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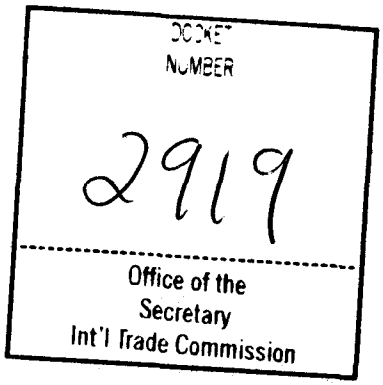

October 23, 2012

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NON-CONFIDENTIAL VERSION

VIA HAND DELIVERY
Ms. Lisa R. Barton
Acting Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

Re: *Hydroxyprogesterone Caproate and Products Containing the Same*: Motion for Temporary Relief

Dear Ms. Barton:

On behalf of K-V Pharmaceutical Company ("KV"), Complainant in the captioned proceeding, please find enclosed, pursuant to 19 C.F.R. § 210.8(a)(2), an original and eight copies (plus one copy for each Proposed Respondent) of the confidential version of the Motion for Temporary Relief and Memorandum in Support of same, in the captioned proceeding.

Certain information in the Memorandum in Support of Motion for Temporary Relief is bracketed to protect its confidentiality.

Pursuant to Section 777(b)(1) of the Tariff Act of 1930, as amended, and in accordance with 19 C.F.R. §§ 201.6 and 210.5(a), we hereby request confidential treatment for the bracketed business proprietary information in the confidential version of the enclosed Memorandum in support of Motion for Temporary Relief. The pages on which confidential information appears are listed on the cover page of the Memorandum. The information for which confidential treatment is requested pertains to KV's operations, production of the pharmaceutical product in question, sales volumes, the identity of its suppliers and contractors, inventories, and amount and source of income, profits, losses, and expenditures. The disclosure of this information is of commercial value, would cause substantial harm to KV if

released, and KV would be reluctant to divulge such information in the future if this information were disclosed to the public.

The requisite certification is enclosed in accordance with Sections 201.6 and 207.3 of the Commission's rules. In addition, in accordance with Section 201.16 and 210.52 of the Commission's rules, a non-confidential version of this document has been served on all respondents.

If you have any questions regarding this submission, please do not hesitate to contact the undersigned

Sincerely yours,

Adam H. Gordon
Counsel to K-V Pharmaceutical Company

Enclosures

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of HYDROXYPROGESTERONE CAPROATE AND PRODUCTS CONTAINING SAME	Inv. No. 337-TA-_____

MOTION FOR TEMPORARY RELIEF

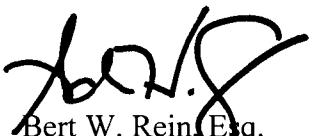
Pursuant to 19 U.S.C. § 1337 and 19 C.F.R. § 210.52, Complainant K-V Pharmaceutical Company ("KV") requests that the Commission issue a temporary general exclusion order and temporary cease and desist order pending the outcome of a proceeding initiated this day pertaining to unfair methods of competition arising from importation of 17α hydroxyprogesterone caproate (17-hydroxypregn-y-3, 20-dione hexanoate) (CAS # 630-56-8) ("HPC"). Specifically, the Commission should: (1) issue a temporary general exclusion order prohibiting imports of HPC in any form, including but not limited to HPC compounds and powder, except as authorized by Complainant; and (2) issue a temporary cease and desist order prohibiting owners, importers, and consignees from importing, selling, offering for sale (including via the Internet or electronic mail), distributing, or soliciting any HPC, HPC compound, and/or HPC composition, except for HPC or drug products produced from HPC whose importation has been authorized by Complainant.

As set out more fully in the accompanying memorandum in support, Complainant may be in liquidation prior to the termination of this proceeding in the absence of temporary relief. The continued existence of the company could depend on the granting of this Motion.

Complainant's merits case centers on the importation of HPC for the purpose of unlawfully manufacturing unlicensed copies of KV's FDA-approved drug Makena®, which is used to treat the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth, and which enjoys seven years of market exclusivity pursuant to Congressionally granted "orphan drug" status. The flooding of the market with cheap, unapproved copies of Makena® using imported HPC has denied Makena® substantial market share and has injured KV greatly. Respondents have few if any protectable rights, given that they are in the business of manufacturing or facilitating the manufacture of an illegal product, and the public health is best advanced by having all patients treated with Complainant's FDA-approved product or, in those rare cases where necessary, compounded formulations using FDA-authorized HPC provided by Complainants. A bond should not be required because Respondents are engaged in an unlawful enterprise or contributing to an unlawful enterprise and therefore have no protectable interests in continuing the activity to be precluded by the granting of temporary relief.

For these reasons, we respectfully submit that this Motion should be granted.

Respectfully submitted,



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K-V PHARMACEUTICAL COMPANY

Date: October 23, 2012

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of HYDROXYPROGESTERONE CAPROATE AND PRODUCTS CONTAINING SAME

Inv. No. 337-TA-_____

ORDER GRANTING TEMPORARY RELIEF

Pursuant to 19 U.S.C. § 1337, and after consideration of Complainant's Motion for Temporary Relief and all of papers related thereto, it is hereby

ORDERED that Complainant's Motion for Temporary Relief is **GRANTED**; and it is further

ORDERED that imports of 17α hydroxyprogesterone caproate (17-hydroxypregn-y-3, 20-dione hexanoate) (CAS # 630-56-8) ("HPC") in any form, except as authorized by Complainant, are hereby **EXCLUDED** from the United States Customs territory; and it is further

ORDERED that owners, importers, and consignees immediately shall cease and desist from importing, selling, offering for sale (including via the Internet or electronic mail), distributing, or soliciting any HPC, HPC compound, and/or HPC composition, except for HPC or drug products produced from HPC whose importation has been authorized by Complainant.

This Order shall remain in place until the conclusion of the proceeding or until the Commission rescinds it.

SO ORDERED.

Dated: November __, 2012

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of HYDROXYPROGESTERONE CAPROATE AND PRODUCTS CONTAINING THE SAME	Inv. No. 337-TA-_____ **NON-CONFIDENTIAL VERSION** Confidential information has been removed fromon pages 4, 12, 14, 15, 18-22

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR TEMPORARY RELIEF

Pursuant to 19 U.S.C. § 1337 and 19 C.F.R. § 210.52, Complainant K-V Pharmaceutical Company ("KV") requests that the Commission grant it temporary relief in the form of a general exclusion order and a cease and desist order pending the outcome of the proceeding initiated this day pertaining to unfair methods of competition arising from importation of 17α hydroxyprogesterone caproate (17-hydroxypregn-y-3, 20-dione hexanoate) (CAS # 630-56-8) ("HPC," also commonly known as "17P"), that are substantially injuring and threaten to destroy the domestic 17P pharmaceutical industry.

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Issuance of a temporary general exclusion order and a temporary cease and desist order is necessary and appropriate to stop ongoing, irreparable substantial injury to the domestic industry, and to forestall its potential imminent destruction. As discussed below, all of the elements supporting temporary relief are amply and compellingly satisfied in this case. While such measures are extraordinary, the facts and circumstances of this case are extraordinary, and strongly support the issuance of these forms of relief.

KV owns Makena®, the only drug approved by the United States Food and Drug Administration ("FDA") to treat a rare, but severe, condition: the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. HPC is the active pharmaceutical ingredient ("API") in Makena®. Makena® is the only currently FDA-approved drug that uses HPC for any indication. HPC is not used in any other known commercial pharmaceutical or non-pharmaceutical application apart from the preparation of drugs to treat the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Because this condition affects fewer than 200,000 patients annually, FDA has determined it to be an "orphan condition."

Makena® is an "orphan drug," – a drug developed to treat this "orphan condition." Given the size of the patient population they treat, orphan drugs necessarily have relatively limited markets. To provide incentive for the investment of the substantial resources required to develop such drugs and satisfy the rigorous requirements to obtain their approval by FDA, the manufacturer of an orphan drug is entitled by federal law to, among other things, a seven-year period of marketing exclusivity, akin to patent protection. This promotes the development of drugs that otherwise would not occur, and allows pharmaceutical companies who develop orphan drugs to recoup their investments.

Because of its exclusive right to market the drug for its approved indication, KV constitutes the entire legitimate domestic 17P pharmaceutical industry. However, the seven years of market exclusivity to which Makena® is entitled is being severely undermined by the production of what are essentially inexpensive copies (or essentially copies) of Makena® ("compounded 17P formulations"), manufactured on a commercial scale by compounding pharmacies in the United States. While compounding can be a legitimate practice in specific,

limited circumstances, the practice is rife with risks to public health and safety and exists at FDA's sufferance. As a matter of law, there is an absolute prohibition on large-scale manufacturing of unlicensed copies of approved products under the guise of "compounding."

The risks of unlawful, large-scale "compounding" have been amply illustrated by the ongoing tragic epidemic of deadly fungal meningitis, caused by mass-produced, compounded steroid injections manufactured by one of the Proposed Respondents in this investigation, the New England Compounding Center. As of the date of this filing, no fewer than 23 persons have unnecessarily lost their lives as the result of unlawful commercial-scale drug manufacturing that has been performed under the guise of traditional "compounding."

Compounding pharmacies obtain their API from unregistered sources, often from abroad (China in particular), and market their products like FDA-approved pharmaceuticals. *See* FDA, The Special Risks of Pharmacy Compounding, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm (last visited Oct. 17, 2012); *see also Compounding pharmacies rise in popularity but bring questions about safety*, Washington Post (Oct. 13, 2012). Indeed, potency and purity issues like those at the center of the recent meningitis epidemic linked to compounded drugs are precisely what led to the passage of the Food, Drug, and Cosmetic Act in the first place.

The same kind of large-scale, unlawful manufacturing of drugs fueled by unauthorized imports in violation of the FDCA is precisely what is at issue in this case. Compounded 17P formulations are being manufactured in mass quantities by compounding pharmacies using imported API, all of which appears to be from China. Chinese HPC is easily imported into the United States directly by air from manufacturers and exporters in China. KV's investigators have been able to simply place orders by email and have had Chinese HPC delivered within 5-8

business days. Declaration of Michael Jozwiakowski at ¶¶ 30, 32 and accompanying exhibits, attached as Exhibit 1 ("Jozwiakowski Dec."). The unregulated and uninspected compounded 17P formulations produced from imported HPC are undercutting Makena® on price and diverting massive market share from Makena® that Congress intended KV to have by virtue of its Orphan Drug approval. In fact, "compounders" have taken an estimated [ ] of the market. Declaration of Scott Goedeke at ¶ 19, attached as Exhibit 2 hereto ("Goedeke Dec."). The practice is so widespread, and the allure of low-priced, unlawfully produced copies of Makena® so strong, that certain states have developed and implemented policies favoring the unlawful products over FDA-approved Makena® for their Medicaid patients, based solely on the low price of those products.

There is no private remedy for these compounders' violations of the FDCA; only FDA can take action, and it contends that it is short on resources. Even if resources were abundant, pursing enforcement actions against the scores of pharmacies unlawfully manufacturing compounded 17P formulations across the country would be an enormous challenge. Moreover, KV could never bring legal action grounded in some other theory against every state violating the Medicaid laws, as the practice is too widespread. These unlawful activities have forced KV into bankruptcy and, unless stopped, threaten to destroy KV and hence the United States industry.

As discussed below, KV is likely to succeed in demonstrating a violation of Section 337 of the Tariff Act of 1930, as amended ("the Act"). Substantial injury and, indeed, the potential destruction of the domestic industry absent temporary relief is obvious and well-supported. Every lost sale of Makena® to an unlawfully compounded 17P formulation causes irreparable harm to KV. The unfair competition resulting from importation of HPC is on such a broad scale

that KV has been forced into Chapter 11 bankruptcy. Indeed, absent the granting of temporary relief, Complainant may be unable to reorganize and could cease to exist as a going concern prior to the completion of this proceeding or even the issuance of a preliminary finding.

The public interest squarely favors having all women who need 17P therapy with access to safely manufactured injections of the only FDA-approved drug for the condition, which is precisely what granting temporary relief would accomplish. Limiting use to the FDA-approved drug, manufactured according to FDA's good manufacturing processes using HPC sourced from FDA-approved and inspected facilities, is unquestionably a public interest, as it greatly reduces risks to public health and safety, such as the recent deaths and infections caused by compounded steroid injections. To the extent that a very small number of women cannot take Makena® itself because of a legitimate medical problem (such as allergic reaction to one of the inert ingredients), KV has agreed to provide HPC from its FDA-approved and inspected supplier to an independent third-party administrator to distribute the HPC to compounding pharmacies so that they may fill individual prescriptions for a compounded formulation. Thus, no woman who needs Makena® (or HPC) will go without, and women will have access to safe and FDA-approved drugs. Similarly, to the extent a need exists for HPC to conduct research and development, KV will satisfy that need, which itself is consistent with a strong public interest in ensuring that such R&D uses HPC of reliable provenance and known purity and efficacy.

Finally, the balance of the interests also favors temporary relief. Proposed Respondents are engaged in the unlawful manufacture of new drugs in violation of state and federal law, and the shipment of HPC to the United States is for the sole purpose of facilitating such unlawful activity. It is difficult to conceive of any cognizable interest these parties can assert in support of continuing such activities. The new drugs made with HPC that is not purchased from FDA-

registered or approved sources have demonstrated purity and potency issues—issues that go to the heart of health and safety. By contrast, Makena® is manufactured under FDA's rigorous regulatory oversight, and its HPC supplier is FDA-inspected.

Complainant requests two forms of temporary relief to save the domestic industry from continued substantial injury and potential destruction. First, Complainant requests a general exclusion order prohibiting imports of HPC in any form, including but not limited to HPC powder and compounds prepared therefrom, except as authorized by Complainant. This temporary relief would bar the foreign product from entering the country and would cut off the "compounders'" ability to obtain product to support their illegal drug manufacturing.

Second, Complainant requests a cease and desist order prohibiting owners, importers, and consignees from importing, selling, offering for sale (including via the Internet or electronic mail), distributing, or soliciting any HPC, HPC compound, and/or HPC composition, except for HPC or drug products produced from HPC whose importation has been authorized by Complainant. This form of temporary relief would prevent domestic parties from selling unlawfully compounded 17P formulations manufactured from imported API that has been stockpiled.

The general exclusion and cease-and-desist remedies would work hand-in-hand to cut off the key ingredients used in the unlawful enterprise, while allowing KV to obtain HPC from its FDA-registered source and allowing HPC into the country for purposes of individually prepared compounded formulations of the drug for those who, for legitimate medical reasons, cannot take the FDA-approved drug.

II. BACKGROUND

A. Makena® And Its Indications

Preterm birth is a serious and costly problem in the United States. Jozwiakowski Dec. ¶ 4. Each year, approximately 140,000 women in the United States who have a history of singleton spontaneous preterm birth are at risk of preterm birth, with grave and costly health effects on both mother and child. Jozwiakowski Dec. ¶¶ 4, 6. Prematurity costs the United States more than $26 billion annually. Jozwiakowski Dec. ¶ 4. On average, the cost of a preterm birth in the United States is approximately $51,600, and the average medical costs for a preterm infant's first year of life are about 10 times greater ($32,325) than for a full-term infant ($3,325). Jozwiakowski Dec. ¶ 5. There is, therefore, a critical need for pharmaceutical products that safely help prevent instances of premature delivery.

Because premature delivery, while widespread, affects a relatively small number of patients, pharmaceutical companies ordinarily would not have the incentive to devote the resources necessary to develop drugs to treat this condition. The federal Orphan Drug Act is intended to address that particular problem: it provides pharmaceutical companies with, among other things, a seven-year marketing exclusivity period for the orphan indication—akin to patent exclusivity—as an incentive to invest the extraordinary time and money necessary to develop and obtain FDA approval for drugs that are vital, but benefit relatively small "orphan" patient populations (*i.e.*, fewer than 200,000 patients). 21 U.S.C §§ 360bb(a)-360cc(a); *see also* Orphan Drug Act § 1(b)(5) ("{S}ome promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs.").

FDA approved Makena® (a sterile injection) on February 3, 2011, as an orphan drug that is a safe and effective treatment for the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Jozwiakowski Dec. ¶¶ 3, 15.

B. Compounding of HPC

Prior to FDA approval of Makena®, women with a singleton pregnancy who have a history of singleton spontaneous preterm birth had two options: use unapproved, non-federally regulated compounded 17P formulations, or nothing at all. Neither option was particularly appealing. Jozwiakowski Dec. ¶ 7.

Traditionally, drug compounding is a process by which a pharmacist combines, mixes, or alters ingredients to create a medication customized to the particular medical need of an individual patient. Jozwiakowski Dec. ¶ 8. This is required, for example, when no drug approved by FDA to treat the patient's disease is commercially available, or when no drug that has been approved by FDA can successfully treat that patient. Jozwiakowski Dec. ¶ 8. Before the development of large-scale pharmaceutical manufacturing under controlled conditions and government regulation to ensure the quality and safety of drugs, compounding played a prominent role in the preparation of drugs. Jozwiakowski Dec. ¶ 19. Compounded formulations do not undergo FDA premarket review and are distributed without any FDA finding of safety, efficacy, or manufacturing quality. Jozwiakowski Dec. ¶ 9.

When Congress enacted the Food, Drug, and Cosmetic Act ("FDCA") in 1938, compounding became unlawful because compounded formulations are "new drugs" under 21 U.S.C. § 321(p), and because 21 U.S.C. §§ 355(a) and 331(d) prohibit the introduction of new drugs into interstate commerce without FDA approval. Nevertheless, because compounding is

sometimes necessary to tailor a drug to respond to an individual patient's legitimate medical needs, FDA historically has not enforced the new drug approval requirement against pharmacies that make and dispense legitimately customized compounded formulations for individual patients who, for clinical reasons specific to the individual patient as determined by the treating physician, cannot use an FDA-approved drug for their disease or condition. Jozwiakowski Dec. ¶ 11. Pharmacies, including certain of the domestic Proposed Respondents, are authorized by state pharmacy regulations to compound drugs in response to individual prescriptions from licensed prescribers where a legitimate medical need cannot be met by the current FDA-approved formulation. Jozwiakowski Dec. ¶ 10. Compounders, however, are not authorized by federal or state laws to manufacture or sell unapproved new drugs, ship large quantities of compounded formulations across state lines, prepare a compounded formulation without a prescription, or make copies or what are essentially copies of an FDA-approved drug. Jozwiakowski Dec. ¶ 10. Nor are they permitted to use API imported from uninspected foreign facilities for compounding purposes.

FDA, as a matter of policy, considers enforcement against compounders to be appropriate where compounders go beyond legitimate boundaries and engage in manufacturing rather than meeting individual patients' specialized requirements. However, FDA has maintained that it struggles to enforce the FDCA prohibition on the improper "compounding" and distribution of unapproved new drugs in interstate commerce because of scarce agency resources, the ubiquity of licensed compounders, and the difficulty of identifying those "compounders" who cross the line between lawful, traditional compounding to respond to legitimate medical needs of individual patients, and those who engage in unlawful manufacturing under the guise of "compounding."

Thus, even pre-Makena® compounding of HPC was technically impermissible. The drug was not compounded for individual patients, was made in large quantities, and was sold alongside other pharmaceutical products without being FDA-approved "new drugs." With no FDA-approved drug for the indication, however, FDA apparently tolerated the practice because the compounded formulations were more effective for women than receiving no treatment at all. Jozwiakowski Dec. ¶ 11.

FDA has stated that that its position has changed now that Makena® has been approved. Under FDA's normal policy on compounded formulations, the compounding of 17P formulations "should not exceed the scope of traditional pharmacy compounding"; *i.e.*, where the "prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product." Jozwiakowski Dec. ¶ 20; Goedeke Dec. ¶ 27.

Compounded 17P formulations are not, and should not be compared to, a generic version of Makena®. Like Makena®, FDA-approved generics are manufactured under rigorous FDA-mandated good manufacturing practices standards. Jozwiakowski Dec. ¶ 9. Compounded formulations are not. Jozwiakowski Dec. ¶¶ 8-9. They are made by processes that are neither regulated nor approved by FDA, and use unknown sources of HPC. The processes by which those formulations are made can give rise to unknown variability in purity, potency and even sterility, as well as serious medical risks. Jozwiakowski Dec. ¶¶ 8-9.

C. FDA Recognizes That Compounded 17P Formulations Are Presumptively Unlawful

FDA has rightly recognized that compounded 17P formulations in particular are not an appropriate substitute for FDA-approved Makena®. In testifying before Congress in March

2011, FDA Commissioner Margaret Hamburg M.D., touted the benefits of Makena® relative to the compounded formulations:

> I think it is important and an advance that we have an FDA-approved drug to prevent preterm pregnancy and all of its consequent serious medical concerns for both mother and infant. And while the drug has been available through compounding.... compounding as a practice has been associated with serious health risks....

Goedeke Dec. ¶ 14. On November 8, 2011, the FDA stated:

> we remind physicians and patients that before approving the Makena new drug application, FDA reviewed manufacturing information, such as the source of the API used by its manufacturer, proposed manufacturing processes, and [ ] adherence to current good manufacturing practice. Therefore, as with other approved drugs, greater assurance of safety and effectiveness is generally provided by the approved product than by a compounded product.

Goedeke Dec. ¶ 15. On June 15, 2012, the FDA reiterated that:

> approved drug products, such as Makena, provide a greater assurance of safety and effectiveness than do compounded products. Before approving the Makena [ ], FDA reviewed manufacturing information, such as the source of the API used by its manufacturer, proposed manufacturing processes, and the firm's adherence to current good manufacturing practice.

Goedeke Dec. ¶ 16. On June 29, 2012, FDA stated: "when an FDA-approved drug is commercially available," practitioners should "prescribe the FDA-approved drug rather than a compounded drug unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product." Goedeke Dec. ¶¶ 26-27.

D. Compounded 17P Formulations Dominate The Market

In spite of state pharmaceutical laws, the FDA's approval of Makena®, and FDA's normal enforcement policies, Respondent pharmacies and others across the country continue to compound 17P formulations on a commercial scale, and to sell it openly to home health care providers and retail pharmacies. Production of compounded 17P formulations today is not in response to any particular patient needs, but is intended to substitute for the only FDA-approved drug for the indication.

Relying on the anticipated seven-year marketing exclusivity that comes with Orphan Drug status, KV invested or committed approximately [ ] dollars to bring Makena® to market, including purchasing the rights to the drug itself, performing required pre-approval trials, performing post-approval trials, and performing required reporting, monitoring, and other compliance issues. Declaration of Thomas McHugh at ¶ 12, attached as Exhibit 3 hereto ("McHugh Dec.").

In order to recoup those investments, FDA-mandated expenditures, and the higher cost of obtaining FDA-approved pharmaceutical ingredients, the list price for Makena® is now $690 per injection, before considering statutorily required discounts for Medicaid (23.1%), substantial supplemental rebates offered to Medicaid, negotiated discounts for commercial insurers, and KV's many programs designed to distribute Makena® with little or no copayment to women in need of financial assistance. McHugh Dec. ¶¶ 15-17. It also does not include the thousands of injections that have been provided at little or no charge to patients through KV's patient assistance program. KV's net price averages approximately [ ] per injection. McHugh Dec. ¶ 16.

Compounders, however, have made no expenditures on research and development, need not conduct clinical trials, have no ongoing monitoring costs, and obtain their HPC from unapproved producers. Jozwiakowski Dec. ¶ 9. They are, therefore, able to price their compounded 17P formulations much lower than Makena®. McHugh Dec. ¶ 21; Goedeke Dec. ¶ 25. Consequently, a huge volume of sales are diverted to compounded 17P formulations instead of FDA-approved Makena®. McHugh Dec. ¶ 21.

Moreover, because of the lower price of compounded 17P formulations, several states have developed and implemented policies that formally favor the unlawfully manufactured drugs over the FDA-approved drug. Goedeke Dec. ¶¶ 25-32. KV has taken legal action to stop three states – Georgia, Illinois, and South Carolina – from enforcing such policies, with some degree of success. Goedeke Dec. ¶¶ 31-33.

For example, KV sued the Georgia Department of Community Health, arguing that its formal preference for compounded 17P formulations over Makena® violated the Medicaid statutes and regulations, and seeking a preliminary injunction against the practice. *See K-V Pharmaceutical Co. v. Cook*, No. 1:12-cv-2491-CAP, 2012 WL 3715276, *1 (N.D. Ga. Aug. 9, 2012).

The U.S. District Court for the Northern District of Georgia granted the preliminary injunction, finding a likelihood of success on KV's claim that Georgia's preference for unlicensed compounded 17P formulations over Makena® is a violation of federal law. *Id.* at *2-3. The court further found that public health considerations favored granting a preliminary injunction (given that Makena® is FDA-approved and manufactured according to strict GMP standards), that the state was only minimally injured by having to pay more for the superior

FDA-approved drug, and that "every lost sale of Makena® to Georgia Medicaid patients is a financial blow to {KV}." *Id.* at *3.

It would be impracticable if not impossible, however, for KV to sue every state with such a policy, or to challenge every compounding pharmacy that engages in unlawful manufacture of compounded 17P formulations (even if that were permissible given FDA's exclusive right to enforce the FDCA). In addition, certain insurance providers continue to favor compounded 17P formulations over Makena®, and certain in-home health care providers routinely refuse to supply their patients with Makena® and will only supply compounded 17P formulations. Goedeke Dec. ¶ 35.

As a result, while Makena® is the only 17P drug approved by the FDA for the treatment of women with a history of spontaneous preterm birth, and has exclusive marketing rights for this indication, it has accounted for only [ ] of all sales of HPC-based pharmaceutical products since being approved, even during its best sales periods. Jozwiakowski Dec. ¶ 21; McHugh Dec. ¶ 19. Based on orphan drug exclusivity, in combination with the extremely low rate of legitimate medical need for a compounded formulation, Makena® should account for approximately 99% of all sales of HPC preparations in the United States. Jozwiakowski Dec. ¶ 19. KV estimates that just in the past year, more than [ ] patients have received up to [ ] injections of compounded 17P formulations instead of Makena®. Goedeke Dec. ¶ 19. Thus, many tens of thousands of at-risk pregnant women are being treated with unlawful compounded 17P formulations rather than FDA-approved Makena®.

As a result of its difficulties in realizing market share, KV commissioned an investigation of the HPC compounding industry. Jozwiakowski Dec. ¶ 21. KV's commissioned investigator in the United States, obtained ten samples of imported HPC. Jozwiakowski Dec. ¶ 28. Seven of

the suppliers were original manufacturers of the API which operated unapproved facilities in China; the remaining three suppliers, based in the United States, were "resellers" of API that originated in China. Jozwiakowski Dec. ¶¶ 28-30; Goedeke Dec. ¶¶ 21 and attachments 23-35 thereto.

This importation of HPC, solely for the purpose of contributing to the unlawful compounding of HPC in violation of KV's rights under the Orphan Drug Act, has substantially injured and is destroying the domestic HPC pharmaceutical industry. KV's revenues, like its sales, thus far have missed its targets by approximately [ ]. McHugh Dec. ¶ 31. KV must sell a full course of injections to many more women than it is currently treating simply to recover its research and development costs, let alone cover its operational costs relating to Makena® or realize a profit. McHugh Dec. ¶¶ 22-23. The revenue KV realizes from sales of Makena® is far less than necessary to cover KV's substantial expenses incurred to bring Makena® to market, are clearly not enough to cover KV's ongoing operational costs, and far less than necessary to turn a profit. McHugh Dec. ¶¶ 21-23, 32.

As a result, on August 4, 2012, KV sought protection under Chapter 11 of the United States Bankruptcy Code to attempt to reorganize and emerge with more manageable debts. McHugh Dec. ¶ 38. In an effort to reduce costs, KV has also attempted to restructure its debt and has dramatically reduced its workforce. McHugh Dec. ¶ 37.

The ongoing substantial injury caused by the importation of HPC for purposes of manufacturing illegal drugs, however, is so serious that it threatens to preclude KV's successful reorganization through bankruptcy if temporary relief is not provided. McHugh Dec. ¶ 39. Given FDA's stated inability to stop this pervasive unlawful compounding, no relief short of a temporary general exclusion order precluding importation of the API except as authorized by

KV, and a temporary cease and desist order prohibiting the sale by domestic entities of imported HPC and compounded 17P formulations prepared therefrom, except as authorized by Complainant, will realistically preserve the United States 17P pharmaceutical industry during the pendency of this proceeding. McHugh Dec. ¶ 40.

III. ARGUMENT

A. Standard for Temporary Relief

In determining whether temporary relief is appropriate, the Commission "will apply the standards the U.S. Court of Appeals for the Federal Circuit uses in determining whether to affirm lower court decisions granting preliminary injunctions." 19 C.F.R. § 210.52(a). Four factors are weighed in considering a motion for a preliminary injunction: (1) immediate and irreparable injury to the movant; (2) the movant's likelihood of success on the merits; (3) the public interest; and (4) the balance of hardship on all the parties. *Zenith Radio Corp. v. United States*, 710 F.2d 806, 809 (Fed. Cir. 1983). The Federal Circuit reviews the grant of a preliminary injunction by the trial court for abuse of discretion. *Id.*

The relief sought herein is fully justified in light of the strong likelihood that Complainant will show unfair methods of competition based on imports of the API into the United States, the fact that temporary relief will help avoid KV's liquidation and hence destruction of the domestic industry, the fact that the public health and safety will be enhanced when women are provided full and fair access to the only FDA-approved drug for a serious medical condition, and the fact that the balance of hardships weighs squarely in favor of protecting the domestic industry over the producers of illegal knockoff products.

B. Complainant Has a Substantial Likelihood of Success on the Merits

Under Section 337 of the Act, "{u}nfair methods of competition and unfair acts in the importation of articles . . . into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is . . . to destroy or substantially injure an industry in the United States," are "unlawful." 19 U.S.C. § 1337(a)(1)(A). To prove a violation of this section, a complainant must show: (1) an unfair act; and (2) resulting detrimental effect or tendency. *New England Butt Co. v. International Trade Comm'n*, 756 F.2d 874, 876 (Fed. Cir. 1985).

1. Substantial Imports Of HPC Are Taking Place

KV has documented no fewer than 11 instances of importation of HPC from seven different Chinese manufacturers or exporters, which confirm that unlawful imported HPC is readily available to manufacturing compounders in the United States. In July 2011, an outside consultant retained by KV ordered and received HPC in powder form from Betapharma (Shanghai) Co., Ltd.; Hubei Gedian Humanwell Pharma; Hubei Saibo Chemical Co., Ltd.; Jinan Haohua Industry Co., Ltd.; Shanghai JinHong BioPharmaceutical Ltd.; Wuhan Xianghe Pharmaceutical, Co., Ltd.; and Xianju Hongyan Pharmaceutical Chemicals Co., Ltd. Jozwiakowski Dec. ¶¶ 26-32. Although one sample did not contain the API, but instead contained glucose, all seven samples were sold and identified as HPC at the time of importation. Jozwiakowski Dec. ¶¶ 28-29, 55.

The independent consultant subsequently ordered and received four additional samples of HPC in powder form from Betapharma (Shanghai) Co., Ltd.; Hubei Gedian Humanwell Pharma;

Jinan Haohua Industry Co., Ltd.; and Xianju Hongyan Pharmaceutical Chemicals Co., Ltd. Jozwiakowski Dec. ¶ 32.[1]

Given that (1) Makena® is an appropriate treatment for 99% of the women with a singleton pregnancy who have a history of singleton spontaneous preterm birth, but that (2) Makena® represents only approximately [ ] of the market for HPC pharmaceuticals, (3) there is no domestic production of HPC, and (4) KV's supplier of HPC, the only producer with an FDA DMF, does not supply HPC to any party producing compounded 17P formulations, it is without question that API is being imported. Indeed, the specific instances of importation discussed above demonstrate just how easy it is to obtain enough ample supply from abroad to unfairly manufacture compounded 17P formulations, and substantially injury the domestic industry.

2. Proposed Respondents Have Engaged in Unfair Methods of Competition, and Unfair Unfair Acts In the Importation of HPC

Proposed Respondents are engaged in unfair methods of competition and unfair acts in the importation of HPC, and in the sale of imported HPC. Their actions violate federal drug law and undermine Complainant's exclusive right to market the 17P pharmaceutical product sold under the brand name Makena® for its approved indication, causing substantial injury and threatening destruction of the domestic industry.

When an FDA-approved drug is available to treat a condition, whether or not that drug has been granted orphan drug status, compounding of that drug lawfully may occur only when a particular patient has a specialized need for a compounded product as opposed to the branded

[1] These later shipments demonstrate the Chinese manufacturers' willingness and ability to seek to evade Customs requirements. Three of the Chinese manufacturers, Betapharma (Shanghai) Co., Ltd., Xianju Hongyan Pharmaceutical Chemicals Co., Ltd., and Jinhan Haohua Industry Co., Ltd. intentionally misidentified the API as different products, and undervalued the imports to reduce duty liability, at the time of importation. Jozwiakowski Dec. ¶¶ 57-61.

drug. Jozwiakowski Dec. ¶ 10. In other words, there is a legal requirement that Makena® be used, subject to an exception in the rare instances where the "compounded product is necessary." Goedeke Dec. ¶ 27. That, however, is not happening: "compounders" not authorized by federal or state laws to manufacture or sell unapproved new drugs are doing so, shipping large quantities of compounded formulations across state lines, preparing compounded formulations without a prescription, and making copies or what are essentially copies of an FDA-approved drug. Indeed, [ ] of the prescriptions for 17P therapy today are being filled with unlawful compounded 17P formulations instead of the FDA-approved drug, Makena®. Jozwiakowski Dec. ¶ 21.

Imported HPC is the essential component of this unlawful practice. There is no domestic source of HPC, and the evidence shows that *all* HPC comes from foreign sources. Jozwiakowski Dec. ¶¶ 22, 26. And because there are currently no other known commercial pharmaceutical or non-pharmaceutical products that use HPC, the manufacture of Makena® or unlawful copies of Makena® is the *only* purpose for which HPC is being imported to the United States. Jozwiakowski Dec. ¶ 15. Importation solely for the purpose of undermining Complainants' statutory orphan drug exclusivity is clearly an unfair act and an unfair method of competition.

3. Proposed Respondents' Unfair Practices are Substantially Injuring and Threaten to Destroy the Domestic Industry

Given Makena®'s Orphan Drug designation and market exclusivity, and the fact that HPC is not currently known to have any other commercial pharmaceutical or non-pharmaceutical uses, KV constitutes the domestic HPC pharmaceutical industry.

The domestic 17P pharmaceutical industry should be vibrant, but has been severely injured. In February 2011, when FDA approved Makena®, KV and its subsidiaries employed

[ ] people in the United States, in positions at all levels, including specialized technical research and development staff and marketing and administrative staff. McHugh Dec. ¶ 28.

KV made substantial research and development outlays and investments in FDA-required Good Manufacturing Practice requirements. McHugh Dec. ¶ 12. KV also is currently performing FDA-required post-approval clinical testing. This testing is significant, involving 1,700 patients and 500 infants worldwide. Jozwiakowski Dec. ¶ 18. Since FDA approval of Makena® on February 3, 2011, the domestic industry has spent approximately [ ] million on required post-approval activity. McHugh Dec. ¶ 12. In all, the domestic industry has invested or will invest approximately [ ] million on research and development, clinical studies, and required post-marketing surveillance and reporting adverse events to FDA. McHugh Dec. ¶ 12. The bulk of KV's employees are dedicated to supporting Makena®, including in pharmacovigilance (science and activities relating to the detection, understanding, assessment, and prevention of adverse effects of medicines), sales, marketing, and compliance. McHugh Dec. ¶¶ 24-25. All of KV's employees are involved in its Makena® operations either directly or indirectly. McHugh Dec. ¶ 28.

Physician education is a large part of KV's activity with regard to Makena®. While direct-to-consumer advertising is not commercially warranted, KV employs a large sales force that provides Makena® education to the majority of physicians who care for pregnant women (approximately 2,000 maternal-fetal medicine specialists and 18,000 obstetrician-gynecologists). McHugh Dec. ¶ 24. In addition to developing and providing materials to its sales force, the domestic industry engages in traditional pharmaceutical product marketing activities in accordance with FDA regulations. McHugh Dec. ¶ 24. These activities include, but are not limited to, advertising in trade journals; providing informational materials to healthcare providers

via mail, email, and fax; maintaining a product website; and making information available through exhibit booths at professional society meetings. McHugh Dec. ¶ 24.

The domestic industry has been substantially injured and is threatened with destruction by the unlawful manufacture of compounded 17P formulations. Complainant's exclusive right to market Makena® for the indication of risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth was earned by virtue of expending substantial time and money required for research, development, and trials of a drug that could treat, at most, only 140,000 women per year. "Orphan drug" status, with its concomitant seven-year exclusivity period, is the *only* way in which the expenditure of such resources for the treatment of such a small patient population makes any sense at all. McHugh Dec. ¶ 13. Because Proposed Respondents, while actually engaged in the manufacture of drugs, do not bear the cost of conforming to FDA Good Manufacturing Practice requirements and have not expended the substantial resources necessary to establish the safety and efficacy of their formulations under the FDCA, they can and do price their products much lower than Makena®, and divert substantial sales to their unlawful HPC products. McHugh Dec. ¶ 21.

KV estimates that more than 99 percent of the relevant patient population for Makena® can be treated with Makena®, and that less than one percent of the patient population requires a customized compounded formulation. Jozwiakowski Dec. ¶ 19. In a properly structured market, Makena® should account for over 99 percent of the sales of HPC in the United States. Jozwiakowski Dec. ¶ 19. Instead Makena® currently accounts for approximately [ ] percent of the total prescriptions for HPC products. McHugh Dec. ¶ 19; Jozwiakowski Dec. ¶ 21.

KV's litigation against the state of Georgia, noted above, provides a useful illustration of the problem. As a matter of state Medicaid policy based solely on the relative *cost* of the

products, Georgia has formally favored compounded 17P formulations over FDA-approved Makena®, and has required prior approval before Georgia would pay for Makena® over a compounded 17P formulation. *K-V Pharmaceutical*, 2012 WL 3715276, at *1. As the federal district court in Georgia found when it granted KV's motion for a preliminary injunction against Georgia's policy, "every lost sale of Makena® to Georgia Medicaid patients is a financial blow to [ ]." *K-V Pharmaceutical*, 2012 WL 3715276, at *3.

The effect of unfair imports on KV's revenues – and consequently the health of the domestic industry – has been dramatic. Whereas KV conservatively projected that it could achieve gross revenues in excess of [ ] over the first twelve months following the launch of Makena®, KV actually achieved only [ ] in gross revenues over that period. McHugh Dec. ¶ 31. At the current estimated average net price of [ ] per injection, approximately [ ] paying patients would need to initiate and complete, on average, a 15-injection course of therapy in order for KV to recoup its acquisition and R&D costs. McHugh Dec. ¶ 22. At the rate of patient enrollment (patients who start therapy) that KV is currently experiencing – currently [ ] new patients a month (which includes patients who receive Makena® at no charge) – it will take much longer than the seven-year orphan-drug exclusivity period to recoup just the acquisition and R&D costs. McHugh Dec. ¶ 22. In order to cover its operational costs, KV needs another [ ] paying patients annually. McHugh Dec. ¶ 23. If KV cannot cover its operational costs, which, at Makena®'s current rate of market penetration, is not possible, KV cannot afford to keep Makena® on the market. McHugh Dec. ¶ 23. In its fiscal year ended March 31, 2011, KV had an [ ] attributable to Makena®. McHugh Dec. ¶ 32. For its fiscal year 2012, the [ ]. McHugh Dec. ¶ 32.

As a result of importation and selling of the API and KV's reduced revenues, along with the bankruptcy filing that followed as a direct consequence of the unfair methods of competition, KV has been forced to significantly reduce its workforce. McHugh Dec. ¶ 37. KV currently employs approximately [ ] people overall (as compared to [ ] employees in February 2011). McHugh Dec. ¶¶ 28, 37. One hundred percent of KV's employees spend all or some of their time on Makena®-related activities. *Id.*

Thus, the domestic industry is being substantially injured by the importation of HPC into the country, as its only known commercial use apart from the manufacture of Makena® is the preparation of compounded 17P formulations, which undercut Makena® on price and are threatening to destroy KV and hence this domestic industry.

C. Complainant Will Be Irreparably Harmed If Temporary Relief Is Denied

KV could be in liquidation prior to the completion of this proceeding if temporary relief is denied. The federal district court in Georgia, in granting KV a preliminary injunction against Georgia's unlawful preference for compounded 17P formulations over Makena®, specifically found that "corporate extinction has been recognized as a form of irreparable harm," and determined that KV's bankruptcy filing, along with evidence of substantial losses since Makena®'s approval, demonstrated "financial dire straits" sufficient to meet the irreparable harm portion of the preliminary injunction standard. *See K-V Pharmaceutical*, 2012 WL 3715276, at *3 (citing *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975)). As stated in the Declaration of KV's Chief Financial Officer, Makena® is KV's only hope for survival. McHugh Dec. ¶ 36. Even obtaining the full relief sought by KV herein at the completion of the projected sixteen-month timeline for this proceeding could be futile, however, as KV's financial condition is so dire that it may not be able to reorganize under Chapter 11 if it does not receive immediate,

temporary relief. McHugh Dec. ¶¶ 39-40. The Federal Circuit has found that it is improper to allow a business in the domestic industry to liquidate before a decision on the merits is reached, and that the threat of liquidation constitutes irreparable harm warranting temporary relief. *See Zenith*, 710 F.2d at 810. This element is easily met here.

D. The Public Interest Favors Granting Temporary Relief

Prevention of preterm births, ensuring safe and effective drugs in the marketplace, preservation of a domestic industry, and effectuating Congressional intent to motivate development of drugs to treat rare conditions are obviously significant public interests. KV is ready, willing, and able to supply sufficient quantities of Makena® to satisfy the entire domestic patient population in need of the drug. Goedeke Dec. ¶ 37. KV is also ready, willing, and able to supply HPC to an independent third-party to distribute the HPC to any compounding pharmacy that legitimately needs to prepare a compounded formulation for a specific patient who cannot take Makena®. Goedeke Dec. ¶ 37. No woman who needs the drug and obtains a prescription for it will go without. Goedeke Dec. ¶ 37. Moreover, women needing financial assistance would not be negatively affected by the grant of temporary relief. Federally mandated Medicaid coverage of Makena®, KV's copayment assistance program (which covers co-payments for certain insured low-income women who do not qualify for Medicaid), and KV's practice of distributing free vials already help ensure that all patients needing Makena® will receive it. McHugh Dec. ¶ 17; Goedeke Dec. ¶ 38. Thus, granting temporary relief will not cause a supply shortage or endanger the public health in any way.

Ensuring that pharmaceutical products are safe and effective is also in the public interest. A critical difference between Makena® and compounded 17P formulations is the source of the HPC used in the products and the efficiency and purity of the finished product. Jozwiakowski

Dec. ¶¶ 48-49; 53. Makena®, which has been deemed safe and effective by FDA for the treatment of its indication, is manufactured in FDA-approved and inspected facilities with HPC sourced from [ ]. Jozwiakowski Dec. ¶ 22. FDA has emphasized that compounded formulations are not FDA-approved and warned that "compounding large volumes of drugs that are copies of FDA-approved drugs circumvents important public health requirements . . . ." Goedeke Dec. ¶ 17. This is vividly illustrated by the tragic consequences of the recent meningitis outbreak stemming from the activities of the New England Compounding Center.

Compounded 17P formulations, by contrast, are exclusively or nearly exclusively formulated with API manufactured in facilities, all of which are believed to be in China, which are not inspected or regulated by FDA. Jozwiakowski Dec. ¶ 49. KV commissioned independent testing on seven samples of Chinese API and 24 samples of compounded 17P formulations in finished dosage form that were compounded from Chinese API. Of the API samples tested, the majority failed at least one of the specifications FDA sets for Makena® (primarily, presence of unknown impurities), and one sample contained no active ingredient at all (instead, it contained glucose; *i.e.*, it was fraudulent and would have resulted in patients receiving "useless" drugs if used to manufacture compounded 17P formulations). Of the samples in finished dosage form, the majority failed at least one of the specifications set by FDA for Makena®, primarily due to unacceptable potency and/or impurities. Jozwiakowski Dec. ¶¶ 53-56.

FDA has also conducted its own investigations. All of the samples of API that FDA tested, although meeting certain other specifications, exceeded the limit for unidentified impurities that applies to Makena®. FDA requirements would prohibit KV from using such API

to produce Makena®. Jozwiakowski Dec. ¶ 56. There are also substantial uncertainties regarding the reliability of the manufacturing processes used by compounding pharmacies. Since they are not regulated by FDA, compounding pharmacies are not required to conform to good manufacturing practices. Jozwiakowski Dec. ¶¶ 8-10; FDA, *The Special Risks of Pharmacy Compounding*, available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm. Indeed, although compounded 17P formulations were available when FDA was reviewing the application for approval of Makena®, FDA designated the NDA for Priority Review, which is reserved for "drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists." Jozwiakowski Dec. ¶ 14. Thus, FDA considered Makena® a "major" advance on compounded 17P formulations and/or considered compounded 17P formulations inadequate therapy.

The federal district court in KV's action against the Georgia Department of Community Health, responding to arguments from the State that "there are no major safety issues" with compounded 17P formulations, found that the public health interest clearly favored the use of the FDA-approved product:

> Regardless of the absence of evidence of major safety concerns with {compounded 17P formulations}, the defendants' position would render the FDA approval process meaningless. The court is unwilling to make such a holding. Moreover, this court agrees with the Supreme Court's view of the traditional and appropriate role of compounding: "so that patients with particular needs may obtain medications suited to those needs." *Thompson*, 535 U.S. 357, 358. In other words, compounding is an option for patients for whom the FDA-approved drug is inappropriate.
>
> Because the court finds that the FDA drug approval process means something, the defendants' current policy favoring {compounded 17P formulations} over Makena® is the opposite of what it should be.

K-V Pharmaceutical, 2012 WL 3715276, at *3. The court was absolutely correct: FDA approval "means something." Granting KV the temporary relief that it seeks would put the FDA-approved drug into the hands of the patients who need it, and would reduce the risks that come from using unapproved new drugs are in essence are copies of Makena®.

E. The Balance of Harms Favors Saving the Domestic Industry

Considering the parties' respective rights, the only harm that is legally cognizable in the proceeding is that being suffered by KV. KV has a Congressionally-granted seven-year exclusive right to market Makena® to treat the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. McHugh Dec. ¶ 5. KV has already lost 20 months of exclusivity because of the unfair importation and compounding activities of the Proposed Respondents. By contrast, the Proposed Respondents have few or no protectable rights. The Proposed Respondents include compounders unlawfully manufacturing and selling commercial quantities of compounded 17P formulations, resellers selling HPC to compounders for unlawful manufacture, and importers of HPC, who sell to resellers and compounders for unlawful manufacture. Goedeke Dec. ¶ 21. There is no known reason for bringing HPC into the country or re-selling it other than for the purpose of contributing to the infringement of KV's rights under the Orphan Drug Act. Proposed Respondents should not be heard to complain that temporary relief would interfere with their illegal enterprise or activities in support thereof.

Consideration of the parties' respective financial harms also favors granting temporary relief. KV is essentially a one-drug company – while the company offers other products, its financial future depends on the success of Makena®. McHugh Dec. ¶ 36. Makena® is expected to account for the vast majority of KV's projected revenue over the remaining Makena®

exclusivity period, and KV's survival as a going concern depends entirely on transitioning patients from compounded 17P formulations to Makena®. McHugh Dec. ¶ 36. By contrast, Proposed Respondents' businesses do not rise or fall on their dealings in HPC; the pharmacies that compound HPC compound many other products (in several cases hundreds, if not thousands, of other products), and the importers and resellers deal in many products other than HPC. *See, e.g.,* Exhibit 4. Thus, even if those companies were placed into a position in which they could no longer deal in foreign HPC or unlawfully manufacture compounded 17P formulations, the harm to them would not be great. They could simply stop dealing in HPC altogether, or they could obtain properly sourced HPC from KV for legitimate, individual prescriptions requiring a compounded formulation.

Consideration of patients also favors granting temporary relief. By being ensured of the safety and efficacy of the drugs they receive, they would be much better off than they are today. As the district court in Georgia found when it granted KV's motion for preliminary injunction against Georgia's unlawful preference for compounded 17P formulations, "the plaintiffs face the financial loss of sales to Georgia Medicaid patients. The defendants on the other hand {by arguing that compounded 17P formulations are less expensive} do not compare apples to apples. The court recognizes that drug costs will increase; however, patients will receive an FDA-approved drug as opposed to a non-approved, compounded product." *K-V Pharmaceutical*, 2012 WL 3715276, at *4. In any event, the increase in cost is simply a product of Makena®'s FDA approval, and will have no effect on nearly all patients, who will still pay their regular copayments (if insured, including Medicaid coverage), or who would be eligible for copayment assistance or free vials from KV. McHugh Dec. ¶¶ 16-17; Goedeke Dec. ¶ 38.

IV. POSTING A BOND

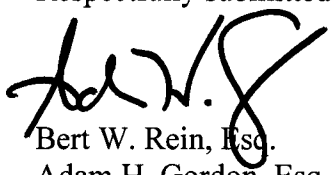
Pursuant to 19 C.F.R. §§ 210.52(b)(2) and 210.68, KV submits that a bond should be waived in this case. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1385 (Fed. Cir. 2006) (in the context of Fed. R. Civ. P. 65, finding that "{t}he amount of a bond is a determination that rests within the sound discretion of a trial court."). The effect of granting temporary relief herein cannot be the subject of damages to the Proposed Respondents. Proposed Respondents should have no expectation of continuing to illegally manufacture compounded 17P formulations or engaging in importation or sale of HPC for the sole purpose of such unlawful activity.

Moreover, a bond would be financially burdensome to KV, which is in bankruptcy and cannot afford to post a bond in any significant amount.

V. CONCLUSION

For the foregoing reasons, Complainant's motion for temporary relief should be granted.

Respectfully submitted,



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Date: October 23, 2012

CERTIFICATE OF SERVICE

In the Matter of Hydroxyprogesterone Caproate and Products Containing the Same
U.S. International Trade Commission

Pursuant to the requirements contained in 19 C.F.R. § 210.54, I certify that a copy of the non-confidential version of this document was served on the following parties, via messenger, overnight delivery, or equivalent means, on October 23, 2012.

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