The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at http://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 25, 2010, based on a complaint filed by Hewlett-Packard Company of Palo Alto, California and Hewlett-Packard Development Company, L.P., of Houston, Texas (collectively “HP”). 75 FR 36442 (June 25, 2010). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain inkjet ink cartridges with printheads and components thereof by reason of infringement of various claims of United States Patent Nos. 6,234,598 (“the ‘598 patent”); 6,309,053 (“the ‘053 patent”); 6,398,347 (“the ‘347 patent”); 6,481,817 (“the ‘817 patent”); 6,402,279 (“the ‘279 patent”); and 6,412,917 (“the ‘917 patent”). The ‘917 patent was subsequently terminated from the investigation. The complaint named the following entities as respondents: MicroJet Technology Co., Ltd. of Hsinchu City, Taiwan (“MicroJet”); ain Asia Pacific Microsystems, Inc. of Hsinchu City, Taiwan (“APM”); Mipo Technology Limited of Kowloon, Hong Kong (“Mipo Tech.”); Mipo Science & Technology Co., Ltd. of Guangzhou, China (“Mipo”); Mextec d/b/a Mipo America Ltd. of Miami, Florida (“Mextec”); SinoTime Technologies, Inc. d/b/a All Colors of Miami, Florida (“SinoTime”); and PTC Holdings Limited of Kowloon, Hong Kong (“PTC”).

Respondents Mipo, Mipo Tech., SinoTime, and Mextec were subsequently terminated from the investigation. Respondent MicroJet defaulted. Respondent PTC did not participate in the hearing and failed to file post-hearing briefs. Pursuant to 19 CFR 210.17(d) and (e), the ALJ drew an adverse inference against PTC that “PTC imported accused products into the United States, that those products were manufactured by MicroJet, and that those products contain ICs [integrated circuits] made by APM.” Final Initial Determination (“ID”) at 29.

On June 10, 2011, the Administrative Law Judge (“ALJ”) issued his final ID, finding a violation of section 337 by the respondents. Specifically, the ALJ found that the Commission has subject matter jurisdiction: in rem jurisdiction over the accused products and in personam jurisdiction over APM. The ALJ also found that there has been an importation into the United States, sale for importation, or sale within the United States after importation of the accused inkjet ink cartridges with printheads and components thereof. Regarding infringement, the ALJ found that MicroJet and PTC directly infringe claims 1–6 and 8–10 of the ‘598 patent; claims 1–6 and 8–17 of the ‘053 patent; claims 1, 9–5, and 8–12 of the ‘347 patent; claims 1–14 of the ‘817 patent; and claims 9–15 of the ‘279 patent. The ALJ also found that MicroJet induces infringement of those claims. The ALJ further found that APM does not directly infringe the asserted claims of the ‘598 and does not induce infringement of the asserted patents. The ALJ, however, found APM liable for contributory infringement. With respect to validity, the ALJ found that the asserted patents were not invalid. Finally, the ALJ concluded that an industry exists within the United States that practices the ‘598, ‘053, ‘347, ‘817, and ‘279 patents as required by 19 U.S.C. 1337(a)(2).

On June 24, 2011, HP filed a contingent petition for review of the ID. On June 27, 2011, APM and the Commission investigative attorney filed petitions for review of the ID. On July 5, 2011, the parties filed responses to the various petitions and contingent petition for review.

On August 11, 2011, the Commission determined to review a single issue in the final ID and requested briefing on the issue it determined to review, and on remedy, the public interest and bonding. 76 FR 51055 (Aug. 17, 2011). Specifically, the Commission determined to review the finding that HP failed to establish a preponderance of the evidence that Respondent APM induced infringement of the asserted patents. On August 25, 2011, the parties filed written submissions on the issue under review, remedy, the public interest, and bonding. On September 1, 2011, the parties filed reply submissions. Although Respondent PTC failed to appear at the hearing and failed to file post-hearing briefs, resulting in the ALJ drawing an adverse inference against PTC (ID at 29), PTC filed a letter dated August 24, 2011, responding to the issue under review. However, by failing to file a post-hearing brief, PTC has waived any arguments it has or may have had about any issues in this investigation.

Having examined the record of this investigation, including the ALJ’s final ID, the Commission has determined that there is a violation of section 337. The Commission has determined to reverse the ALJ’s finding that HP failed to establish by a preponderance of the evidence that Respondent APM induced infringement of the asserted patents, and finds that HP established by a preponderance of the evidence that APM induced infringement of the asserted patents. The Commission adopts the ALJ’s findings in all other respects.

The Commission has further determined that the appropriate remedy is a general exclusion order prohibiting the entry of inkjet ink cartridges with printheads and components thereof that infringe any of the asserted claims. The Commission has also determined that the public interest factors enumerated in section 337(d) (19 U.S.C. 1337(d)) do not preclude issuance of the general exclusion order. Finally, the Commission has determined that a bond of 100 percent of the entered value is required to permit temporary importation during the period of Presidential review (19 U.S.C. 1337(j)) of inkjet ink cartridges with printheads and components thereof that are subject to the order. The Commission’s order and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.


Issued: October 24, 2011.

James R. Holbein,
Secretary to the Commission.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DOCKET NO. 2011-036]

Treasure Coast Specialty Pharmacy

Decision and Order

On September 14, 2011, Administrative Law Judge (ALJ) Gail A. Randall issued the attached recommended decision. There were no exceptions filed to the ALJ’s decision. Having reviewed the record in its entirety including the ALJ’s
recommended decision. I have decided to adopt the ALJ’s rulings, findings of fact, conclusions of law, and recommended decision to grant the Government’s Motion for Summary Decision.

Order
Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration, BT9856002, issued to Treasure Coast Specialty Pharmacy, be, and it hereby is, revoked. I further order that any pending application of Treasure Coast Specialty Pharmacy, to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: October 7, 2011.
Michele M. Leonhart,
Administrator.

Scott Lawson, Esq., for the Government
Richard K. Alan, II, Esq., for the Respondents

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

I. Facts
Gail A. Randall, Administrative Law Judge. On June 27, 2011, the Administrator, Drug Enforcement Administration (“DEA” or “Government”), issued an Order to Show Cause and an Immediate Suspension of Registration (“Order”), immediately suspending the DEA Certificate of Registration, No. BT9856002, of Treasure Coast Specialty Pharmacy (“Treasure Coast”), as a retail pharmacy pursuant to 21 U.S.C. 824(d) (2006), because Treasure Coast’s continued registration constitutes an imminent danger to the public health and safety. The Order also proposed to deny any pending DEA registration applications by Treasure Coast and to deny the pending application for DEA registration by Pappy’s Drugs d/b/a Prima Vista Pharmacy (“Pappy’s Drugs”) because their registrations would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f).

Specifically, the Order alleged that Treasure Coast “has dispensed and continues to dispense controlled substances, primarily Schedule III anabolic steroids and Schedule II narcotics under circumstances demonstrating that [Treasure Coast] knew or should have known” that those prescriptions were not issued for a legitimate medical purpose. [Order at 2]. The Order explains that this knowledge must be inferred from Treasure Coast’s association with and filling of prescriptions issued by physicians who have pled guilty in federal court to unlawfully distributing steroids, and who market themselves as providing “hormone replacement therapy” and “anti-aging” services. [Id.]. In addition, the Order alleges that Treasure Coast dispensed controlled substances based on invalid prescriptions where the prescribing practitioners were not licensed to prescribe controlled substances in the various states where their patients were located.” [Id.]. Further, the Government alleges that despite Treasure Coast being apprised that it is illegal for it to practice in North Carolina without a license, the pharmacy continued to ship anabolic steroids to customers located in that state. [Id. at 3-4].

Next, the Government alleged that Treasure Coast filled prescriptions for Schedule II controlled substances prescriptions “under circumstances indicating that the drugs are diverted from legitimate channels, misused, or abused.” [Id. at 4].

On July 28, 2011, counsel for Treasure Coast and Pappy’s Drugs (collectively, “Respondents”) timely filed a request for a hearing in the above-captioned matter.

On July 29, 2011, the Government filed its Motion For Summary Disposition And Motion To Stay Proceedings (“Government’s Motion”). Therein, the Government moved for summary disposition of the portion of these proceedings that relate to Treasure Coast’s registration. The Government based its motion on the fact that the State of Florida suspended Treasure Coast’s registration as a community pharmacy and, therefore, Treasure Coast currently lacks state authority to handle controlled substances.

On August 1, 2011, I ordered the Respondents to file a response to the Government’s Motion, if any, on or before August 5, 2011.

On August 5, 2011, counsel for the Respondents filed their Respondents’ Response to DEA’s Motion For Summary Disposition And Motion To Stay Proceedings (“Respondents’ Response”). Therein, the Respondents argued that the Government is precluded from using Treasure Coast Pharmacy’s lack of state licensure as a basis for revocation of its DEA registration, through summary disposition or otherwise, as the Government failed to state those grounds in its Order to Show Cause. Consequently, the Respondents aver that Treasure Coast’s due process rights require the Government “to serve an Order to Show Cause * * * stating the DEA’s new or substituted basis for revocation and calling upon [Treasure Coast] to appear at the time and place stated in the Order to Show Cause, but in no event less than thirty days after the date of receipt of this order.” [Resp. Response at 2]. In addition, the Respondents argue that under applicable Florida law the owner of a pharmacy need not be licensed as such, yet must designate a managerial pharmacist that is so licensed. Further, citing Fedegro v. Department of Professional Regulation, 452 So.2d 1063 (Fla. 3rd DCA 1984), the Respondents state that alleged wrongdoing of a pharmacist does not trigger nor support the suspension of the pharmacy’s state license. [Id. at 3].

On August 5, 2011, I ordered the Government to reply to the Respondents’ Response no later than August 12, 2011.

On August 9, 2011, counsel for Treasure Coast filed its Respondents’ Supplemental Response to DEA’s Motion For Summary Disposition And Motion To Stay Proceedings. Therein, the Respondents argue that Treasure Coast has a valid Florida retail pharmacy drug wholesale distribution license, and on that basis summary disposition is inappropriate.

On August 12, 2011, counsel for the Government filed its Government’s Reply To Respondent’s Initial And Supplemental Responses To Government’s Motion For Summary Disposition (“Government’s Reply”). In its Reply the Government argues that its Motion for Summary Disposition remains valid. First, the Government addresses the Respondents’ due process argument in stating:

The Administrative Procedures Act (APA), 5 U.S.C. 551 et seq, does not * * mandate * * * an inelastic application of the strictures of administrative due process: “[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.” Citizens State Bank of Marshall v. FDIC, 751 F.2d 209, 213 (8th Cir. 1984) (quoting Aloha Airlines v. Civil Aeronautics Bd., 598 F.2d 250, 262 (DC Cir. 1979), cited in Liddy’s Pharmacy, L.L.C., 76 FR 48887, 48896, fn 15. As noted in Liddy’s, “the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.” Id. Due process is traditionally measured by the notice accorded respondents not by the contents of the OTSC but by subsequent prehearing statements. Id. citing Darrell Risner, DMD, 61 FR 728, 730 (1996); Nicholas A. Sybak, d/b/a Medicap Pharmacy, 65 FR 75959, 75961 (2000); John Stafford Noell, 59 FR 47359, 47361 (1994).

[Government’s Reply at 3–4]. Therefore, the Government argues that it accorded
the Respondent due process when it notified Treasure Coast of its basis for summary disposition in the Government’s prehearing Motion for Summary Disposition [Id. at 4].

Next, the Government addresses the substantive basis for its Motion. Specifically, the Government argues that Treasure Coast’s possession of a wholesale distributor permit is meaningless, as the loss of its community pharmacy license renders that permit useless. [Id. at 5–6]. The Government points to Florida Statute Sections 499.01(2)(f) and 499.003(51) for the proposition that a pharmacy’s possession of a wholesale distributor permit is conditioned on that pharmacy’s maintenance of a community pharmacy license. [Id. at 5]. The Government buttresses this argument via provision of a letter from the Chief Legal Counsel for the Emergency Action Unit of the Florida Department of Health, stating “[b]ecause Treasure Coast’s community pharmacy permit is presently suspended, Treasure Coast may not operate under either its community pharmacy permit or its wholesale distributor permit.” [Id.]. Hence, the Government argues that the Respondent currently lacks state authority to handle controlled substances and, therefore, summary revocation of its DEA registration is appropriate.

For the reasons set forth below, I will grant the Government’s Motion and recommend that the Deputy Administrator revoke Treasure Coast’s DEA Certificate of Registration and deny any currently pending applications to renew its registration.

II. Discussion

a. Procedural Due Process

First, I reject Treasure Coast’s argument that it will not be afforded procedural due process if its registration is revoked due to its lack of state licensure, as that basis was not noticed in the Government’s Order. As correctly stated by the Government, the confines of this administrative proceeding are not defined by the Government’s Order to Show Cause, but rather the Government’s prehearing disclosures, in toto. [See George Mathew, M.D., 75 FR 66,138, 66146 (DEA 2010)]. Further, the DEA has consistently followed Goldberg v. Kelly, 397 U.S. 254, 270 (1970), by writing: “In Goldberg, the Supreme Court held that ‘where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government’s case must be disclosed to the individual so that he has an opportunity to show that it is untrue.’” [Beau Boshers, M.D., 76 FR 19,401, 19,403 (DEA 2011) (citing Goldberg, 397 U.S. at 270 (quoting Greene v. McElroy, 360 U.S. 474, 496 (1959))]. The Court has further explained that “[a] party is entitled * * * to know the issues on which [the] decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it. Indeed, the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation.” [Id. (citing Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 288 n.4 (1974))].

Here, the Government put the Respondent on notice through its Motion for Summary Disposition. Accordingly, Treasure Coast’s due process rights are not violated because the Government, through its prehearing Motion, timely notified Treasure Coast of its intent to pursue revocation of its registration on the basis of the pharmacy’s lack of state licensure. In its Response, Treasure Coast had the opportunity to rebut the factual basis upon which the Government based its Motion. For this reason, Treasure Coast’s due process argument fails.

b. Wholesale Distribution Permit and State Authority

The DEA will not maintain a controlled substances registration if the registrant is without state authority to handle controlled substances. The Controlled Substances Act (“CSA”) provides that obtaining a DEA registration is conditional on holding a state license to handle controlled substances. [See 21 U.S.C. 823(f) (“the Attorney General shall register practitioners (including pharmacies * * *) * * if the applicant is authorized to dispense * * controlled substances under the laws of the State in which he practices”). See also 824(o)(3) (stating “a registration may be suspended or revoked by the Attorney General upon a finding that the registrant has had his State license or registration suspended, revoked or denied by competent State authority”).]

The DEA, therefore, has consistently held that the CSA requires the DEA to revoke the registration of a registrant who no longer possesses a state license to handle controlled substances. [See e.g. Joseph Baumstark, 74 FR 17,525, 17,527 (DEA 2009) (stating the “ALJ applied the Agency’s long-settled ruled [sic] that a practitioner may not maintain his registration if he lacks authority to handle controlled substances under the laws of the state in which he practices”); Roy Chi Lung, M.D., 74 FR 20,346 (DEA 2009); Gabriel Sagun Orzame, M.D., 69 FR 58,959 (DEA 2004); Alton E. Ingram, Jr., M.D., 69 FR 22,562 (DEA 2004); Graham Travers Schuler, M.D., 65 FR 50,570 (DEA 2000); Dominick A. Ricci, M.D., 58 FR 51,104 (DEA 1993)].

The parties do not dispute that the State of Florida suspended Treasure Coast’s retail pharmacy registration. Therefore, Treasure Coast no longer possesses authority under that license to handle controlled substances. However, Treasure Coast argues that it currently possesses other state authority to handle controlled substances, through its maintenance of a wholesale distributor permit.

Nevertheless, I am persuaded by the Government’s argument that the State of Florida did not intend a pharmacy, who lacks authority to handle controlled substances under a retail pharmacy registration, to be permitted to handle controlled substances under a wholesale distributor permit. Not only is the alternative plainly inconsistent with Florida law, it renders an absurd interpretation of those laws. [See Fla. Stat. 499.01(2)(f) (2010) (only permitting a retail pharmacy to obtain a wholesale distributor permit); 499.003(51) (defining “retail pharmacy” as “a community pharmacy licensed under chapter 465”); Durr v. Shinseki, 638 F.3d 1342, 1348 (11th Cir. 2011) (“[b]ecause the legislature is presumed to act with sensible and reasonable purpose, statute should, if at all possible, be read so as to avoid unjust or absurd conclusion.”)].

This interpretation is consistent with the letter from the Chief Legal Counsel, Emergency Action Unit, Florida Department of Health, who wrote that, “[b]ecause Treasure Coast’s community pharmacy permit is presently suspended, Treasure Coast may not operate under either its community pharmacy permit or its wholesale distributor permit.” [Government’s Reply, attachment 3]. Therefore, because, as a matter of law, Treasure Coast no longer possesses state authority to handle controlled substances, its DEA registration must be revoked.

c. Respondents’ Other Arguments

Treasure Coast’s other arguments for denial of the Government’s Motion are irrelevant to this proceeding. First, the Respondent’s argument that Florida law does not require the owner of a retail pharmacy to be registered as a pharmacist, but instead permits a pharmacy to designate a pharmacist, is irrelevant because despite the truth or
falsity of that assertion, the DEA registers pharmacies, not pharmacists, and Treasure Coast as a retail pharmacy currently lacks state authority to operate.

In addition, the Respondents’ argument that the State of Florida may not revoke a pharmacy’s registration on the basis of its pharmacist’s wrongdoing is equally irrelevant. Upon a motion for summary disposition due to lack of state licensure, the DEA will not consider whether the State has a valid basis for revoking the Respondent’s registration; it will only consider whether the Respondent currently possesses state authority. As Treasure Coast does not, its registration must be revoked.

III. Conclusion, Order, and Recommendation

It is well-settled that when no question of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required under the rationale that Congress does not intend administrative agencies to perform meaningless tasks. [See Layfe Robert Anthony, M.D., 67 FR 35,582 (DEA 2002); Michael G. Dolin, M.D., 65 FR 5,661 (DEA 2000); see also Philip E. Kirk, M.D., 48 FR 32,887 (DEA 1983), aff’d sub nom. Kirk v. Mullen, 749 F.2d 97 (6th Cir. 1984); Puerto Rico Acqueduct & Sewer Auth. v. EPA, 35 F.3d 600, 605 (1st Cir. 1994)]. Consequently, there is no genuine dispute of material fact as the Respondent currently lacks state authority to handle controlled substances. Therefore, summary disposition for the Government is appropriate.

Accordingly, I hereby grant the Government’s Motion for Summary Disposition.

I also forward the portion of this case that relates to Treasure Coast’s registration to the Deputy Administrator for final disposition. I recommend that Treasure Coast’s DEA Certificate of Registration, Number BT9656002, be revoked and any pending renewal applications for this registration be denied.

Dated: August 16, 2011.

Gail A. Randall,
Administrative Law Judge.

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1 21 U.S.C. 823(f).

2 This opinion does not reach the other factual issues made in the Order to Show Cause. Rather, this opinion solely addresses Treasure Coast’s loss of ability to handle controlled substances in the State of Florida, and, thus, ability to maintain a DEA registration.

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Abelardo E. Lecompte-Torres, M.D.
Decision and Order

On April 29, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Abelardo E. Lecompte-Torres, M.D. (Respondent), of Ponce, Puerto Rico. The Show Cause Order proposed the denial of Respondent’s application for a DEA Certificate of Registration, on the ground that his registration “would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).” Show Cause Order at 1.

The Show Cause Order specifically alleged that “[o]n or about April 7, 2009, [Respondent] filed an application for registration[,] seeking a DEA Certificate of Registration as a practitioner in Schedules II through V * * * * at the registered location of 620 Lady Di Street, Apartment #10, Parque Los Almendros, Ponce, Puerto Rico 00716.” Id. The Show Cause Order then alleged that on August 21, 2006, Respondent had voluntarily surrendered his previous DEA registration pursuant to a Memorandum of Understanding he entered into with DEA on July 11, 2006. Id.

The Show Cause Order further alleged that on May 2, 2007, Respondent was indicted in the United States District Court for the District of Puerto Rico and charged with violations of 18 U.S.C. 2; 1349; 1956(h) and (a)(1)(A)(i); as well as 21 U.S.C. 841(a)(1) and 846. Show Cause Order at 2. The Show Cause Order also alleged that the indictment alleged that Respondent had authorized multiple prescriptions for controlled substances, including hydrocodone, for internet customers who resided in multiple prescriptions for controlled substances, including hydrocodone, a violation of 21 U.S.C. 841(a)(1) and 846. Id. The Order then alleged that Respondent was subsequently convicted and sentenced to three years probation. Id.

On May 22, 2010, the Show Cause Order, which also notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to do either, was served on him by certified mail as evidenced by the signed returned receipt card. See id. at 2 (citing 21 CFR 1301.43(a)); see also GX 10. Thereafter, on June 22, 2010, Respondent’s counsel timely submitted a letter to the Office of Administrative Law Judges (ALJ) wherein he waived his right to a hearing but requested the opportunity to file a written statement. See GX 11.

However, when, as of September 21, 2010, the Government had not received his statement, it filed its Request for Final Agency Action and forwarded the Investigative Record to this Office. Subsequently, on December 17, 2010, the Government filed an Addendum to its Request for Final Agency Action, stating that it had since learned that Respondent had entered into an agreement with the Puerto Rico Board of Licensing and Medical Discipline (Board), and that on September 22, 2010, the Board had issued a resolution, the terms of which include, inter alia, that Respondent surrender his authority to prescribe controlled substances for a term of three years, effective September 29, 2010.

On December 17, 2010, the Government served the Addendum to Respondent’s counsel by first class mail. Since Respondent’s June 2010 letter, DEA has not received any other correspondence from Respondent or his counsel.

I therefore find that Registrant has waived his right to a hearing and to submit a written statement beyond that contained in his June 2010 letter. See 21 CFR 1301.43(e). Accordingly, I issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government, including Respondent’s statement that he does not contest the allegations...