or its price. Invamed also did not keep ACIC informed of Invamed's anticipated launch date, commercial requirements or delivery forecasts. Before it submitted its purchase order, Invamed did not provide ACIC with a projection of its commercial or launch quantities, and did not discuss with Brantford the price, quantity, annual requirements, payment terms, delivery schedule, packaging or labeling 106

[12] Although it was not Patel's practice to send purchase orders by certified mail, he sent the October 1, 1997 purchase order by certified mail because he believed Brantford had a history of «playing games» with Invamed and because he was concerned that Brantford would be evasive in acknowledging its receipt.

[13] Brantford operates a multi-purpose facility that manufactures many different chemical products. It is in operation 24 hours a day, seven days a week. Brantford manufactures API in campaigns. A «campaign» means the completion of the various steps for a series of batches of the API within a given period of time. Campaigns avoid inefficiencies (such as equipment cleaning and validation) that result from changing the facility over from manufacturing one API to another. Brantford schedules campaigns based on requirements that have been identified by customers as well as lead times for the raw materials required for production.

requirements, or in any other way determine whether the terms were acceptable to Brantford.

There were no discussions at any time between Invamed and ACIC regarding a guarantee by Invamed to purchase clathrate from ACIC or Brantford. Patel never asked Getrajdman or Calenti about the possibility of entering a written supply contract, and Invamed never sought or discussed an exclusive with ACIC or Brantford. 107

B. Brantford Rejects Invamed's Purchase Order

In early October 1997, James Berhalter, Brantford's new director of finance and administration («Berhalter») received the order. Plaintiffs claim that upon receipt of the letter ACIC/Brantford immediately advised Barr that Invamed was seeking to purchase clathrate. 108

On October 16, 1997, Patel sent letters to Calenti and Berhalter threatening legal action against ACIC Fine Chemicals, Inc. and Brantford if Invamed did not receive clathrate from ACIC by October 20, 1997. Berhalter was wary of dealing with Invamed because of Brantford's earlier problems with Invamed. After conferring with the company's president, Dr. Murthy, Berhalter decided to reject Invamed's purchase order and sent a letter to Invamed to that effect on October 20, 1997. ACIC/Brantford thereafter refused to accept Invamed's orders, and plaintiffs learned for the first time that ACIC/Brantford would not supply clathrate to Invamed as a result of its agreement with Barr. 109

Plaintiffs claim that ACIC/Brantford had the capacity to manufacture clathrate for plaintiffs and would have filled plaintiffs' order if not for its agreement with Barr. ACIC/Brantford had planned the production of 1100 kilograms of clathrate in the fall of 1997, even though Barr had only requested 900 kilograms. In fact, it was unable to produce 1100 kilograms because it did not obtain timely delivery of raw material. 110

VIII. Invamed Obtains Expedited FDA Approval to Include Banyan and Apothecon Launches Its Product

Upon learning that they would not obtain clathrate from ACIC/Brantford, plaintiffs determined that the fastest way to get to market was to assist Banyan in developing a processfor manufacturing clathrate. 111

A. Invamed Supplements Its ANDA with Banyan's Clathrate

On May 2, 1998, Banyan submitted its DMF, compiled with Invamed's assistance, to the FDA. On May 13, 1998, Banyan sent the FDA a DMF reference letter for Invamed. 112

Three days later, on May 16, 1998, Invamed submitted a supplement to its ANDA seeking approval to manufacture warfarin sodium tablets using Banyan clathrate. Invamed sought expedited approval of this supplement. Invamed's supplement to its ANDA to add Banyan as a supplier was approved on October 8, 1998, and Apothecon began marketing warfarin sodium tablets on October 21, 1998. Plaintiffs claim that its entry caused the price of generic warfarin sodium to decline substantially.

At the time, Barr had been selling its product for sixteen months. Plaintiffs claim that, as a result, Barr had the «first mover's» advantage, and that customers were unwilling to switch to plaintiffs' product even though its price was lower than Barr's.

B. Invamed Supplements with Shanghai's Clathrate

On October 8, 1997 Invamed submitted a purchase order to ChemWerth for thirty kilograms of Shanghai's clathrate. Prior to submission of the purchase order, Patel and Dave discussed price, quantity and delivery date particulars with ChemWerth representatives. Invamed used the clathrate obtained from Shanghai to make several trial batches of dosage form warfarin sodium. This material met Invamed's specifications. 113

Invamed ordered an additional fourteen kilograms of Shanghai's clathrate from ChemWerth on March 13, 1998 and an additional sixteen kilograms on April 13, 1998. ChemWerth submitted a DMF reference letter for Invamed to the FDA on May 29, 1998. On July 14, 1999, Invamed filed a supplement to its ANDA to add Shanghai's clathrate.

IX. The Warfarin Sodium Market

A. Plaintiffs Recognize that Generic Warfarin Sodium Competes with Coumadin

Apothecon's marketing, training, and business documents state that (1) «This product ... will compete with the innovator product, DuPont's Coumadin»; (2) the «competition» is «Coumadin» and «Barr's warfarin»; (3) the «introduction of Barr's warfarin and [Apothecon's] warfarin sodium has placed Coumadin in a defensive position for the first time»; (4) Apothecon's two «competitors» are DuPont and Barr; (5) the «competition» for Apothecon's generic warfarin sodium is «Barr's warfarin and Coumadin»; (6) Apothecon's generic warfarin sodium product is «NO DIFFERENT THAN [THE] INNOVATOR PRODUCT!!!» 114

Sales representative training materials issued by Apothecon contain competitive analyses of Coumadin and also specifically addressed strategies and selling points regarding the substitution of Apothecon's warfarin sodium product for Coumadin.

For the following facts, plaintiffs state that «[i]n light of the material facts discussed in Plaintiffs' affirmative statement, there exists a genuine issue to be tried as to whether Coumadin competes in the same market as generic warfarin sodium.» As discussed above, this Court will accept the facts below despite this response because the plaintiffs failed to point to specific material facts in its affirmative statement to support the existence of a triable issue of material fact. 115

Apothecon presented its generic product as «a reliable, predictable, lower-cost bioequivalent alternative to Coumadin,» and highlighted its AB-rated therapeutic equivalence to the brand and its adoption of DuPont's content-uniformity standards. 116

Apothecon and Invamed personnel admit that their warfarin sodium competes against Coumadin and Barr's warfarin sodium. Patel agreed that with respect to warfarin sodium, «the other competitors in the marketplace are Barr and DuPont.» 117

In setting prices for its warfarin sodium, Apothecon considered and compared its own prices with that of Coumadin. For example, in a memorandum from March 1999, Joseph Grotzinger stated: «Apothecon recently learned that both of our competitors (brand and generic) have raised their wholesale list prices. This action has resulted in a competitive disadvantage to Apothecon. ... It is recommended that the attached list prices be established for Apothecon's Warfarin Sodium Tablets.» 118

Apothecon actively attempted to switch customers using Coumadin to the Apothecon product. Apothecon had market share programs providing financial incentives to customers in order to increase the amount of plaintiffs' product dispensed as a percentage of «all warfarin sodium tablets dispensed.» 119

In analyzing their potential and actual market share, Apothecon routinely included plaintiffs' warfarin sodium, Barr's warfarin sodium, and Coumadin in one market. Upon the launch of plaintiffs' product, for example, Apothecon analyzed total warfarin sodium sales and market share, defining the total market to include both Coumadin and Barr. In February 1999, Apothecon measured its share of new patient starts against both Barr and Coumadin. In October 1999, Apothecon examined its share of new and total prescriptions for warfarin sodium – including Coumadin and Barr in both categories of the market. 120

Apothecon's sales of generic warfarin sodium, as well as its market share, come at the expense of Coumadin, the branded version of warfarin sodium. Generic warfarin sodium takes market share from Coumadin as a result of the generic's lower price and conversion incentives offered to encourage switching. 121

This is the end of one section that plaintiffs dispute because they claim that there exists a genuine issue to be tried as to whether Coumadin competes in the same market as generic warfarin sodium. As discussed, supra, plaintiffs have failed to prove that such issue of material fact exists. 122

B. Relative Growth Of Brand And Generic Warfarin Sodium Sales

Total warfarin sodium sales grew from 3.41 billion milligrams in 1998 to 3.53 billion milligrams in 2000, an increase of 0.13 billion milligrams. From 1998–2000, annual sales of generic warfarin sodium increased by approximately 0.57 billion milligrams, while sales of Coumadin decreased by approximately 0.45 billion milligrams. The growth in generic warfarin sodium sales thus exceeded the growth in total warfarin sodium sales. Consequently, at least 77 percent of the increase in generic warfarin sodium sales realized between 1998 and 2000 came directly from former Coumadin sales. 123

C. DuPont Recognizes that Coumadin Competes with Generic Warfarin Sodium

Prior to the launch of either the Barr or Apothecon generic warfarin sodium products, DuPont conducted research and concluded that the «Availability of a Generic Sodium Warfarin Will Impact Coumadin Sales.» In addition, DuPont set forth strategies and selling points to be implemented immediately after generic availability. DuPont responded to Barr's entry by implementing incentive and rebate programs to encourage numerous wholesalers and 124

retailers to purchase Coumadin instead of Barr's generic warfarin sodium. DuPont considered launching, and could have launched at the same time as a generic competitor, its own generic warfarin sodium product. DuPont priced Coumadin as a generic for certain customers.

On March 22, 1996, DuPont requested that the USP tighten its content uniformity specifications for warfarin sodium tablets so that generic manufacturers would have to utilize the stricter content uniformity manufacturing standards for warfarin sodium utilized by DuPont. In March and July 1997, the USP denied DuPont's request. DuPont also petitioned state legislatures and formulary boards to place restrictions on the substitutability of NTI drugs such as warfarin sodium. 125

On September 18, 1996, DuPont filed a Petition For Stay of Action with the FDA asking that approval of any pending applications for generic warfarin sodium be stayed until such time as the FDA adopted new, more restrictive bioequivalence approval standards for generic warfarin sodium. In its Petition, DuPont also noted that its content uniformity specifications for warfarin sodium were stricter than those set forth by the USP and proposed that the FDA adopt DuPont's stricter standards. Concluding that the standards DuPont proposed «were neither necessary nor appropriate,» on March 25, 1997, the FDA rejected DuPont's request. 126

On July 28, 1997, the date on which Barr came to market with its generic warfarin sodium product, DuPont issued a press release warning that «if warfarin sodium products are interchanged, patients should receive additional blood tests to ensure the amount of drug in their blood stream is appropriate for their condition.» The press release also stated that Barr «focuse[d] on producing a 'cheaper' » product while DuPont «focuses on patient safety and education and the future health of ... patients.» DuPont repeated its claims in nationwide communications to physicians and pharmacists, to the FDA and to industry regulators. 127

In an August 26, 1997 letter to DuPont, the FDA called DuPont's Coumadin promotional activities «false and misleading.» Specifically, the FDA criticized DuPont's suggestion that generic warfarin sodium was not therapeutically equivalent to Coumadin. The FDA stressed that «[a]ll FDA approved dosage forms of generic drugs classified as therapeutically equivalent and coded AB can be substituted for the reference product with the full expectation that the substituted product will produce the same clinical effect and safety profile.» 128

D. Barr Competes against DuPont

Barr sponsored two clinical studies that separately established the interchangeability of Barr's product for DuPont's Coumadin and disseminated the studies' findings to physicians, pharmacists and other health care providers.[14] Barr also disseminated the positive results of a third clinical study on product interchange (between Barr's product and Coumadin) that had been conducted by an independent organization. 129

[14] Barr, among other things, utilized direct mailings, physician panels, journal advertising in both trade and medical publications, trade show seminar booths, telemarketing, and continuing education courses involving live panelists of pharmacists. Barr also implemented a toll-free «Warfarin Hotline» available to patients, physicians, and other care givers.

Barr extended numerous discounts and incentives to customers in order to encourage pharmacies to switch Coumadin sales to generic sales of warfarin sodium tablets.

In determining its own price for warfarin sodium, Barr considered and analyzed the price of Coumadin. Barr even adjusted the price of its generic warfarin sodium prior to launch in response to a Coumadin price increase so that Barr's price could be sustained at 70% of the price of Coumadin.

X. Market Share Data

As of March 2001, Barr accounted for close to 80 percent of the generic warfarin sodium sales. 130

Its representation in the total sales of generic and branded warfarin sodium is consistently lower. At the end of 1997, Barr's share was 8%. It grew to 15% at the end of 1998 and 18% at the end of 1999. At the end of 2000, Barr's share was 24%, dropping to 20% in March 2000. By contrast, at the end of 2000, Apothecon's share of the total sales of generic and branded warfarin sodium was 5% and Taro's share was 3%.

Discussion

Jurisdiction

This Court has jurisdiction pursuant to 28 U.S.C. § 1337 in that it involves a federal question under the antitrust laws of the United States, particularly the Sherman Antitrust Act, 15 U.S.C. § 1 et seq. and sections 4, 7 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 18, & 26 and pursuant to this Court's supplemental jurisdiction under 28 U.S.C. § 1367(a) and Rule 18(a) of the Federal Rules of Civil Procedure. 131

Standards for Summary Judgment

Rule 56(e) of the Federal Rules of Civil Procedure provides that a court shall grant a motion for summary judgment «if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits ... show that there is no genuine issue as to material fact and that the moving party is entitled to a judgment as a matter of law.» Fed.R.Civ.P. 56(e); *Celotex Corp. v. Catrett,* 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); *Silver v. City Univ.,* 947 F.2d 1021, 1022 (2d Cir. 1991). «The party seeking summary judgment bears the burden of establishing that no genuine issue of material fact exists and that the undisputed facts establish her right to judgment as a matter of law.» *Rodriguez v. City of New York,* 72 F.3d 1051, 1060–61 (2d Cir. 1995). In determining whether a genuine issue of material fact exists, a court must resolve all ambiguities and draw all reasonable inferences against the moving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); *Gibbs-Alfano v. Burton,* 281 F.3d 12, 18 (2d Cir. 2002). 132

[1] Plaintiffs contend that summary judgment is inappropriate in complex antitrust litigation, relying on *Poller v. Columbia Broad. Sys., Inc.,* 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962) (holding that summary judgment was often inappropriate in antitrust cases because of the emphasis on motive, intent, hostile witnesses, and the fact that the proof is largely in the 133

hands of the alleged conspirators). Following *Matsushita,* 475 U.S. at 578, 106 S.Ct. 1348, *Anderson v. Liberty Lobby,* 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986), and *Celotex,* 477 U.S. at 323-24, 106 S.Ct. 2548, however, the federal courts have confirmed that summary judgment is a useful tool to «isolate and dispose of factually unsupported claims» in antitrust cases. *Virgin Atlantic Airways, Ltd. v. British Airways PLC,* 257 F.3d 256, 262 (2d Cir. 2001) (recognizing the difficulty of granting summary relief in antitrust cases but upholding district court's grant of summary judgment); see also *H.L. Hayden Co. v. Siemens Med. Sys., Inc.,* 879 F.2d 1005, 1011–12 (2d Cir. 1989) («Both the Supreme Court and [the Second Circuit] have encouraged the use of summary judgment in complex cases to avoid unnecessary trials.»). As discussed below, the antitrust claims in this case may be resolved without regard to issues of intent or motive and without reliance on facts in the hands of defendants or hostile witnesses.

I. Monopolization and Attempted Monopolization

Plaintiffs' monopolization claims relate both to the warfarin sodium product and to the clathrate used to make such products. Counts 1 and 2 (monopolization and attempted monopolization) accuse Barr and ACIC/Brantford of violating § 2 of the Sherman Act by using their «monopoly power» in the clathrate market to foreclose competition in the «market(s) for generic warfarin sodium and/or branded and generic warfarin sodium. ... » **134**

[2][3][4] The offense of monopolization under § 2 of the Sherman Act has two elements: «(1) possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident.» *United States v. Grinnell Corp.,* 384 U.S. 563, 570–71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966). The offense of attempted monopolization requires plaintiffs to prove «(1) that the defendant has engaged in predatory or anti-competitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.» *Spectrum Sports, Inc. v. McQuillan,* 506 U.S. 447, 456, 113 S.Ct. 884, 122 L.Ed.2d 247 (1993). In order to determine whether there is a dangerous probability of monopolization, courts consider the relevant market and the defendant's ability to lessen or destroy competition in the market. *Id.* **135**

A. Warfarin Sodium

1. The Relevant Market

The first step in assessing whether a defendant possesses monopoly power is to define correctly the relevant market in which that power is allegedly being exercised. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,* 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965) («[W]ithout a definition of that market, there is no way to measure [a defendant's] ability to lessen or destroy competition.»); *Berkey Photo, Inc. v. Eastman Kodak Co.,* 603 F.2d 263, 268 (2d Cir. 1979) («[T]he first step in a court's analysis must be a definition of the relevant market.») (citing *United States v. E.I. du Pont de Nemours & Co.,* 351 U.S. 377, 391–93, 76 S.Ct. 994, 100 L.Ed. 1264 (1956)). **136**

Plaintiffs' § 2 claims turn on whether the relevant market is comprised solely of generic warfarin sodium or whether it includes the branded warfarin sodium (Coumadin).

[5] The relevant market for purposes of antitrust litigation is the «area of effective competition» within which the defendant operates. *Tampa Elec. Co. v. Nashville Coal Co.,* 365 U.S. 320, 327–28, 81 S.Ct. 623, 5 L.Ed.2d 580 (1961). As the Court explained in *E.I. du Pont de Nemours*: 137

> «The market which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration. The tests are constant. The market is composed of products that have reasonable interchangeability for the purposes for which they are produced – price, use and qualities considered.» 351 U.S. at 404, 76 S.Ct. 994.

[6] Products need not be identical to be part of the same market. *Id.* at 394, 76 S.Ct. 994 («[W]here there are market alternatives that buyers may readily use for their purposes, illegal monopoly does not exist merely because the product said to be monopolized differs from others.»). Two products or services are reasonably interchangeable where there is sufficient cross-elasticity of demand. *Brown Shoe Co. v. United States,* 370 U.S. 294, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962) («The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.»). 138

> «Cross-elasticity of demand exists if consumers would respond to a slight increase in the price of one product by switching to another product.» *AD/SAT, Div. of Skylight, Inc. v. Associated Press,* 181 F.3d 216, 227 (2d Cir.1999); *Ally Gargano/MCA Adver., Inc. v. Cooke Props., Inc.,* No. 87 Civ. 7311 (RWS), 1989 WL 126066, at *21 (S.D.N.Y. Oct.13, 1989)

[7] Within the relevant markets, there may also exist «well-defined submarkets[15] ... which, in themselves, constitute product markets for antitrust purposes.» *Brown Shoe,* 370 U.S. at 325, 82 S.Ct. 1502. A submarket may be determined by examining such practical indicia as (1) industry or public recognition of the submarket as a separate economic entity, (2) the product's peculiar characteristics and uses, (3) the unique production facilities, (4) distinct customers, (5) distinct prices, (6) sensitivity to price changes, and (7) specialized vendors. *Id.* 139

[8] Plaintiffs argue that generic warfarin sodium products are a well-defined submarket within the larger warfarin sodium market. The issue of generic and branded pharmaceuticals has been discussed by other courts in antitrust cases. 140

For instance, the District Court for the Eastern District of Michigan addressed the issue of competition between branded drugs and their generic equivalents. 141

> «Cardizem CD and its AB-rated generics are identical in all material respects. AB-rated generics are freely substitutable and interchangeable with their brand name

[15] Many courts today avoid the term «submarkets» as potentially confusing. E.g., *Allen-Myland, Inc. v. Int'l Business Machines Corp.,* 33 F.3d 194, 208 n. 16 (3d Cir. 1994); *FTC v. Staples, Inc.,* 970 F.Supp. 1066, 1080 n. 11 (D.D.C. 1997) («Whatever term is used – market, submarket, relevant product market – the analysis is the same.»).

counterparts. Industry experts describe them as perfect substitutes for the brand name drug. Defendants' hypotheticals (e.g., Seiko v. Rolex watches) are unavailing as they fail to recognize that the pharmaceutical market is fundamentally different from the market for other products. In the pharmaceutical industry, there is a government-assured complete interchangeability of drug products. This is why pharmacies are allowed to substitute the lower-priced generic versions of brand name drug products that have been demonstrated to the FDA to be therapeutically equivalent. Market behaviour, which shows generics capturing a significant percentage of the branded drug market soon after they are introduced, likewise supports the conclusion that the brand and generic drugs are essentially fungible and interchangeable. Cardizem CD and its generic bioequivalents are two interchangeable versions (one less costly than the other) of the same drug product. Antitrust law requires only that the two products at issue be close substitutes for each other. Cardizem CD and its generic bioequivalents meet this requirement.» *In re Cardizem CD Antitrust Litig.,* 200 F.R.D. 297, 310–11 (E.D.Mich. 2001).

142 See also *Barr Labs. Inc. v. Abbott Labs.,* 978 F.2d 98, 102 (3d Cir. 1992) (stating that jury determined that the relevant market included generic and branded erythoromycin); *In re Terazosin Hydrochloride Antitrust Litig.,* 203 F.R.D. 551, 558 n. 9 (S.D.Fla. 2001) (looking to price difference of branded and generic pharmaceutical in measuring overcharge because no material difference between branded and generic pharmaceutical product); *In re Warner Lambert Co.,* 87 F.T.C. 812, 877 (1976) (branded and unbranded thyroid products constituted a single product market despite the existence of price differences between the two products).

143 There is no dispute that the parties' generic warfarin sodium products are fully interchangeable with each other and with Coumadin. In order to obtain FDA approval, Barr, Taro, and plaintiffs were required to demonstrate that their generic warfarin sodium products were bioequivalent to Coumadin and have the same active ingredient, conditions of use, route of administration, dosage form, strength, and labelling. By law, generic sodium warfarin is sold with the same package insert as the brand and is subject to the same prescribing indications and warnings. Barr and the plaintiffs use the same tablet colors as Coumadin to signify different dosage sizes. Finally, Barr and Apothecon also conducted hospital-based studies demonstrating that their products had the same clinical effects as Coumadin.

144 The generic can be freely prescribed by doctors or substituted at the pharmacy in lieu of the brand. The Orange Book gives an AB rating to all generic warfarin sodium product available today. Consequently, generic warfarin sodium is eligible for unrestricted substitution for Coumadin under most state pharmacy regulations. *Inwood Labs., Inc. v. Ives Labs. Inc.,* 456 U.S. 844, 847 n. 4, 102 S.Ct. 2182, 72 L.Ed.2d 606 (1982) («Since the early 1970's, most States have enacted laws allowing pharmacists to substitute generic drugs for brand name drugs under certain conditions.»); E.g. Ariz.Rev.Stat. Ann. § 32-1963.01 (West 2001); Cal. Bus. & Prof.Code § 4073 (West 2001); N.Y. Educ. Law § 6810(6)(a) (West 2001).

145 Generic warfarin sodium and Coumadin are sold to the same customers, i.e., wholesalers, hospitals, retail pharmacy chains, mail order houses, clinics and managed care organizations.

There is no evidence that these consumers view the generic and branded drugs to be in two economically distinct markets.

Moreover, plaintiffs have admitted that their product competes with Coumadin and Barr's generic warfarin sodium. Barr and Apothecon price their products at a discount to Coumadin and in competition with each other. Apothecon produced extensive marketing, training and business documents that address in detail Apothecon's strategies for competing with Barr and DuPont. Apothecon has actively attempted to switch customers using Coumadin to its product by offering various incentive programs to promote Apothecon's product in competition with Barr and DuPont. Apothecon routinely included all generic products and Coumadin in one market when analyzing potential and actual market share. **146**

In addition, DuPont recognized that generic and branded warfarin sodium compete with each other for sales. DuPont designed and implemented its own marketing plans and incentive programs to meet the threat posed by generic warfarin sodium. Indeed, DuPont considered launching and could have launched its own generic warfarin sodium product. **147**

Barr, Apothecon and Taro have gained market share at the expense of DuPont. At least 77% of the increase in generic warfarin sodium sales realized between 1998 and 2000 came directly from former Coumadin sales. From July 1997 to November 2001, Coumadin's share fell from 92% to 61% of the market. **148**

In order to establish the existence of a submarket consisting solely of the generic sodium warfarin, plaintiffs primarily rely on a supposed price increase on the part of Coumadin and price decrease on the part of Barr's generic product after the plaintiff's entry into the market.[16] Yet, *Brown Shoe* itself rejected a market defined by price. There the merging parties contended that because they competed in different markets-medium-priced shoes and low-priced shoes – their merger would not reduce competition. The Court rejected this argument, holding that a division of the product lines based on «price/quality» was «unrealistic.» *Brown Shoe,* 370 U.S. at 326, 82 S.Ct. 1502; see also *Nifty Foods Corp. v. Great Atlantic & Pac. Tea Co.,* 614 F.2d 832, 839 & n. 13 (2d Cir. 1980) («It is even less realistic to make such division in this case where the two types of waffles are sold side by side in the same frozen food case and distinguished only by label and price, and not quality.»); *Twin City Sportservice, Inc. v. Charles O. Finley & Co., Inc.,* 512 F.2d 1264, 1274 (9th Cir. 1975) («The scope of the relevant market is not governed by the presence of a price differential between competing products»). **149**

Similarly, in Warner Lambert the FTC rejected the notion that branded and unbranded thyroid drugs were in separate product markets. The Administrative Law Judge («ALJ») had determined that «there are substantial differences in the way the two companies' products are manufactured, the customers and methods used in selling their products, the way they are priced, and, since they are sold only on prescription of a physician, the way they are dispensed to the ultimate user.» The FTC reversed the ALJ, reasoning: **150**

[16] The defendants aver that the prices remained the same for months before and after the plaintiff's entry into the market.

> «Although there may be lack of price elasticity between branded and unbranded products at existing price levels, we cannot assume that all physicians are so fixed in their prescribing habits that a substantial increase in the existing price differential between branded and unbranded thyroids would never cause some shift toward more prescriptions of the lower-priced USP thyroids. ... Also, we can take notice that some physicians, even if a minority, are conscious of price differences between generic and branded versions of the same or similar preparations since a substantial number will prescribe generic drugs despite promotions of branded varieties. We see no reason to believe that price would never enter into some physicians' decisions in the area of thyroid medication. It is not necessary that two products battle inch for inch on the same turf in order for them to be in the same market.» 87 F.T.C. at 877.

Significantly, the thyroid drugs in Warner Lambert were not AB rated and were, therefore, more susceptible to market distinctions than the products at issue here, which the FDA certifies as equivalent and interchangeable. **151**

The cases plaintiffs offer merely stand for the proposition that price and quality distinctions can be indicative of separate markets because the products are not interchangeable. E.g., *Beatrice Foods Co. v. FTC,* 540 F.2d 303, 309–10 (7th Cir. 1976) (noting absence of «clearly separate price grouping based on quality distinctions»); *United States v. Aluminum Co. of Am.,* 377 U.S. 271, 275, 84 S.Ct. 1283, 12 L.Ed.2d 314 (1964) («Insulated aluminum conductor is so intrinsically inferior to insulated copper conductor that in most applications it has little consumer acceptance.»). Here, the products at issue exhibit no quality differences and are fully interchangeable. **152**

In addition, plaintiffs' analysis of the separate market based on price ignores a number of factors. First, it does not explain why, often, branded drugs will raise their prices at the entrance of a generic drug into the market. Clearly there is some interrelationship. In addition, the analysis did not determine the effect on Barr's average price as a result of Apothecon's entry, did not calculate the impact of Apothecon's entry separately on the price of Coumadim, did not try to separate the effect of Apothecon's entry from other factors that may have contributed to Barr's changing prices, and failed to conduct a formal test regarding the degree of purported differential impact that Apothecon's entry had on the price of Barr's warfarin sodium and Coumadin. **153**

In a letter submitted after oral argument, plaintiffs offered a recent opinion holding that a triable issue of fact existed as to whether brand name and generic tires for vintage automobiles constituted separate submarkets. *Lucas Automotive Eng'g Inc. v. Bridgestone/Firestone Inc.,* 275 F.3d 762 (9th Cir. 2001). The case is distinguishable, however, in the lack of the evidence plaintiffs have offered in this case concerning the *Brown Shoe* analysis. In Lucas, the plaintiff presented evidence of physical differences between the products; the «brand name» tires are authentic reproductions of the tires originally sold on vintage cars while the «generic» private label brand tires are not. *Id.* at 765. Because enthusiasts value authenticity, this physical difference is significant. *Id.* at 767. The plaintiff also presented a declaration from defendant as well as defendant's own advertising material that revealed that the defendant marketed the brand name tires to distinct customers. *Id.* **154**

at 767–68. Finally, the plaintiff also presented deposition testimony from independent dealers and declarations from other tire manufacturers supporting plaintiff's proposed market definition. *Id.*

Here, there are no significant physical differences between the generic and branded pharmaceuticals. They are marketed to the same customers, and the market participants themselves define the competition to be between the generics and Coumadin. Therefore, plaintiffs' reliance on Lucas is misplaced. The relevant product market is the combined group of generic and the branded warfarin sodium. 155

2. Monopoly Power in the Relevant Market

[9] In order to demonstrate monopoly power, a plaintiff must show that defendant had a significant share of the market and that the market share could be sustained over time. *CDC Techs. Inc. v. IDEXX Labs. Inc.,* 7 F.Supp.2d 119, 130 (D.Conn. 1998), aff'd 186 F.3d 74 (2d Cir. 1999) (citing *Rebel Oil Co. v. Atlantic Richfield Co.,* 51 F.3d 1421, 1434–43 (9th Cir. 1995)); see also *United States v. Syufy Enter.,* 903 F.2d 659, 665–66 (9th Cir. 1990) («In evaluating monopoly power, it is not market share that counts, but the ability to maintain market share.») (emphasis in original); *Colorado Interstate Gas Co. v. Nat'l Gas Pipeline Co. of Am.,* 885 F.2d 683, 696 n. 22 (10th Cir. 1989) («[M]arket power must be persistent to make a firm a monopolist for purposes of the antitrust laws.»). 156

[10] During the time that plaintiffs claim their launch was delayed, from October 1997 to October 1998, Barr's share of the relevant market including branded and generic warfarin sodium grew from 11% to 14%. As of December 2000, Barr's share was about 24%. These percentages cannot support a claim for monopolization or attempted monopolization. E.g., AD/SAT, 181 F.3d at 229 (finding 20% market share insufficient for attempted monopolization); *United Air Lines, Inc. v. Austin Travel Corp.,* 867 F.2d 737, 742 (2d Cir. 1989) (holding 31% market share insufficient to constitute monopoly power); *Nifty Foods,* 614 F.2d at 841 (upholding summary judgment on monopolization and attempted monopolization claims where defendant had 33% market share); *Caldwell v. The American Basketball Ass'n,* 825 F.Supp. 558, 575 (S.D.N.Y. 1993) (finding 36% market share insufficient for monopolization claim to survive summary judgment). 157

Plaintiffs have relied on *Tops Markets, Inc. v. Quality Markets, Inc.,* 142 F.3d 90 (2d Cir. 1998). There, the Second Circuit reversed the entry of summary judgment on a claim of attempt to monopolize, notwithstanding its ruling that defendants lacked monopoly power. The Court reasoned that the defendant's large market share percentage at the time when defendant took other anticompetitive actions was sufficient to create a triable issue of fact as to whether there was a dangerous probability that the defendant would achieve monopoly power. *Id.* at 100–01. Here, however, Barr had only a market share of up to 8% at the times plaintiffs allege other anticompetitive actions. That percentage is insufficient as a matter of law to create a dangerous probability that Barr would achieve monopoly power in the applicable market as defined here. 158

For these reasons, claims I and II are dismissed as they relate to warfarin sodium.

B. Clathrate Used in Making Warfarin Sodium

Plaintiffs allege that Barr and ACIC/Brantford had monopoly power over the market for clathrate and used that power to foreclose competition in the warfarin sodium market. **159**

1. Claims Against Barr

[11] The allegation against Barr is based on the plaintiffs' claim that Barr controlled ACIC/Brantford. There is no evidence that Barr ever controlled or owned any interest in ACIC/Brantford. Barr is a public corporation, which manufactures finished tablets. It buys raw materials from others, including ACIC/Brantford. The fact that Barr and ACIC/Brantford have a stockholder in common does not mean that one controls the other for § 2 purposes. *Invamed, Inc. v. Barr Labs. Inc.,* 22 F.Supp.2d 210, 219 (S.D.N.Y. 1998).[17] Barr has never competed in the clathrate market and could not possibly have exercised any control over that market. **160**

Therefore this claim is dismissed as against Barr.

2. ACIC/Brantford

a. Power in the Relevant Market

[12] The relevant market is clathrate used to produce warfarin sodium (both generic and Coumadin). Plaintiffs claim that no other suppliers besides ACIC/Brantford were willing and able to sell clathrate during the relevant times for this lawsuit. This contention is not supported by the undisputed facts, however. **161**

[13] It is undisputed that Chemoswed produced commercial quantities of clathrate during all the relevant time periods for this lawsuit. While most or all of its clathrate was dedicated to DuPont, internal or captive sources of a product still are included in the relevant market. *California v. Sutter Health Sys.,* 84 F.Supp.2d 1057, 1068 (N.D.Cal.), aff'd 217 F.3d 846, 2000 WL 531847 (9th Cir. 2000); 2A Phillip E. Areeda & Herbert Hovenkamp, *An Analysis of Antitrust Principles and Their Application,* 570g (1995) («Internal or captive transfers of a product should be included in the market. It is part of the supply, and control over supply determines the existence of market power. ... »). **162**

In addition, there is no dispute that Hoechst had the capability and desire of producing commercial quantities of clathrate by early 1996. Hoechst estimated it would be able to manufacture commercial quantities of clathrate in the range of 1,000 kilograms a year. Moreover, Hoechst was willing and able to enter into a long-term supply contract with **163**

[17] The issue of whether Barr controls ACIC/Brantford will also reappear, infra, in a discussion of whether Barr and ACIC/Brantford legally are capable of conspiring. In that context, plaintiffs argue that Barr – through its common shareholder, Sherman – does not exert control over ACIC/Brantford.

Invamed for clathrate.[18] In April 1996, Invamed began manufacturing warfarin sodium using Hoechst's clathrate. In August 1996, Hoechst submitted its DMF for clathrate.

A number of other manufacturers were also in the process of developing or sought Invamed's partnership in developing clathrate. Shanghai, for instance, sought a supply contract with Invamed in 1997. Banyan was producing clathrate and filed a DMF in 1997. Arenol, Chemagis, Diosynth, Lacheme, Taro and Vinchem all also were manufacturing clathrate or sought Invamed's partnership in doing so in 1996 to 1997. Invamed challenges whether these companies actually could or would have supplied to them, but in many instances it is undisputed that Invamed did not even investigate the possibility or refused it for various reasons. *Discon, Inc. v. NYNEX Corp.,* 86 F.Supp.2d 154, 161 (W.D.N.Y. 2000)(«All of [the] choices – whether a particular buyer decides to consider them or instead ignore all options but one – must be included in the relevant market.»). Thus, ACIC/Brantford was not the only supplier in the market. **164**

In addition, plaintiffs were not «locked in» to using the ACIC/Brantford clathrate. The Supreme Court has acknowledged the possibility of a single relevant market when there was no interchangeability with other products. *Eastman Kodak Co. v. Image Tech. Servs., Inc.,* 504 U.S. 451, 482, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992). In *Kodak*, independent service organizations (ISOs) sued Kodak for unlawfully tying the sale of service of its copying machines to the sale of repair parts and for monopolizing the market for Kodak parts. *Id.* at 459, 112 S.Ct. 2072. The ISOs brought their claims after Kodak stopped selling parts to the ISOs thereby forcing customers to deal only with Kodak. The Court ruled that the relevant market consisted of Kodak repair parts and services because Kodak copiers could only use Kodak parts. Thus, there were no reasonably available market alternatives. 504 U.S. at 481–82, 112 S.Ct. 2072. **165**

The facts in this case are much different. Nothing in this record suggests that the ACIC/Brantford clathrate was not interchangeable with the clathrate from other sources, such as Chemoswed and Hoechst. In fact, Invamed used the Hoechst material in its product development and further preparation of its ANDA, even if it did not include Hoechst as its supplier on that application. **166**

Plaintiffs' theory is that Invamed was «required» to purchase clathrate from ACIC/Brantford because it «chose to develop its product and submit its ANDA» with ACIC/Brantford clathrate. Invamed's decision to rely on one of any number of suppliers does not lead to the type of lock-in described in Kodak. A plaintiff's business decision to vest economic power in another party cannot sustain an antitrust claim. *Hack v. President and Fellows of Yale College,* 237 F.3d 81, 85–86 (2d Cir. 2000) (finding no «lock-in costs» where Yale students could have chosen to attend other universities but chose to attend Yale); *Queen City Pizza, Inc. v. Domino's Pizza Inc.,* 124 F.3d 430, 441 (3rd Cir. 1997) (rejecting plaintiff's antitrust claims as plaintiff's acceptance of franchise from defendants limited plaintiff's remedies to breach of contract); see also *Re-Alco Indus., Inc. v. National Ctr. For Health Educ.,* 812 F.Supp. 387, 392 (S.D.N.Y. **167**

[18] Invamed refused to enter into the contract because it would not commit to Hoechst as its sole supplier, although it did attempt to create a one-sided long-term agreement whereby Hoechst would only supply to Invamed.

1993) («fact that plaintiff chose to operate in a single market ... does not make it a relevant market for antitrust purposes») (quoting *Theatre Party Assocs., Inc. v. Shubert Org., Inc.,* 695 F.Supp. 150, 155 (S.D.N.Y. 1988)).

Invamed came to market within one year of switching to another source, Banyan. Invamed could have used other clathrate sources (such as Hoechst) and come to market sooner. Because «the existence of ... switching costs alone» does not render «an otherwise invalid relevant market valid,» plaintiffs' *Kodak* lock-in claim is rejected. *Queen City Pizza, Inc.,* 124 F.3d at 439; see also *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.,* 140 F.3d 494, 514 (3d Cir. 1998) («Product market definition turns on the existence of close substitutes for a particular product, not on the ability of any particular consumer to switch effortlessly to such substitutes.»). 168

b. Exclusionary Behaviour

[14] In any case, plaintiffs fail to establish «exclusionary» behaviour on the part of ACIC/Brantford. Exclusionary behaviour (1) tends to impair the opportunities of rivals and (2) either does not further competition on the merits or does so in an unnecessarily restrictive manner. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.,* 472 U.S. 585, 605, 105 S.Ct. 2847, 86 L.Ed.2d 467 (1985); *United States Football League v. Nat'l Football League,* 842 F.2d 1335, 1359 (2d Cir. 1988). 169

First, the «exclusive» agreement permitted ACIC/Brantford to supply commercial quantities of clathrate to Barr and lesser quantities to anyone. Further, the agreement did not prevent ACIC/Brantford from brokering clathrate produced by other manufacturers to its clients. 170

[15] Further, legitimate business justifications for challenged conduct prevent a rational trier of fact from inferring § 2 liability. *Trans Sport Inc. v. Starter Sportswear Inc.,* 964 F.2d 186, 189–90 (2d Cir. 1992); *United States Football League,* 842 F.2d at 1360. Exclusive supply contracts have been recognized as having procompetitive benefits and thereby serving legitimate business objectives. In *Standard Oil Co. v. United States,* 337 U.S. 293, 306–07, 69 S.Ct. 1051, 93 L.Ed. 1371 (1949), the Supreme Court reasoned that exclusive supply contracts can assure supply, afford protection against price increases, enable long-term planning on the basis of known costs, and obviate expense and risk of storage in the quantity necessary for having a fluctuating demand. Accord *CDC Techs.,* 186 F.3d at 80 («exclusive distributorship arrangements are presumptively legal»). But see *U.S. Healthcare Inc. v. Healthsource Inc.,* 986 F.2d 589, 595 (1st Cir. 1993) («There is one common danger for competition: an exclusive agreement may 'foreclose' so much of the available supply or outlet capacity that existing competitors or new entrants may be limited or excluded and, under certain circumstances, this may reinforce market power and raise prices for consumers.»). 171

Plaintiffs allege that Barr arranged for the exclusive supply contract in order to thwart the development of other generic warfarin sodium. Moreover, they allege that Barr demanded the confidentiality provision as a means of further delaying Invamed's entry into the generic warfarin sodium market. Plaintiffs fail to produce evidence, however, that ACIC/Brantford entered into the agreement for the purpose of foreclosing the available supply of clathrate so 172

that Barr's competitors would be limited or excluded from competing in the relevant warfarin sodium market.

This claim also fails.

II. Conspiracy under §§ 1 and 2

Plaintiffs allege as Counts III and IV that «Brantford and Barr conspired and agreed that Brantford would not supply clathrate to plaintiffs despite Brantford's prior representation to plaintiffs that it would do so.» Apothecon Compl. 41. Further, the purported objective of defendants' conspiracy was to preserve Barr's monopoly as the sole manufacturer of warfarin sodium and to delay the plaintiffs' entry into the market for as long as possible. *Id.* 173

A. Barr and ACIC/Brantford Are Legally Capable of Conspiring under Copperweld

[16] In *Copperweld Corp. v. Independence Tube Corp.,* 467 U.S. 752, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984), the Supreme Court held that «the coordinated activity of a parent and its wholly-owned subsidiary must be viewed as that of a single enterprise for purposes of § 1 of the Sherman Act.» *Id.* at 771, 104 S.Ct. 2731. The Court's rationale was that «two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit.» *Id.* at 769, 104 S.Ct. 2731. Coordinated action between a parent and subsidiary, in contrast, does not pose the same risk because «there is no sudden joining of economic resources that had previously served different interests.» *Id.* at 771, 104 S.Ct. 2731. The lower courts have extended Copperweld to hold that sister corporations are incapable of conspiring, *Gucci v. Gucci Shops, Inc.,* 651 F.Supp. 194, 197 (S.D.N.Y.1986), as are affiliated corporations that are less than wholly owned. *Bell Atlantic Business Sys. Servs. v. Hitachi Data Sys. Corp.,* 849 F.Supp. 702, 706–07 (N.D.Cal.1994) (80% subsidiary); *Novatel Comms. v. Cellular Tel. Supply,* 1986 WL 15507 at *5 (N.D.Ga.1986) (51% subsidiary). 174

Courts have applied Copperweld to conspiracies to monopolize under § 2 in addition to «contracts, combinations or conspiracies» challenged under § 1. *Lambtek Yogurt Machines v. Dreyer's Grand Ice Cream, Inc.,* 1997 WL 108718, at *3 (N.D.Cal. Mar.3, 1997); *H.R.M., Inc., v. Tele-Communications Inc.,* 653 F.Supp. 645, 647 (D.Colo. 1987); *Rosemount Cogeneration Joint Venture v. Northern States Power Co.,* 1991 WL 13729 at *3 (D.Minn. Jan.18, 1991). 175

In September 1995, when Barr and ACIC signed their exclusive and confidential contract, Sherman effectively owned 62% of Barr and 75% of ACIC. In October 1997, when Invamed's purchase order was rejected, Sherman owned 100% of Brantford and 63% of Barr. Defendants claim that Barr and ACIC were «sister corporations» with Sherman as the common parent and therefore incapable of conspiring. 176

Copperweld does not apply here because Barr and ACIC/Brantford were admittedly independent entities with an overlap only in the ownership of the entities. It is akin to the situation presented in *Fishman v. Estate of Wirtz,* 807 F.2d 520 (7th Cir.1986). The court acknowledged that «there was some overlap between the investors in CSC and CPSC since Arthur Wirtz owned and controlled CSC (along with his son, William Wirtz) and also invested in CPSC; however CSC and CPSC were not under common control in the same sense as is a 177

corporation and its wholly-owned subsidiary or as are two corporations owned in identical proportions by the same set of investors.» *Id.* at 541 n. 19 (citing *Century Oil Tool Inc. v. Production Specialties, Inc.,* 737 F.2d 1316 (5th Cir.1984) (two corporations were commonly owned by three persons, two of whom each owned 30% of each corporation and one of whom owned 40% of each)); see also *American Vision Centers, Inc. v. Cohen,* 711 F.Supp. 721 (E.D.N.Y.1989) (denying motion to dismiss where defendants owned 54% of stock of one publicly-traded company and 100% of stock of another; common ownership and majority interest were not enough to invoke *Copperweld*).

In addition, there was no «unity of purpose or a common design» between ACIC/Brantford and Barr. *Copperweld,* 467 U.S. at 771, 104 S.Ct. 2731. Sherman never exercised any control over Barr and took pains to conceal his passive ownership of ACIC/Brantford prior to 1996. Even after he acquired the remaining shares of ACIC's parent corporation, he continued to use ACIC Fine Chemicals as its independent sales arm. In addition, Barr was unaware of Sherman's or Apotex's ownership in ACIC/Brantford at the time the exclusive supply contract was signed, and Barr and ACIC/Brantford conducted their business at arms' length. **178**

Copperweld does not bar this claim.

B. Agreement and Intent to Monopolize Is Lacking

[17] Plaintiffs must present evidence that Barr and ACIC/Brantford «had a conscious commitment to a common scheme designed to achieve an unlawful objective.» *Monsanto Co. v. Spray-Rite Serv. Corp.,* 465 U.S. 752, 764, 104 S.Ct. 1464, 79 L.Ed.2d 775 (1984); *Invamed, Inc.,* 22 F.Supp.2d at 220, 222. In order to prove «conscious commitment,» plaintiffs must set forth facts from which a reasonable jury could find that the defendants' actions «were concerted rather than independent.» *AD/SAT,* 181 F.3d at 233 («To survive a motion for summary judgment a plaintiff ... must present evidence that tends to exclude the possibility that the alleged conspirators acted independently.» (citations omitted)); *Invamed,* 22 F.Supp.2d at 221 (conduct «consistent with unilateral action» does not violate the antitrust laws);[19] *Edward J. Sweeney & Sons, Inc. v. Texaco, Inc.,* 637 F.2d 105, 110 (3d Cir.1980) («[U]nilateral action, no matter what its motivation, cannot violate § 1.»). **179**

Plaintiffs identify four types of conduct to establish the conspiracy between ACIC and Barr: (1) Sherman's ownership in ACIC and Barr; (2) the exclusive supply contract and the confidentiality agreement; (3) two 1997 Barr documents; and (4) ACIC's failure to tell Invamed it would not supply commercial quantities of clathrate upon request. **180**

1. Sherman's Ownership in ACIC and Barr

Sherman's joint ownership interests in Barr and ACIC/Brantford cannot serve as the basis for an antitrust conspiracy. His ownership interests in each company long pre-dated the relevant time-frame (1994–1997), going back to the 1980's in Barr's case. It has already been held that **181**

[19] This Court previously dismissed Invamed's Sherman Act conspiracy claims as to all defendants except Barr and Brantford, which did not move to dismiss. *Invamed,* 22 F.Supp.2d at 220–22. Invamed failed to allege, inter alia, that «there was concerted action between any of the defendants. ... » *Id.* at 221.

the alleged acquisition of ACIC could not form the basis of a Sherman Act conspiracy, *Invamed,* 22 F.Supp.2d at 222, and neither can the routine communications of Sherman or his representatives on the subject of warfarin sodium. Such communications are to be expected in light of his business interests in the companies named in this lawsuit. *Minpeco, S.A. v. Hunt,* 686 F.Supp. 427, 435 (S.D.N.Y. 1988) (majority shareholder has a legitimate interest in corporation's decisions and constitute ordinary business conduct that is not valid evidence of a conspiracy); see also *Monsanto,* 465 U.S. at 762, 104 S.Ct. 1464 («A manufacturer and its distributor have legitimate reasons to exchange information about prices and the reception of their products in the market.»)

2. Supply Contracts and Confidentiality Agreements

Plaintiffs point to the supply agreement and the confidentiality agreements between Barr and ACIC executed in September 1995, and testimony that the confidentiality agreement required ACIC to refrain from disclosing the Barr-ACIC contract to others and that Barr enforced its exclusive rights in October 1997 after Invamed placed its order for 750 kg of clathrate. **182**

Defendants argue that Barr did not know of the alleged contract between Invamed and ACIC/Brantford and thus could not have the intent to prevent Invamed from utilizing its rights. There is a disputed issue of material fact as to whether Barr knew of the alleged contract between Invamed and ACIC/Brantford. Plaintiffs posit that Barr was aware that ACIC/Brantford had supplied sufficient quantities of clathrate to support an ANDA application, and that it was industry practice that such supply would create an implied-in-fact contract.

Nonetheless, the claim fails because the plaintiffs fail to prove intent on the part of ACIC/Brantford. As discussed earlier, there is no allegation that the exclusive supply agreement was anything but a legitimate business tactic on ACIC/Brantford's part. «[I]t is settled law that the mere existence of an exclusive contract is not evidence of an antitrust conspiracy.» *Williamson v. Sacred Heart Hosp.,* 1993 WL 543002 at *45 (N.D.Fla. 1993)(rejecting «out of hand» a conspiracy claim which was «essentially an attack on the economic validity of the exclusive contract»), *aff'd,* 41 F.3d 667 (11th Cir.1994). The record establishes that ACIC was shopping a supply arrangement to a number of companies, including Barr. Further, Invamed concedes that confidentiality agreements are not uncommon in the industry; Invamed negotiated or entered into such agreements with Banyan and other API suppliers. If «one party's intent to monopolize is not shared by another party, there can be no conspiracy to monopolize.» *CDC Techs.,* 7 F.Supp.2d at 131 (citing *Belfiore v. New York Times Co.,* 826 F.2d 177, 183 (2d Cir. 1987)). **183**

3. The Two Post-Hoc Barr Documents

Plaintiffs also rely on two internal documents from Barr from 1997. **184**

On April 14, 1997, Mary Casatelli, Barr's former Manager of Purchasing («Casatelli»), drafted a memorandum addressing potential sources of clathrate that Invamed may have used. The memorandum stated that ACIC/Brantford had previously sold clathrate to Invamed, but refused to sell additional clathrate to Invamed after the exclusive supply agreement was signed in September 1995. Casatelli also wrote about Hoechst as a supplier of clathrate and

wondered whether «We should give thought to the strategy we should pursue in order to deny a reliable source to Invamed.»

In marginalia on the same memorandum, Mary Petit, Barr's Vice President of Operations («Petit»), wrote: « [W]ill purchasing the [Hoechst] supply (even though we can't use it) be less than our losses if Invamed enters the market? Would Brantford or Barr purchase the [Hoechst] Coventry [raw material] and sell to Brantford's overseas customers to keep them out of supplying Invamed?» 185

There is no evidence that this document represents any employee's view but that of Casatelli and Petit, nor that their views were ever acted upon. In fact, senior management told Petit that Barr would not pursue a strategy of purchasing Hoechst material. There is also no evidence that, although ACIC/Brantford was mentioned, Barr ever discussed this strategy with ACIC/Brantford or that ACIC/Brantford would be willing to comply with it. Casatelli's and Petit's comments show only at most that Barr wanted to «win the competitive struggle» which, without proof of an intent to do so in an illegal manner, «is not unlawful.» *Northeastern Tel. Co. v. American Tel. & Tel. Co.,* 651 F.2d 76, 86 (2d Cir. 1981) (holding in Sherman Act conspiracy case that district court should not have relied on testimony of officials that they were opposed to competition and would fight it without any more proof conspiracy). 186

Plaintiffs also rely on Barr's September 1997 bond offering circular for Barr securities that says that, as a result of the exclusive agreement between ACIC/Brantford and Barr, Barr had «an exclusive source of active ingredient that to date is the only source available to the generic industry.» This circular was created two years after Barr and ACIC/Brantford entered the exclusive supply agreement, and therefore cannot show the intent of both parties at the time. At most, it reveals Barr's rationale in pursuing the exclusive supply contract. There is no mention of ACIC/Brantford's role. As discussed above, this unilateral evidence is insufficient. 187

4. ACIC's Dealings with Invamed

Plaintiffs also rely on the assertion that ACIC/Brantford misled Invamed about its willingness to sell clathrate. Assuming the truth of the two instances plaintiffs cite, there is no evidence in the record that Barr knew about these misrepresentations or had anything to do with them. ACIC's dealings with Invamed are merely examples of unilateral conduct that, as discussed above, the Sherman Act does not proscribe. 188

Plaintiffs have failed to present evidence from which a reasonable jury could find the defendants' actions were other than unilateral actions. In more than 60 depositions, not a single witness testified that a conspiracy existed. Among the hundreds of thousands of documents produced, not one states that Barr and ACIC/Brantford agreed to thwart plaintiffs' entry into the warfarin sodium market. Plaintiffs' Counts III and IV must therefore be dismissed.[20]

[20] In any case, absence of any prospect for success of the alleged § 2 conspiracy precludes a finding that the requisite intent existed. *Hudson Valley Asbestos Corp. v. Tougher Heating & Plumbing Co.*, 510 F.2d 1140 (2d Cir. 1975); *Apex Oil Co. v. DiMauro,* 713 F.Supp. 587, 600 (S.D.N.Y. 1989) (granting summary judgment on conspiracy

III. Clayton Act § 7

Plaintiffs challenge Sherman's acquisition of ACIC/Brantford under Section 7 of the Clayton Act in Count V of their complaints. Section 7 prohibits the acquisition of «the whole of any part of the stock» of an entity where «the effect of such acquisition may be substantially to lessen the competition or to tend to create a monopoly.» 15 U.S.C. § 18. 189

In 1990, a Sherman affiliate bought 75% of ACIC. In August 1996, Apotex Inc. bought out the remaining 25% of ACIC. Plaintiffs allege that Apotex's 1996 buy-out violated § 7 of the Clayton Act because it lessened competition. They reason that prior to the 1996 buyout, «Sherman was a passive investor and Mr. Calenti ran the company.» After Sherman gained total control, however, «he was no longer under any fiduciary duty to any other shareholders» and «was free to cause ACIC/Brantford to take actions that were not in its independent economic interests.» These purported actions include misleading Invamed and refusing to fill Invamed's purchase order for clathrate.

A. Claims Against All But Acquirer Fail

[18] «By its express terms Section 7 of the Clayton Act is directed only against the acquiring corporation.» *Tim W. Koerner & Assoc., Inc. v. Aspen Labs, Inc.,* 492 F.Supp. 294, 300 (S.D.Tex. 1980), *aff'd,* 683 F.2d 416 (5th Cir. 1982); see 15 U.S.C. § 18 («No person ... shall acquire ... »). Plaintiffs state that the legal cases cited by the defendants merely stand for the proposition that sellers of shares or assets cannot be held liable under § 7.[21] They do not, however, point to a single case that extends § 7 liability beyond the acquirer. In light of the clear language of the statute and in the absence of any case to the contrary, the only entity that may be held liable under § 7 is the acquirer, Apotex Inc. Thus, Count V is dismissed as against all but Apotex Inc. 190

B. Plaintiffs Did Not Suffer Antitrust Injury from the Buyout

[19] Plaintiffs present no economic evidence that the August 1996 buyout reduced competition in any relevant market or that their claimed injury (the delay in entering the warfarin sodium market) flowed from the allegedly unlawful acquisition. 191

By the time Apotex bought out the remaining 25% of ACIC in 1996, the exclusive agreement and the confidentiality agreements had already been entered. Under those agreements, ACIC could not fulfill Invamed's purchase order for clathrate and could not tell Invamed why it could not fulfill that order. The 1996 buy out therefore did not give Barr any «advantage» it did not

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to monopolize claim where «the alleged activities of the ... defendants, both intended and completed, ... could not amount to § 2 monopolization»). As discussed above, Barr's share of the relevant product market – that consisting of generic and branded warfarin sodium – was low. In addition, because of actual and potential entry into the market, it was and is incapable of attaining or maintaining monopoly power.

[21] E.g., *Arbitron Co. v. Tropicana Product Sales Inc.,* 1993 WL 138965 (S.D.N.Y. April 28, 1993) (holding that § 7 does not apply to seller of stock or assets). But see *United States v. Coca-Cola Bottling Co. of Los Angeles,* 575 F.2d 222, 230–31 (9th Cir. 1978) (holding that seller may be joined in § 7 action where plaintiff seeks rescission and court needs jurisdiction over seller in order to effectuate such equitable relief).

already have and did not cause ACIC/Brantford to mislead Invamed. Plaintiffs' § 7 claims fail, and Count V is dismissed.

IV. Donnelly Act Claims

Apothecon states a cause of action under the New York state antitrust act, the Donnelly Act (Count VI) **192**

[20] The Donnelly Act was modeled on the Sherman Act and is to be construed in accordance with it. *Anheuser-Busch, Inc. v. Abrams,* 71 N.Y.2d 327, 335, 525 N.Y.S.2d 816, 520 N.E.2d 535 (1988) (act «should generally be construed in light of Federal precedent and given a different interpretation only where state policy, differences in statutory language or the legislative history justify such a result»). Apothecon's sixth cause of action simply re-alleges the federal antitrust claims under the Donnelly Act and fails to allege any state policy, differences in statutory language or legislative history that would justify giving the Donnelly Act a different interpretation than the federal antitrust statutes. Therefore, its claim under the state antitrust law fails for the same reasons it does under federal law. Bijan Designer for Men, Inc. v. Katzman, 1997 WL 65717, at *10 n. 10 (S.D.N.Y. Feb. 1997) (dismissing claims under New York antitrust law for same reasons it fails under federal antitrust law); *Clorox Co. v. Winthrop,* 836 F.Supp. 983, 988 n. 3 (E.D.N.Y. 1993)(«no separate analysis required» in analyzing Sherman Act and Donnelly Act claims in summary judgment motion). Apothecon's Count VI is dismissed.

V. Apothecon's Standing to Bring State Law Claims

[21] As a preliminary matter, ACIC/Brantford claims that Apothecon has no standing to assert any of its state law claims against ACIC/Brantford because it is not a joint venturer with Invamed. Plaintiffs argue that Apothecon and Invamed are joint venturers, and thus Apothecon has standing to recover for injury to the joint venture.[22] **193**

[22] New Jersey cases decided since the 1919 enactment of the Uniform Partnership Law almost invariably hold that joint ventures are subject to the same legal rules as partnerships. E.g., *Walter v. Holiday Inns, Inc.,* 784 F.Supp. 1159, 1167 (D.N.J. 1992) (share fiduciary duties); *Hellenic Lines, Ltd. v. Commodities Bagging & Shipping, Process Supply Co.,* 611 F.Supp. 665, 679 (D.N.J. 1985) («Elements of a joint venture are virtually identical to those required for a partnership.») (citing *Kozlowski v. Kozlowski,* 164 N.J.Super. 162, 171, 395 A.2d 913 (Ch.Div. 1978)); *Wiley v. Wirbelauer,* 116 N.J.Eq. 391, 393, 174 A. 20 (Ch.Div. 1934) («[T]he rules applied to partnerships apply to joint ventures. ... »). Defendants challenge whether Apothecon meets two factors that New Jersey requires, among others, for a partnership (and therefore a joint venture): (1) joint property interest in the subject of the venture and (2) the sharing of profits and losses. *Kozlowski,* 395 A.2d at 917. **194**

[22] Even if a joint venture exists, Apothecon could not sue individually, but only for the injury to the joint venture. E.g., *Int'l Television Prods. v. Twentieth Century-Fox,* 622 F.Supp. 1532, 1536 (S.D.N.Y. 1985) (claims belong to joint venture and not to entities making up venture in their individual capacities).

[23] Invamed and Apothecon signed an agreement on June 28, 1996, upon which Apothecon bases its claim of being a joint venturer.[23] In its preamble, the agreement is labeled «an exclusive Supply Agreement.»[24] Plaintiffs claim that «Invamed and Apothecon combined their resources for the specific purpose of developing, manufacturing, and marketing specified drug products, including generic warfarin sodium.» Further, the parties «committed to invest substantial sums towards the development and manufacture of the identified products.» 195

The agreement will only create a joint venture if both parties share ownership in the subject of the venture. The agreement «provided that Apothecon at all times would retain ownership and title to the raw materials, including clathrate, used in the production of warfarin sodium.» Apothecon Compl. 30. Apothecon either would pay the cost of such raw materials to the supplier or reimburse Invamed for any payments it made on Apothecon's behalf. *Id.* It is unclear from the Agreement or the parties' submissions who owned the warfarin sodium, i.e., whether both Apothecon and Invamed or merely Invamed. However, because the Agreement is in the nature of a supply agreement, it appears as though Invamed would own the finished products and supply them to Apothecon for sale. This situation does not constitute joint property interest in the subject of the venture, and in its absence there can be no joint venture. 196

Defendants also urge that Apothecon and Invamed did not agree to share losses as well as profits. Plaintiffs point to the fact that they each invested substantial sums in the venture. Thus, each party stood to lose its initial investment if the venture failed. However, Invamed must have agreed to «mak[e] good the losses» and assume financial obligations of the venture to establish a joint venture. *Rivkin v. Coleman,* 978 F.Supp. 539, 542–43 (S.D.N.Y.1997). The potential to lose a portion of its own costs does not equate to shared losses. *Id.* 197

Therefore, there is no joint venture and Apothecon has no standing to bring its claims. Therefore, Apothecon's state law claims are dismissed.[25]

VI. Invamed's State Law Claims against ACIC/Brantford

Invamed alleges claims against ACIC/Brantford based on breach of contract, promissory estoppel, negligence and negligent misrepresentation. Each is adressed in turn. 198

A. Breach of Contract

[24] Invamed alleges that an «implied-in-fact contract» was created for Brantford to supply Invamed with clathrate under the Convention for the International Sale of Goods («CISG»), 199

[23] The agreement also refers to «an earlier agreement dated December 22, 1995 for the manufacture and distribution of certain products.»

[24] Under New Jersey law, a joint venture may still be formed in the absence of an express statement that it is a joint venture. E.g., *Ditscher v. Booth,* 13 N.J.Super. 568, 572, 80 A.2d 648, 650 (1951) (contract «need contain no particular form or expression»).

[25] Apothecon's complaint listed several additional state law counts that were not included in Invamed's complaint. These include Count VIII (fraud against ACIC/Brantford and Barr); Count XIV (breach of fiduciary duty against Barr); and Count XV (unfair competition against Barr). These are all dismissed and will not be discussed below.

15 U.S.C.App. 52,[26] and that ACIC/Brantford breached the contract by failing to supply clathrate in response to a specific purchase order. Invamed Compl. Count VI. Invamed alleges that an implied-in-fact contract existed because it (1) purchased research and development quantities of clathrate from ACIC/Brantford (at $2,500 per kilogram); (2) invested a substantial amount of money in developing its warfarin sodium product based on ACIC/Brantford's raw material; and (3) relied on the reference letter provided by ACIC/Brantford in connection with the ANDA for warfarin sodium that it submitted to the FDA.

[25] The CISG, intended to ensure the observance of good faith in international trade, CISG Art. 7(1), embodies a liberal approach to contract formation and interpretation, and a strong preference for enforcing obligations and representations customarily relied upon by others in the industry. E.g., *MCC-Marble Ceramic Center, Inc. v. Ceramica Nuova d'Agostino, S.p.A.,* 144 F.3d 1384, 1387 (11th Cir. 1998) (CISG abandons parol evidence rule); *Delchi Carrier S.p.A v. Rotorex Corp.,* 71 F.3d 1024, 1028 (2d Cir. 1995) (UCC case law is not per se applicable to cases governed by the CISG). A contract may be proven by a document, oral representations, conduct, or some combination of the three. CISG Art. 11. The usages and practices of the parties or the industry are automatically incorporated into any agreement governed by the Convention, unless expressly excluded by the parties. CISG Art. 9. **200**

While embodying a liberal approach, the CISG does not vitiate the need to prove concepts familiar to the common law, including offer, acceptance, validity and performance. ACIC/Brantford challenges all of these elements. **201**

1. Offer

Article 14 of the CISG states two requirements for the creation of an offer: it must (1) be «sufficiently definite,» meaning that it indicates the goods and expressly or implicitly fixes or makes provision for determining the quantity and price; and (2) indicate the intention of the offeror to be bound in case of acceptance. CISG Art. 14(1). **202**

Invamed claims that a well-established custom in the industry was to rely on implied, unwritten supply commitments.[27] Defendant Sherman affirmed under oath that «the predominant practice is for these commitments not to be embodied in formal legal **203**

[26] Because the alleged sales contract involves international trade, Invamed's claims must be analyzed according to the provisions of the United Nations Convention on the International Sale of Goods («CISG»). 15 U.S.C.App. 2. The CISG is an international treaty that embodies a uniform set of rules for the creation of a contract of sale and the related obligations of parties to international sales transactions. *Id.* To the extent that the CISG reserves issues for the application of domestic law, New Jersey law applies, as discussed *infra*.

[27] Defendants point out that Invamed acted inconsistently with the alleged «industry custom,» and Invamed concedes that at least in 1995 it did not adhere to this «industry custom» in dealing with ACIC and Invamed's other suppliers. Dave testified that Invamed's standard practice in dealing with ACIC and most suppliers was to discuss Invamed's interest in placing an order for a specific quantity and then to reach an agreement on terms (price, quantity, delivery dates, payment terms) before submitting a purchase order. This failure to conform to what they allege is industry custom is insufficient to disprove, as a matter of law, that there was not an industry custom to this effect in 1997 and that Invamed relied on it in 1997. It remains an issue of fact as to whether Invamed's general behaviour in 1995 carried over to 1997, when it submitted a purchase order without contacting ACIC/Brantford and without first agreeing to terms.

documents.» Further, he stated, «When a supplier provides access to a manufacturer to its Drug Master File and the manufacturer relies upon such access as the basis of its New Drug Submission, it is the custom and the understanding of both the manufacturer and the supplier that, upon the issuance of the Notice of Compliance, the supplier will supply the product.»

The alleged contract clearly identifies the goods at issue, clathrate. Invamed alleges that the parties had already agreed to a price and to the production of «commercial quantities» of clathrate and admits no discussion took place regarding a delivery schedule.[28] However, accepting as true Invamed's allegations of an industry custom, the contract was sufficiently definite. Further, the alleged contract indicated Invamed's intention to be bound; it would only send in a purchase order if it in fact needed a commercial quantity of clathrate. 204

2. Acceptance

Relying on the provision of the CISG addressing oral offers, defendants argue that the offer had to be accepted immediately. However Invamed is relying on a contract established by the conduct of the parties. In such a situation CISG Art. 18(3) applies. It states that «the offeree may indicate assent by performing an act, such as one relating to the dispatch of goods or payment of the price,» [and] «the acceptance is effective at the moment the act is performed, provided the act is performed» either within the time fixed by the offeror, if no such time is fixed, within a reasonable time. CISG 18(3). Invamed alleges that it was industry custom that the provision of a reference letter indicates acceptance. That defendants dispute this material fact only argues against summary judgment being granted. 205

3. Validity

Under the CISG, the validity of an alleged contract is decided under domestic law. CISG Art. 4(a); *Commentary* at 43. By validity, CISG refers to any issue by which the «domestic law would render the contract void, voidable, or unenforceable.» H. Hartnell, Rousing the Sleeping Dog: The Validity Exception to the Convention on Contracts for the International Sale of Goods, 18 *Yale J. of Int'l Law* 1, 45 (1993). Defendants challenge the requirement of consideration. 206

a. Choice of Law

[26] To determine applicable domestic law, the court «must engage in a traditional conflict of laws analysis to determine what substantive law governs.» Hartnell, *supra,* at 14. When construing international treaties, the forum's choice of law rules apply. E.g., *Pescatore v. Pan* 207

[28] Defendants suggest that the offer fails because it did not specify a delivery date. Depending on the circumstances, additional terms such as delivery dates may be required for an offer. *CISG, Commentary* 105–06 (Schlechtriem, ed.) (2d ed. 1998) (hereinafter «Commentary»). Defendants state that Invamed discussed delivery dates with its API suppliers as a matter of practice, and that delivery dates are important to the supplier because it needs to plan its production schedule to meet customer requirements. Invamed disputes that it discussed delivery dates with its API suppliers as a matter of practice. Thus, this issue cannot be decided as a matter of law.

Am. World Airways, Inc., 97 F.3d 1, 12–13 (2d Cir. 1996) (determining that New York, as opposed to federal, choice of law rules apply in action brought under Warsaw Convention).

[27] In contract cases, New York courts employ a «center of gravity» inquiry to determine the jurisdiction with the most significant relationship to the dispute. *Lazard Freres & Co. v. Protective Life Ins.,* 108 F.3d 1531, 1539 (2d Cir. 1997); *Constitution Reins. Corp. v. Stonewall Ins. Co.,* 980 F.Supp. 124, 126 (S.D.N.Y. 1997). This approach looks to the place of contracting, the places of negotiation and performance, the location of the subject matter of the contract, and the domicile or place of business of the contracting parties. *Id.* 208

[28] Invamed is located in New Jersey. Getrajdman, the ACIC sales representative who dealt with Invamed, had his office in New Jersey and made sales calls on Invamed in New Jersey. Invamed contacted Getrajdman and sent its purchase orders to Getrajdman's New Jersey office. Invamed asked for delivery of the clathrate in New Jersey and intended to manufacture sodium warfarin in New Jersey. The only other potentially applicable law besides that of New Jersey is Canadian law. ACIC/Brantford had its manufacturing facility in Canada, and sent its shipments from Canada. New Jersey law should apply as it has the greater contacts with the subject matter of the case. It was the place of contracting, negotiation and performance and is the plaintiff's domicile. 209

b. Consideration under New Jersey Law

[29] «The essential requirement of consideration is a bargained-for exchange of promises or performance that may consist of an act, or forbearance, or the creation, modification, or destruction of a legal relation.» *Fregara v. Jet Aviation Business Jets,* 764 F.Supp. 940, 948 (D.N.J. 1991) (citing Restatement (Second) Contracts § 71 (1981)). The consideration exchanged need not be of equal value or like manner. *Shebar v. Sanyo Business Systems Corp.,* 111 N.J. 276, 289, 544 A.2d 377, 384 (N.J. 1988) (If the consideration requirement is met, there is no additional requirement of gain or benefit to the promisor, loss or detriment to the promise, equivalence in the values exchanged, or mutuality of obligation.); see also Restatement (Second) Contracts § 79 (consideration need not be equivalent) and § 80 (multiple promises from one side may be exchanged for one promise from the other). 210

[30] Invamed states that the consideration for the implied-in-fact contract was primarily its forbearance, claiming it relied on ACIC/Brantford's reference letter in connection with its submission to the FDA. Forbearance must be part of a bargained-for exchange to qualify as consideration. Restatement (Second) of Contracts § 71 (1981); *Shebar,* 544 A.2d at 383 (N.J. 1988); *Swider v. Ha-Lo Indus., Inc.,* 134 F.Supp.2d 607, 617 (D.N.J. 2001). Further it must induce the consideration of the other. *Id.*; *Shebar,* 544 A.2d at 384 (employee agreed to give up position «in exchange for» promise of a new position). 211

Defendants claim that there is no evidence that ACIC/Brantford made a promise to supply clathrate that induced reliance by Invamed and, reciprocally, that Invamed's reliance induced ACIC/Brantford to promise to supply. Invamed contends that, as a practical matter, its reliance locked it into purchasing raw materials from ACIC/Brantford at least until another reliable 212

source of clathrate could be located and approved by the FDA for use by Invamed.[29] ACIC/Brantford was thus guaranteed a customer of its clathrate. This is sufficient to allege consideration for the purposes of this summary judgment motion.

4. Performance

Defendants challenge whether Invamed met the requirements under CISG Art. 60(a) in terms of its performance. That provision requires that a buyer of goods perform «all of the acts which could reasonably be expected of [it] in order to enable the seller to make delivery.» CISG Art. 60(a). Further, preparatory measures «such as the provisions of plans or data, are also part of the cooperation required of the buyer since ultimately they serve to enable the seller to make delivery.» *Commentary* at 478. **213**

Patel testified that one of the obligations under the implied-in-fact contract was that Invamed was required to give ACIC/Brantford commercially reasonable notice. He also testified that Invamed did not give ACIC/Brantford commercially reasonable notice.

Invamed contends that short notice is consistent with industry practice, and that short notice would not affect ACIC/Brantford's ability to supply clathrate. However, Invamed cannot rely on industry custom to trump an agreed-upon obligation. *Milonas v. Public Employment Relations Bd.,* 225 A.D.2d 57, 648 N.Y.S.2d 779, 785 (1996) (admissible only if agreement is ambiguous); *Western Union Tel. Co. v. American Communications Ass'n,* 299 N.Y. 177, 184, 86 N.E.2d 162 (1949) («Evidence of custom is not permitted for the purpose of contradicting the agreements which the parties have made.»). **214**

Invamed is persuasive, however, in arguing that even if commercially reasonable notice were required, ACIC/Brantford could «not refuse to sell the material altogether and withdraw Invamed's [reference letter].» The alleged contract at issue is not the October 1997 purchase order. Instead, it is an implied-in-fact contract to supply clathrate when given commercially reasonable notice or to inform Invamed that it will not be able to supply in a commercially reasonable time. Under this contract, ACIC/Brantford was not required to supply clathrate in October 1997 because Invamed failed to give it commercially reasonable notice. However, in the absence of terms to the contrary, this failure to give commercially reasonable notice does not amount to a breach of the implied-in-fact supply contract. Thus, Invamed did not breach the agreement by failing to give commercially reasonable notice and ACIC/Brantford did not breach by refusing to fulfill the order. Therefore, when ACIC/Brantford refused to supply any clathrate to Invamed in the future, it did breach the implied-in-fact contract. **215**

The motion for summary judgment is denied on this claim.

[29] Although this Court decided earlier that Invamed was not «locked in» as a matter of antitrust law, it is nonetheless arguable that the resulting delay and cost in changing suppliers practically meant that Invamed would buy from ACIC/Brantford even if it were not required to do so. This is sufficient to establish consideration, even though it is not sufficient as a matter of law to present a *Kodak* lock-in situation.

B. CISG's Preemption of Equitable and Tort Claims

[31] The issue of whether or not the CISG preempts state law is a matter of first impression in this Circuit. **216**

[32][33] In the case of federal statutes, «the question of whether a certain action is preempted by federal law is one of congressional intent. The purpose of Congress is the ultimate touchstone.» *Pilot Life Ins. Co. v. Dedeaux,* 481 U.S. 41, 45, 107 S.Ct. 1549, 95 L.Ed.2d 39 (1987) (internal quotations and citations omitted). Confronting the question of preemption by a treaty, the Court focuses on the intent of the treaty's contracting parties. *Husmann v. Trans World Airlines, Inc.,* 169 F.3d 1151, 1153 (8th Cir. 1999) (finding Warsaw Convention preempts state law personal injury claim); *Jack v. Trans World Airlines, Inc.,* 820 F.Supp. 1218, 1220 (N.D.Cal. 1993) (finding removal proper because Warsaw Convention preempts state law causes of action). **217**

The intent of the contracting parties to the CISG can be discerned from the introductory text, which states that «the adoption of uniform rules which govern contracts for the international sale of goods and take into account the different social, economic and legal systems would contribute to the removal of legal barriers in international trade and promote the development of international trade.» 15 U.S.C.App. at 53. The CISG further recognizes the importance of «the development of international trade on the basis of equality and mutual benefit.» *Id.* These objectives are reiterated in the President's Letter of Transmittal of the CISG to the Senate as well as the Secretary of State's Letter of Submittal of the CISG to the President. *Id.* at 70–72. The then-Secretary of State, George P. Shultz, noted: **218**

> «Sales transactions that cross international boundaries are subject to legal uncertainty – doubt as to which legal system will apply and the difficulty of coping with unfamiliar foreign law. The sales contract may specify which law will apply, but our sellers and buyers cannot expect that foreign trading partners will always agree on the applicability of United States law. ... The Convention's approach provides an effective solution for this difficult problem. When a contract for an international sale of goods does not make clear what rule of law applies, the Convention provides uniform rules to govern the questions that arise in making and performance of the contract.» *Id.* at 71.

This Court concours that «the expressly stated goal of developing uniform international contract law to promote international trade indicates the intent of the parties to the treaty to have the treaty preempt state law causes of action.» *Asante Tech., Inc. v. PMC-Sierra, Inc.,* 164 F.Supp.2d 1142, 1151 (N.D.Cal. 2001). **219**

In *Asante,* the court held in a case of first impression that state contract causes of action are pre-empted, as **220**

> «[t]he availability of independent state contract law causes of action would frustrate the goals of uniformity and certainty embraced by the CISG. Allowing such avenues for potential liability would subject contracting parties to different states' laws and the very same ambiguities regarding international contracts that the CISG was designed to

> avoid. As a consequence, parties to international contracts would be unable to predict the applicable law, and the fundamental purpose of the CISG would be undermined.»

Id. at 1151; see also William S. Dodge, Teaching the CISG in Contracts, 50 *J. Legal Educ.* 72, 72 (March 2000) («As a treaty the CISG is federal law, which preempts state common law and the UCC.»); David Frisch, Commercial Common Law, The United Nations Convention on the International Sale of Goods, and the Inertia of Habit, 74 *Tul. L.Rev.* 495, 503–04 (1999) («Since the CISG has the preemptive force of federal law, it will preempt article 2 when applicable.»). **221**

Although the plaintiff in *Asante* brought claims sounding in tort and contract, the court focused only on the state contract claims, recognizing the limited scope of CISG's preemption. 164 F.Supp.2d at 1151–52; see also *Viva Vino Import Corp. v. Farnese Vini S.r.l.,* 2000 WL 1224903, at *1 (E.D.Pa. Aug. 29, 2000); Peter Schlechtriem, The Borderland of Tort and Contract: Opening a New Frontier?, 21 *Cornell Int'l L.J.* 467, 473–74 (1988) (CISG does not preempt claims for «misrepresentation, fraud, betrayal and intentional harm to economic interests»). **222**

Invamed's other claims include promissory estoppel, negligence, negligent misrepresentation and tortious interference. The CISG clearly does not preempt the claims sounding in tort. *Viva Vino Import Corp. v. Farnese Vini S.r.l.,* 2000 WL 1224903 (E.D.Pa. Aug. 29, 2000) («The CISG does not apply to tort claims.»).[30] **223**

The question of whether it preempts a separate claim for promissory estoppel presents a closer question. Breach of contract and promissory estoppel «are two sides of the same coin, and that coin is a cause of action for breach of contract.» *Qatar Nat'l Navigation & Transp. Co. v. Citibank N.A.,* No. 89 Civ. 464 (CSH), 1998 WL 516117, at *7 (S.D.N.Y. Aug. 20, 1998) («Promissory estoppel is an equitable remedy, the effect of which ... is to estop [the defendant] from denying the existence of the contract pleaded.»); *Pitak v. Bell Atl. Network Servs. Inc.,* 928 F.Supp. 1354, 1367 (D.N.J.1996)(«Promissory estoppel is a cause of action closely related to breach of contract.»); *Leonardis v. Burns Intern. Sec. Servs. Inc.,* 808 F.Supp. 1165 (D.N.J. 1992) (same). **224**

Commentary on the CISG has not specifically addressed the issue of whether it should preclude a claim for promissory estoppel. However, one commentator's discussion of the provision for «firm offers» under the CISG provides insight into the issue. Article 16(2)(b) provides that an offer is irrevocable «if it was reasonable for the offeree to rely on the offer as being irrevocable and the offeree has acted in reliance on the offer.» CISG, Art. 16(2)(b). The commentator writes: **225**

> «Paragraph 2(b) looks very much like American promissory estoppel doctrines, although it does not expressly require that the offeree's reliance must have been foreseeable to the offeror and does not expressly require that the offeree's reliance be detrimental. Despite these omissions, we can expect that many tribunals will apply

[30] Just because a party labels a cause of action a «tort» does not mean that it is automatically not pre-empted by the CISG. A tort that is in actuality a contract claim, or that bridges the gap between contract and tort law may very well be pre-empted. Schlechtriem, *supra,* at 474.

paragraph 2(b) in much the same fashion as American courts have used promissory estoppel.» Henry Mather, Firm Offers Under the UCC and the CISG, 105 *Dick. L.Rev.* 31, 48 (Fall 2000).

The fact that Article 16(2)(b) appears to employ a modified version of promissory estoppel suggests that if a plaintiff were to bring a promissory estoppel claim to avoid the need to prove the existence of a «firm offer,» that claim would be preempted by the CISG. The CISG establishes a modified version of promissory estoppel that does not appear to require foreseeability or detriment, and to apply an American or other version of promissory estoppel that does require those elements would contradict the CISG and stymie its goal of uniformity. 226

Here, Invamed utilizes promissory estoppel to prove that a promise on which it relied should be recognized as binding as if it were a contract. Thus, if the CISG had contemplated a similar «reliance» principle in its determination of whether a contract had formed, this promissory estoppel claim would be preempted. The defendants have presented no argument that the CISG does so, and therefore this particular promissory estoppel claim is not preempted.[31] 227

C. Negligence and Negligent Misrepresentation

[34] The New Jersey Supreme Court[32] held in *Spring Motors Dist., Inc. v. Ford Motor Co.,* 98 N.J. 555, 489 A.2d 660 (1985) that «economic expectations» protected by contract principles are not entitled to «supplemental protection by negligence principles.» *Id.* at 673. While the majority of courts have carved out exceptions for intentional fraudulent conduct, the rule still holds for negligence actions. E.g., *Henry Heide Inc. v. WRH Products Co.,* 766 F.2d 105, 109 (3d Cir. 1985) (dismissing claim for negligent misrepresentation because «it should be analyzed within the framework of the UCC rather than by the rules of nonintentional tort law»); *Boyes v. Greenwich Boat Works, Inc.,* 27 F.Supp.2d 543, 550 (D.N.J.1998) («Plaintiff's claim that negligent misrepresentation is an exception to th[e Spring Motors] rule is unavailing.»); *Hoke, Inc. v. Cullinet Software Inc.,* 1992 WL 102715, *2 (D.N.J. March 18, 1992) («[T]he court is convinced that under New Jersey law, the Spring Motors holding would extend to bar tort suits for negligent misrepresentation inducing the formation of contracts between commercial parties.»). 228

Invamed's cases stand only for the proposition that intentional torts, such as fraud, are not subject to the economic loss doctrine. E.g., *Coastal Group, Inc. v. Dryvit Systems,* 274 N.J.Super. 171, 177, 643 A.2d 649, 652 (1994); *Lo Bosco v. Kure Eng'g Ltd.,* 891 F.Supp. 1020, 229

[31] This holding is limited to promissory estoppel as claimed by Invamed. Other promissory estoppel claims, such as that discussed above, could be preempted.

[32] New York courts apply an «interest analysis to determine whether a state's substantive law applies to tort claims.» *Official Comm. of Unsecured Creditors of Color Tile, Inc. v. Investcorp, S.A.,* 80 F.Supp.2d 129, 135 (S.D.N.Y. 1999). The focus on this analysis is on the parties' domiciles and the locus of the tort. *AroChem. Inter., Inc. v. Buirkle,* 968 F.2d 266, 270 (2d Cir. 1992). In the context of conduct regulating torts such as those asserted by Invamed, the law of the place of the wrong governs. *La Luna Enters. Inc. v. CBS Corp.,* 74 F.Supp.2d 384, 389 (S.D.N.Y. 1999). In this case, the place of the wrong is where the injury occurred, New Jersey. *Id.*; *Rosenberg v. Pillsbury Co.,* 718 F.Supp. 1146, 1150 (S.D.N.Y. 1989).

1032–33 (D.N.J. 1995) (individual may sue alleged joint venture partner for fraud as well as breach of contract).

[35] Invamed claims that ACIC/Brantford was required and failed to disclosed the fact that after September 19, 1995, it was no longer willing or able to supply Invamed with clathrate for a commercial launch. Moreover, Invamed claims that it reasonably relied on the belief that ACIC/Brantford would supply Invamed with clathrate for a commercial launch. These allegations are also involved in Invamed's breach of contract claim and the economic remedy sought is the same. Therefore, the economic loss doctrine under New Jersey law bars Invamed's claims of negligence and negligent misrepresentation. Invamed's Counts X and XI are dismissed. 230

D. Promissory Estoppel

[36] A claim for promissory estoppel requires: (1) a clear and definite promise, (2) the promise is made with the expectation that the promise will rely on it, (3) the promise in fact reasonably relied on the promise; and (4) the promise suffered a definite and substantial detriment as a result of the reliance. *Royal Assoc. v. Concannon,* 200 N.J.Super. 84, 91–92, 490 A.2d 357, 361 (N.J.Super.Ct.App.Div. 1985); *R.J. Longo Constr. Co. v. Transit America Inc.,* 921 F.Supp. 1295, 1305 (D.N.J. 1996). 231

[37] Defendants argue that Invamed has failed to demonstrate a clear and definite promise and reasonable reliance and that summary judgment is therefore appropriate. They cite to three cases, only one of which applies New Jersey law, where courts granted summary judgment in promissory estoppel cases. In all three cases, the courts found that the plaintiff had failed to prove multiple elements of the cause of action. *Aircraft Inventory Corp. v. Falcon Jet Corp.,* 18 F.Supp.2d 409 (D.N.J. 1998) (lack of clear and definite promise and lack of reliance under New Jersey law); *Ellis v. Provident Life & Acc. Ins. Co.,* 3 F.Supp.2d 399, 410 (S.D.N.Y. 1998) (no elements present); *Rosen v. Hyundai Group (Korea),* 829 F.Supp. 41, 48 (E.D.N.Y. 1993) (lack of clear and definite promise, reliance and reliance injury as well as effective Statute of Frauds defense). 232

1. Clear and Definite Promise

«A clear and definite promise is the 'sine qua non for the applicability of [promissory estoppel].'» *Aircraft Inventory,* 18 F.Supp.2d at 416 (citation omitted). 233

A reasonable jury could determine on the basis of the facts alleged that ACIC/Brantford had made a clear and definite promise according to industry custom. In September 1994, ACIC/Brantford advised Invamed that «there is not an exclusive on [clathrate] and we can provide it to Invamed.» Invamed claims that from 1994 to 1997, ACIC/Brantford then encouraged Invamed to develop warfarin sodium based on ACIC/Brantford's clathrate, and solicited Invamed's business. Defendants dispute this latter allegation, but this merely demonstrates that a genuine issue of material fact exists and summary judgment cannot be granted on this basis. 234

Defendants suggest that Aircraft Inventory should be controlling. In Aircraft Inventory, an aircraft buyer engaged in extensive discussions with a seller's broker regarding the purchase of a jet airplane for $3.1 million. During those discussions, the broker purportedly made two oral promises to the buyer to the effect that, «you've got the airplane.» The buyer also issued a written offer to the broker. The broker ultimately decided to put the plane on the market at a higher price and the would-be buyer sued for promissory estoppel. The court found a lack of definite promise because «[d]etails such as warranties, disclaimers, delivery, taxes, and allocation of the risk of loss were not established or even discussed.» *Id.* Moreover, contingencies and conditions existed on both sides. *Id.* **235**

Invamed is persuasive in arguing that the promises in Aircraft Inventory were vague and indefinite as opposed to the laundry list of actual, definite promises that it claimswere made to it. The defendants dispute the fact that such promises were made, but that is an issue for the jury to decide. **236**

2. Reasonable Reliance

Invamed claims that its conduct was consistent with the widespread practice in the industry and that it was not «lax» in not requiring a written agreement. The undisputed facts reveal that many supply contracts in the industry were not put into written form. Defendant Sherman and other witnesses testified to the industry practice of relying on oral representations, and a letter of access, in lieu of a detailed contract. **237**

It is true, as defendants point out, that the parties were sophisticated business persons involved in a multi-year, multimillion deal. These are important considerations. E.g., *In re Resorts Int'l, Inc.,* 181 F.3d 505, 510 (3d Cir. 1999) (companies represented by sophisticated business persons are subject to stricter standard of reasonable reliance); *Harsco Corp. v. Bowden,* 1995 WL 152523, at *7 (S.D.N.Y. April 5, 1995) (finding no reasonable reliance as a matter of law in light of plaintiff's sophistication and size of transaction, $400 million). Given Invamed's allegations about industry custom, however, and the undisputed fact that Barr, ACIC/Brantford and others in the pharmaceutical industry routinely relied on unwritten agreements for multi-year million-dollar contracts, these are considerations for the jury. **238**

VII. Invamed's Business Tort Claims against Barr

In Counts VIII and IX, Invamed asserts claims against Barr for tortious interference with contract and tortious interference with business relations due to ACIC/Brantford's refusal to supply clathrate to Invamed. The two torts are highly similar and so will be discussed together. **239**

[38] Under New Jersey law, to state a claim for tortious interference with contractual relations, a plaintiff must allege: (1) the existence of a valid contract between itself and a third party; (2) defendant's knowledge of that contract; (3) defendant's intentional procuring of its breach; and (4) damages. *Farris v. County of Camden,* 61 F.Supp.2d 307, 321 (D.N.J. 1999); *Printing Mart-Morristown v. Sharp Elec. Corp.,* 116 N.J. 739, 563 A.2d 31, 37 (1989). The level of intent required is malice, meaning that «the harm was inflicted intentionally and without justification or excuse.» *Printing Mart,* 563 A.2d at 37. **240**

[39] The four elements of a prima facie case for tortious interference with business relations are: (1) a reasonable expectation of economic advantage to plaintiff, (2) interference done intentionally and with «malice,» (3) causal connection between the interference and the loss of prospective gain, and (4) actual damages. *Varrallo v. Hammond, Inc.,* 94 F.3d 842, 848 (3d Cir. 1996) (citing *Printing Mart,* 563 A.2d at 37). In addition, some panels of the Third Circuit have recognized the defendant's knowledge of the expected advantage as a fifth element. Varrallo, 94 F.3d at 848 n. 9 (citing *Lightning Lube Inc. v. Witco Corp.,* 4 F.3d 1153, 1167 (3d Cir. 1993)). **241**

Barr's arguments that no contract existed between ACIC/Brantford and Invamed and that the Copperweld doctrine bars the tortious interference claims must be rejected for the reasons stated above. **242**

[40] Barr also contends that Invamed has failed to present evidence showing that Barr knew of the alleged contract between ACIC/Brantford and Invamed. However, there is a disputed issue of material fact as to whether Barr knew of the alleged contract between Invamed and Barr. Invamed posits that Barr was aware that ACIC/Brantford had supplied sufficient quantities of clathrate to support an ANDA application, and that it was industry custom that such supplying would create an implied-in-fact contract. Defendants challenge the «industry custom» argument as discussed earlier, based on Invamed's alleged failure to follow it. These behaviors do not, however, completely vitiate Invamed's argument regarding industry custom. **243**

A material issue of fact also exists as to whether Barr intended to interfere with the alleged implied-in-fact contract. While Barr claims that it was merely upholding the supply agreement signed before the implied-in-fact contract was formed, Invamed alleges that ACIC/Brantford sought Barr's permission to fill the order, and Barr insisted that ACIC/Brantford reject the order. **244**

[41] Barr also contends that any interference, if proven, was privileged. The assertion of legally protected rights is privileged if done in order to prevent the impairment or destruction of one's own legitimate interests. *Printing Mart,* 563 A.2d at 40 («[O]thers too may further their equal interest, and if the means are fair, the advantage should remain where success has put it.» (citation omitted)); *Weinstein v. Clementsen,* 20 N.J.Super. 367, 373–74, 90 A.2d 77 (1952) (holding that real estate broker who had rightfully earned a commission did not tortiously interfere with rival broker's business relations by demanding that client pay commission to her rather than to rival broker); see also Restatement (Second) Torts § 773 (1979); *New York Yankees Partnership v. SportsChannel Assocs.,* 510 N.Y.S.2d 870, 126 A.D.2d 470 (1987) (rejecting tortious interference with contract claim where «supposed tortious acts consist in essence only of [Sportchannel's] refusal to give up its valuable contract rights» and noting that «[i]t cannot be concluded that the failure of Sportschannel to recognize the validity of a purported contract which violates its own contractual rights constitutes interference»). **245**

However, if the means of interference constitutes an unlawful restraint of trade, such restraints are not privileged. *Printing Mart,* 563 A.2d at 40 (profit motivation insufficient if acts are wrongful); *Di Cristofaro v. Laurel Grove Memorial Park,* 43 N.J.Super. 244, 255, 128 A.2d **246**

281 (1957) (finding profit motive no justification where effect was the force the public to buy monuments only from cemetery owners); see also *Six West Retail Acquisition Inc. v. Sony Theatre Mgmt. Corp.,* 2000 WL 264295, at *31–* 32 (S.D.N.Y. March 2000); *Martin Ice Cream Co. v. Chipwich, Inc.,* 554 F.Supp. 933, 946 (D.C.N.Y. 1983) (denying summary judgment in light of evidence that means of interference constituted unlawful restraint of trade); *Guard-Life Corp. v. S. Parker Hardware Mfg. Corp.,* 50 N.Y.2d 183, 191, 428 N.Y.S.2d 628, 406 N.E.2d 445 (1980) (privilege does not include unlawful restraints of trade).

While this Court decided, supra, that defendants had failed to proffer evidence that ACIC/Brantford had entered into the contract for anything other than legitimate business interests, there is a question of fact as to whether Barr's actions in entering into the exclusive agreement constituted an unlawful restraint of trade. Invamed alleges that Barr arranged for the exclusive supply contract in order to thwart the development of other generic warfarin sodium. Moreover, it alleges that Barr demanded the confidentiality provision as a means of further delaying Invamed's entry into the generic warfarin sodium market. Therefore, these claims may not be decided on summary judgment. **247**

Conclusion

For the reasons stated above, defendants' motions are granted in part and denied in part. Plaintiffs' antitrust claims are hereby dismissed entirely. (Invamed Compl. Counts I–V; Apothecon Compl. Counts I–VI.) Further, all of Apothecon's state law claims are dismissed. (Apothecon Compl. Counts VII–XV.) Further, Invamed's counts X and XI are dismissed. **248**

It is so ordered.

[...]