

CIVIL DISTRICT COURT FOR THE PARISH OF ORLEANS

STATE OF LOUISIANA A 9:48

NO. 08-373

DIVISION "B"  
DISTRICT COURT

SECTION 15

CHARLES C. FOTI, JR., in his Official Capacity as the Attorney General  
for the STATE OF LOUISIANA, as *parens patriae* on behalf of the STATE OF LOUISIANA  
and the CITIZENS OF THE STATE OF LOUISIANA, The STATE OF LOUISIANA, and the  
LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS

versus

AMGEN, INC.

FILED: \_\_\_\_\_

DEPUTY CLERK

**PETITION FOR TREBLE DAMAGES, INJUNCTIVE RELIEF**

NOW COME PETITIONERS, CHARLES C. FOTI, JR., a person of the full age of majority, and who currently holds the position of Attorney General for the State of Louisiana, as *parens patriae* on behalf of the State of Louisiana and its citizens, THE STATE OF LOUISIANA (the "State"), and the LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS ("DHH") (hereinafter sometimes referred to collectively as "Petitioners"), and bring this action for injunctive relief, restitution and other damages under the laws of the State of Louisiana against the above-named defendant. This antitrust action, brought solely under state law, involves an anti-competitive tying arrangement and pricing scheme implemented by defendant Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell Growth Factor ("RBCGF") drug to its dominant White Blood Cell Growth Factor ("WBCGF") drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen's scheme is to monopolize the market for sales of RBCGF drugs to oncology clinics. The result will be less competition, less physician and patient choice and an increased expense to the public health system. For their Petition against the Defendant, Petitioners assert the following:

**PARTIES**

1.

Pursuant to Revised Statute §51:138, the Attorney General, Charles C. Foti, Jr., is authorized to enforce *all* suits arising under the Monopolies Act. Pursuant to Art. IV, § 8 of the Louisiana Constitution, the Louisiana Attorney General is mandated to institute, prosecute, or intervene in any civil action or proceeding as necessary for the assertion or protection of any

EXHIBIT  
"1"

state right, and further, pursuant to § 13:5036, he is authorized to bring any suit he deems necessary for the protection of any state right.

2.

Made Defendant herein is the following party:

- A. AMGEN, INC. is a foreign corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California. Amgen, Inc., authorized to do, and doing business in Louisiana, and among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

**JURISDICTION AND VENUE**

3.

This Court has subject matter jurisdiction under Louisiana Revised Statutes § 51:121, *et seq.*, as this action brought is entirely and exclusively under Louisiana state law and is not intended, directly or implicitly, to invoke or assert and federal causes of action.

4.

This Court has personal jurisdiction over the Defendant because the Defendant regularly transacts business in the State of Louisiana, and because the Defendant's unlawful conduct has caused and will continue to cause injury in Orleans Parish and throughout the State of Louisiana.

5.

The acts charged in this Petition as having been done by the Defendant, were authorized, ordered and/or done by its officers, agents, employees, or representatives while actively engaged in the management and conduct of the Defendant's business or affairs.

6.

This Court has jurisdiction over this action because the Defendant is doing business or has done business in the State of Louisiana and has had sufficient contact with the State of Louisiana to meet due process requirements as the Defendant, directly or through agents acting with actual and/or apparent authority, has:

- (a) transacted business in this state;
- (b) contracted to supply or obtain services or goods in this state;
- (c) intentionally availed itself of the benefits of doing business in this state;
- (d) produced, promoted, sold, marketed and/or distributed its products or services in this state and, thereby, has purposefully profited from its access to this state's markets;

- (e) caused tortious damage by act or omission in this state;
- (f) caused intentional and/or tortious damage in this state by act or omission committed outside this state while (i) regularly doing or soliciting business in this state and/or (ii) engaging in other persistent courses of conduct within this state and/or (iii) deriving substantial revenue from goods used or consumed or services rendered in this state; and
- (g) committed acts and omissions which the Defendant knew or should have known would cause damage and, in fact, did cause damage in this state to the Petitioners while (i) regularly doing or soliciting business in this state, and/or (ii) engaging in other persistent courses of conduct within this state and/or (iii) deriving substantial revenue from goods used or consumed or services rendered in this state.

#### FACTUAL ALLEGATIONS

**B. Procrit and Aranesp are the Only Competitors in the Sale of RBCGF Drugs to Payors.**

7.

Amgen and Ortho Biotech Products, L.P. ("Ortho") sell a RBCGF drug. Amgen's version is called Aranesp and Ortho's version is called Procrit. Both of these RBCGF drugs compete head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products are projected to exceed \$2.8 billion in 2005.

8.

Amgen also sells Neulasta and Neupogen, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs.

9.

Aranesp accounts for roughly 66% of RBCGF drug sales to oncology clinics. Aranesp's share has increased by 46% over the past 18 months as the result of Amgen's illegal pricing practices that penalize oncology clinics on purchases of its monopoly WBCGF drugs, when those clinics do not agree to purchase significant volumes of its Aranesp, instead of its competitor.

10.

On October 1, 2005, Amgen's pricing scheme became considerably more coercive. Amgen has now imposed even steeper pricing penalties on Amgen's monopoly WBCGF drugs when doctors or oncology clinics do not purchase up to 75% of their RBCGF drugs from Amgen. In fact, if a doctor or clinic wishes to continue to receive the same level of rebates it had been receiving under the pre-October 1, 2005 contract, they must increase its Aranesp share up to 90%.

11.

Amgen's pricing scheme has reached the point where a doctor or clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government Medicare reimbursement. The doctor or clinic can only gain access to the rebates on Amgen's monopoly WBCGF drug when they purchase virtually all of their RBCGF drug requirements from Amgen.

12.

Defendant's conduct constitutes an illegal tying arrangement in violation of LA. REV. STAT. 51:122, *et seq.* As the result of Amgen's monopoly power in the sale of WBCGF drugs to oncology doctors and clinics, Amgen's pricing scheme leaves them with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. WBCGF and RBCGF drugs are distinct and separate products and a not insubstantial amount of commerce is involved.

13.

The purpose of Amgen's anticompetitive pricing scheme is to monopolize the oncology doctor and clinic market for RBCGF drugs in the United States. There is a dangerous probability that, by engaging in this exclusionary conduct, Amgen will succeed in its monopolistic plans.

14.

The anticompetitive conduct at issue here has irreparably harmed Petitioners, the State of Louisiana, and the public interest by forcing the use of Aranesp and by potentially forcing the only competing drug, Procrit, from the market.

15.

Moreover, denying clinics and ultimately patients' access to competition is not in the public interest and will harm consumers. Citizens of the State of Louisiana should not face economic coercion. Forcing physicians who treat cancer patients to select a drug solely because it is the only economically viable way to gain access to another badly needed drug for their patients, is not, by any measure, in the public interest.

16.

Severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for, HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

17.

Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

18.

Ortho sells Procrit®, a branded version of epoetin alfa. By Product License Agreement ("PLA") executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen's patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease ("ESRD"). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen.

19.

In 1991 the FDA approved the marketing of Procrit for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

20.

Following the FDA ruling, Amgen decided to seek to sell its version of epoetin alfa for all purposes under the name of Aranesp. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa in the PLA. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

21.

Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp are projected to exceed \$2.8 billion in 2005.

**B. Amgen Has a Monopoly on the Sale WBCGF Drugs.**

22.

Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially life threatening. Neutropenia is a side effect of chemotherapy which potentially compromises a patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

23.

Amgen sells two WBCGF drugs, Neupogen and Neulasta®. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that one injection of Neulasta is roughly equal to 7 injections of Neupogen.

24.

The only other WBCGF drug sold is Leukine, which is distributed by Berlex Laboratories.

25.

Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales. Unlike Amgen's WBCGF drugs which are administered by subcutaneous injection, Leukine must be administered intravenously - a longer and more costly process.

**C. Amgen Seeks to Monopolize the Sales of RBCGF Drugs to Oncology Clinics by Leveraging its WBCGF Drug Monopoly.**

**1. Amgen Begins Bundled Pricing on Aranesp and its WBCGF Monopoly Drugs.**

26.

Petitioners, DHH and citizens of Louisiana, both give RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, they must buy WBCGF drugs, particularly Neulasta, from Amgen.

27.

This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Almost from the outset, Amgen's strategy for selling Aranesp has been to penalize payors on the pricing of its dominant WBCGF drugs if they did not purchase substantial amounts of Aranesp, a product that has competition. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to force payors into purchasing Aranesp which is more expensive per dose than Procrit.

**2. The Early 2004 Amgen Contract**

28.

Amgen's penalties became even more coercive in the spring of 2004. At that time, Amgen began offering substantial "rebates" to payors on the condition that they reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC").

29.

Amgen's pricing under its APC is broken into three groups - large, medium and small accounts - based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that, once reached, allows the it to earn a specified level of rebate. The dollar volume targets Amgen puts in each APC represent a specific percentage requirement of market share based on historical usage. Rebates are earned when Amgen's share of the estimated total APC purchases reach those levels.

30.

For example, under the APCs in effect in the first half of 2004, a large account which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug

purchases. However, if it purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen it received significantly greater rebates - a 25% rebate on its Aranesp purchases and a 25% rebate on its Amgen WBCGF drug purchases. Absent the rebates provided due to the illegal tying arrangement, Amgen would provide only a minimal rebate or discount that it new was insufficient based on reimbursement mechanism then in place.

### 3. The Late 2004 Amgen Contract

31.

Later in 2004, Amgen modified its APCs. Amgen apparently recognized that simply providing a combined dollar volume target might give some flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced payors to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

32.

Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered, further penalizing anyone that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

33.

Under the modification to the APCs in late 2004, a large purchaser who obtained roughly 65% of its combined volume of WBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, if it purchased roughly 85% of its combined volume of WBCGF and WBCGF drugs from Amgen would receive a 30.0% rebate on its Aranesp purchases and a 25.0% rebate on its WBCGF drug purchases.

34.

All of these changes forced payors to buy less Procrit (which is less expensive per dose) and more Aranesp (which is more expensive per dose) in order to get access to both the WBCGF and RBCGF rebates.



35.

As a result of its illegal pricing schemes the market share for Amgen's Aranesp went from 45% to 66%.

36.

This significant shift in relative market share is attributable to payors being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

37.

The effect of Amgen's coercive tying arrangements on sales of WBCGF drugs to Petitioners is evidenced by comparing Procrit and Aranesp market shares by Petitioners with the market share in sales to retail drug stores - where Amgen has not introduced these tying arrangements. In the retail drug stores market, where Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs, Procrit has approximately 79% of the market.

**D. Amgen's New Pricing Scheme is Designed to Eliminate Its Competition.**

38.

Having gained a 65% share of sales to payors by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen has now sought to tighten its squeeze on this market. Effective October 1, 2005, Amgen's pricing scheme became significantly more coercive.

39.

As with the old pricing scheme, each payor is given a series of levels of dollar volume targets for its total Amgen purchases of RBCGF and WBCGF drugs, as illustrated below for a large account. The higher the Amgen gross purchases, the higher level of rebate payors can achieve:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%

2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

40.

However, to gain access to even the lowest rebate level described above payors must now meet separate Aranesp and Neulasta dollar volume triggers. To avoid being penalized on its purchases of Amgen's dominant WBCGF drugs, the dollar volume for Aranesp purchases that a Payors must achieve is now based on up to 75% of its total RBCGF product purchases being Aranesp, i.e., a 75% market share.

41.

A higher initial dollar volume threshold for Aranesp is only the start of this latest tying scheme. The true purpose of the new pricing scheme is to require payors to make Aranesp more than 75% of their RBCGF purchases. Under the modified APCs, for payors to receive the same aggregate value it had been receiving while performing under the pre-October 1st APC (described above), it now must reach higher dollar volume i.e., market share, levels of Aranesp. For example, the top Aranesp rebate is now 26%. This is 4% less than under the previous Amgen bundle of 30%. However, the Petitioner can earn back the additional 4% by taking its Aranesp share up to 90% as well as ensuring that Neulasta represents 90% of its WBCGF drug purchases. Thus, this new pricing scheme is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

42.

The new pricing scheme also reduces the highest Neulasta rebate from 25% to 21%. As with the Aranesp rebates, a payor can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases are of Amgen's Neulasta and the higher threshold for Amgen's Aranesp (up to 90%) is met.

43.

The October 2005 addendum to the APC continues to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC does not place caps on Aranesp. This further drives payors to

purchase all or substantially all of their RBCGF drugs from Amgen, even though it is more expensive than its competing drug.

44.

If payors do not meet their Aranesp volume requirement, they will only receive a 4% rebate on Neulasta. Previously, a payor that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is now being penalized an additional 3.1 to 5.5% on its Neulasta purchases.

**E. Amgen's Pricing Schemes Injured Petitioners.**

45.

Failing to achieve a dollar volume of purchases of Aranesp roughly equivalent to a 75% market share will have severe economic consequences on Petitioners. Because the use of WBCGF drugs is the standard of care to treat neutropenia, payors have no choice but to carry and pay for Neulasta.

46.

Amgen's pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces payors to purchase its RBCGF product, Aranesp, as a condition for receiving substantial price rebates on products that they must purchase from Amgen - WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, they will not qualify for the massive rebates provided on Amgen's dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, they are given even higher rebates. The only economically viable option for payors is to purchase all or nearly all of their RBCGF drugs from Amgen, even though it has a higher list price and acquisition price, per dose, than its competitor Procrit.

47.

Thus, Amgen's illegal action of using its monopoly power with its WBCGF drugs to force payors to purchase Aranesp, its RBCGF drug, causes payors to pay a higher price for RBCGF drugs than they would but for Amgen's illegal activity.

48.

Further, Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration

for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula an oncology clinic would have to pay Amgen hundreds of dollars more on each treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

49.

On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The new formula is based on the drugs' average selling price ("ASP" as it is known in the industry) plus 6%. Thus, if Petitioners bought a drug that had an ASP of \$1,000, it would be reimbursed \$1,060. This reimbursement amount is static regardless of the amount actually paid for the drug. The "plus 6%" is not intended to be profit. It is to provide some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

50.

As the term suggests, the ASP of a drug is an average based on the prices paid - and discounts and rebates earned - by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or can not, - avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

51.

Unless a payor qualifies for Amgen's rebates, this is precisely the situation it will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is \$2,603.00. The Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta currently is \$2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or \$524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, a clinic must receive rebates and discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their

modified APCs. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen \$295.87 more per administration of Neulasta than the clinic is being reimbursed by the government.

52.

Amgen's latest pricing scheme has forced payor to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp which has translated into substantial market share benefits for Aranesp. Evidence that Amgen's illegal tying arrangement is having the intended affect is evidenced by Amgen's recent financial statement for the third quarter of 2005 where it reported sales of Aranesp jumped 38 percent to \$840 million in the quarter.

53.

Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing payors if they do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime, causes payors to substantially overpay for RBCGF drugs.

54.

In a similar action brought by Ortho against Amgen, Ortho asserts that Amgen's tying arrangement would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will cause anti-competitive effects by increasing the barriers to entry into RBCGF drug markets.

55.

In addition, Amgen's conduct enhances and reinforces its monopoly power in the market for WBCGF drugs.

**F. There is No Legitimate Business Justification for Amgen's Tying Arrangement.**

56.

There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating its competition and potential entrants as competitors in the sale of RBCGF drugs and thereby causing payors to pay more than in a competitive market.

**G. Sales of RBCGF Drugs to Payors Constitute a Relevant Product Market.**

57.

RBCGF drugs are sold through various channels. The roughly 2,400 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over \$2.8 billion in gross sales projected in 2005. Oncology clinics include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

58.

To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive out-patient administration of RBCGF drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

59.

Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with nondialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

60.

Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of this Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

61.

An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than do hospitals.

62.

The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

63.

There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen's exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, and (2) secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

**H. Sales of WBCGF Drugs to Oncology Clinic Constitute a Distinct and Separate Product Market.**

64.

The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.

65.

WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

66.

Recognizing this, the Federal Trade Commission ("FTC") stated that "the research, development, manufacture and sale of Neutrophil Regeneration Products" (a.k.a. WBCGF drugs) is a "relevant line of commerce" in a Clayton Act 7 administrative Complaint filed against Amgen and the Immunex Corporation.

67.

The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

68.

There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the

United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

**ANTITRUST VIOLATION**

69.

Petitioners repeat and reallege all preceding paragraphs as if set forth fully herein.

70.

Defendant's actions as detailed herein violate LA. REV. STAT. 51:121, *et seq.*

71.

The payment for Defendant's products Aranesp, Neupogen and Neulasta® within the State of Louisiana is commerce within the meaning of LA. REV. STAT. 51:121, *et seq.*

72.

Defendant's actions as detailed herein are a conspiracy within the meaning of LA. REV. STAT. 51:122(A), *et seq.*

73.

Defendant's actions as detailed herein substantially lessens competition within the meaning of LA. REV. STAT. 51:122, *et seq.*

74.

The State of Louisiana and its citizens were substantially injured economically by paying for Defendant's products, Aranesp, Neupogen and Neulasta®.

75.

There is a factual connection between the defendants' actions and the injuries of the State of Louisiana and its citizens.

76.

The policies of the antitrust laws and their system of protection extend to the State of Louisiana and its citizens. Those policies include the court's plain duty to enforce the law, ever mindful of the wrong inflicted on the public resulting from crushing out individual rights using methods of enhanced power that flows from combinations, and the legislative intent to prevent such unreasonable restraints of trade and formation of monopolies, using application of the statutes to the facts using the reasonable man standard of appraisal found in tort law. The statutes were intended to be interpreted in an unbalkanized manner, so that in no way or by no means could public policy be evaded. LA. REV. STAT. 51:122 forbids all means of monopolizing



trade and LA. REV. STAT. 51:123 forbids all restraints of trade by any attempt to monopolize evaluated in light of LA. REV. STAT. 51:122. When any part of trade becomes affected by a restraint, a monopoly has occurred or is in developing stages.

77.


The State of Louisiana and its citizens are entitled to the relief of disgorgement of illegal profits, treble damages and injunctive relief.

**PRAYER FOR RELIEF**

WHEREFORE, Petitioners pray that:

- A. Summons be issued to Defendant to appear and timely give an answer;
- B. After due delays and legal proceedings, judgment be rendered in favor of Petitioners against Defendant for all damages asserted;
- C. That the unlawful conduct alleged herein be adjudged and decreed to be unlawful and committed by the Defendant as prohibited by LA. REV. STAT. §51:121 *et seq.*;
- D. That, the Defendant be found liable, *in solido*, to Petitioners for financial restitution and such other ancillary monetary damages sustained by Petitioners, all of which will be established at the trial of this matter;
- E. Petitioners pray that all deposition and travel expenses be taxed as costs;
- F. That the Defendant be found liable, *in solido*, to Petitioners, under LA. REV. STAT. §51:121 *et seq.*, including treble damages, reasonable attorney's fees, and costs; and
- G. Petitioners further pray for any and all such other, further and, different relief as the nature of the case may require or as may be deemed just and proper by this Court, including, but not limited to, the recovery of all costs of this suit, judicial interest, and attorney's fees to the fullest extent recoverable by law.

Respectfully submitted:

  
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By and through its Registered Agent for Service of Process

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