venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Alcatel-Lucent USA Inc., Mountain View, CA; Arista Networks Inc., Santa Clara, CA; Big Switch Networks, Mountain View, CA; Brocade Communications Systems, Inc., San Jose, CA; Ciena Corporation, Hanover, MD; Cisco Systems Inc., San Jose, CA; Citrix Systems, Inc., Santa Clara, CA; Cyan Inc., Petaluma, CA; Dell Inc., Round Rock, TX; Ericsson Inc., San Jose, CA; Fujitsu Limited, Kawasaki, JAPAN; Hewlett Packard Company, Palo Alto, CA; Huawei Technologies Co. Ltd., Shenzhen, PEOPLE'S REPUBLIC OF CHINA; International Business Machines Inc., Endicott, NY; Inocybe Technologies Inc., Gatineau, Quebec City, CANADA; Intel Corporation, Santa Clara, CA; Juniper Networks, Sunnyvale, CA; Microsoft Corporation, Redmond, WA; NEC Corporation, Tokyo, JAPAN; PLUMgrid Inc., Sunnyvale, CA; Radware LTD, Telaviv, ISRAEL; Red Hat Inc., Raleigh, NC; and VMware Inc., Palo Alto, CA.

The general area of OpenDaylight's planned activity is to (a) Advance the creation, evolution, promotion, and support of an open source software defined network software platform (''Platform''); (b) support and maintain the strategic framework of the Platform through the technologies made available by the organization to make the Platform a success; (c) support and maintain policies set by the Board; (d) promote such Platform worldwide; and (e) undertake such other activities as may from time to time be appropriate to further the purposes and achieve the goals set forth above.

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2013–15640 Filed 6–28–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—DVD Copy Control Association

Notice is hereby given that, on May 31, 2013, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), DVD Copy Control Association (''DVD CCA'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Hakuto Taiwan Ltd., Taipei, TAIWAN, has been added as a party to this venture.

Also, Dongguan ChuDong Electronic Technology Co., Ltd., Guangdong, People's Republic of China; Huizhou Aihua Multimedia Co., Ltd., Guangdong, People's Republic of China; and Kentec, Inc., Taipei, Taiwan, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and DVD CCA intends to file additional written notifications disclosing all changes in membership.

On April 11, 2001, DVD CCA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2001 (66 FR 40727).

The last notification was filed with the Department on February 20, 2013. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 21, 2013 (78 FR 17431).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2013–15641 Filed 6–28–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–63]

Bio Diagnostic International; Denial of Application

On June 8, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Bio Diagnostic International, Inc. (hereinafter, BDI or Respondent), of Brea, California. The Show Cause Order proposed the denial of Respondent's application for a registration as a distributor of list I chemicals, on the ground that Respondent's registration ''would be inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(h) and 824(a)(4)).

The Show Cause Order specifically alleged that on September 1, 2009, Respondent had applied for a DEA registration as a distributor of iodine, a list I chemical. *Id.* The Order alleged that Mr. Paul Anand, Ph.D., was Respondent's owner and operator, and that during a pre-registration investigation, he had failed to provide a Food and Drug Administration registration, that he had failed to obtain a California Department of Justice Bureau of Narcotic Enforcement Controlled Chemical Substances Permit, and that he had ''failed to accurately complete'' employee screening forms as requested by Agency Investigators. *Id.* at 1–2. The Order also alleged that during the inspection, ''investigators discovered that approximately 50 to 100 expired bottles of Lugol's solution, a product containing . . . [i]odine, were left unsecured on a shelf within BDI's proposed controlled location without a proper registration'' and that ''BDI failed to record, secure, or dispose of the expired list I chemical products as required by law.'' *Id.* at 2. Finally, the Order alleged that ''[o]n December 8, 2010 . . . state investigators attempted to conduct a site inspection at BDI's business facility'' but that they ''were not successful because BDI did not cooperate with attempts to conduct this inspection.'' *Id.*

On June 27, Mr. Anand filed a request for a hearing on behalf of Respondent and the matter was placed on the docket of the Office of Administrative Law Judges (ALJ). Thereafter, the assigned ALJ issued an order for pre-hearing statements; both parties complied with the order.

In its pre-hearing statement, the Government provided notice that one of its witnesses would testify that ''Respondent is required to have a valid California Board of Pharmacy license . . . or a California Bureau of Narcotic Enforcement permit . . . and . . . Respondent's state permit expired on June 11, 2011 and was not renewed.'' Gov. Pre-Hearing Statement, at 6–7. The Government noticed that its witness would further testify that ''currently the Respondent is not authorized to handle list I chemicals in the State of California.'' *Id.* at 7.

Based on the above, the ALJ issued a Memorandum to Parties and Order. Therein, the ALJ ordered the parties to address two issues: (1) whether the ''Respondent presently possess[es] a valid . . . state license, registration or other authority to handle listed chemicals, to include list I chemicals,

from the State of California or any other State, territory or U.S. jurisdiction in which Respondent proposes to do business?'' and (2) whether, under Agency precedent and applicable law, the proceeding could be resolved on summary disposition? Memorandum to Parties and Order (citing *Jack's* Sales, Inc., 66 FR 52939 (2001)).

In response, the Government filed a Motion for Summary Disposition. Therein, the Government argued that Respondent is required to hold a California Chemical Substances Permit ''in order to purchase or sell Iodine in the State'' and that its ''permit expired on June 11, 2011 and was not renewed.'' Mot. for Summ. Disp. at 2. The Government thus contended that because ''Respondent is currently without authority to handle list I chemicals in the State of California, the state in which [it] seeks registration with the DEA, [it] is not eligible to possess a DEA registration in that state.'' *Id.* at 3 (citing 21 U.S.C. 823(h) and 824(a)(3)). The Government further argued that ''[t]he Controlled Substances Act (CSA) requires that a list I chemical manufacturer and distributor must be currently authorized to handle list I chemicals in the jurisdiction in which it seeks to maintain a DEA registration,'' and that because ''possessing authority under state law to handle listed chemicals is an essential condition for holding a DEA registration,'' the CSA requires the denial of Respondent's application. *Id.* at 3–4 (citing numerous cases involving practitioners). Finally, the Government argued that summary disposition was warranted even if ''there is the potential that the Respondent's listed chemical privileges may be reinstated, because 'revocation is also appropriate when [a] state license has been suspended, but with the possibility of future reinstatement.''' *Id.* at 4–5 (citing *Roger A. Rodriguez, M.D.,* 70 FR 33207 (2005)).

In its pleading, Respondent did not dispute that its state permit had expired and provided a copy of its expired permit. However, Respondent further stated that it had ''already applied to renew the expired certificate.'' Resp. Pleading (July 14, 2011), at 2.

On July 28, 2011, the Administrative Law Judge (ALJ) granted the Government's motion, holding that because Respondent does not hold authority under California law to handle iodine, it is not entitled to be registered. Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the ALJ (July 28, 2011) (hereinafter, ALJ I). As support for his ruling, the ALJ noted that ''[u]nder 21 U.S.C. 824(a)(3), a practitioner's loss of state authority 'to engage in the manufacturing, distribution or dispensing of controlled substances or a list I chemical' is grounds to revoke a practitioner's registration'' and that DEA ''has consistently held that a registrant or prospective registrant may not hold a DEA registration if the registrant is without appropriate authority under the laws of the state in which it does business.'' *Id.* at 5 (citing *Jack's Sales Inc.,* 66 FR 52939 (2001) (holding that ''[l]oss of state authority to engage in the distribution of list I chemicals is grounds to revoke a distributor's registration'') and numerous cases involving practitioners). The ALJ further explained that ''[s]ummary disposition is warranted even if the respondent's lack of state authority is temporary, because 'revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement.''' *Id.* (citing *Stuart A. Bergman, M.D.,* 70 FR 33193 (2005) and *Rodger A. Rodriguez, M.D.,* 70 FR 33206 (2005)).

Finding it undisputed that Respondent had allowed its California Bureau of Narcotic Enforcement Permit for Controlled Chemical Substances to expire and that ''there is no genuine dispute as to any material fact,'' the ALJ concluded that there is ''substantial evidence that Respondent is presently without state authority to handle list I chemicals in California, the jurisdiction in which it seeks a DEA [registration] to distribute list I chemicals.'' *Id.* at 6. The ALJ thus granted the Government's motion and recommended that its application be denied. *Id.*

On review of the record, I remanded the case for further proceedings. Order Remanding For Further Proceedings (Oct. 17, 2011). In the remand order, I noted that in its motion, the Government relied entirely on Respondent's lack of the permit issued by the California Department of Justice, which the Government argued Respondent must have to purchase or sell iodine in California under state law. *Id.* at 2–3 (citing Gov. Motion, at 2–3 (citing Cal. Health & Safety Code § 11106(a)(1)(A)). Under this provision, ''[a]ny manufacturer, wholesaler, retailer, or any other person or entity in this state that sells, transfers, or otherwise furnishes [iodine] to a person or business entity in this state or any other state or who obtains [the substance] from a source outside of the state . . . shall submit an application to, and obtain a permit for the conduct of that business from[] the [California] Department of Justice.'' Cal. Health & Safety Code § 11106(a)(1)(A). I further noted, however, that the statute exempts from the permit requirement ''any manufacturer, wholesaler, or wholesale distributor who is licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Administration.'' Remand Order, at 3 (quoting Cal. Health & Safety Code § 11106(a)(1)(C)).

On review, I noted that in its motion, the Government did not address the potential applicability of the exemption of subparagraph C and it offered no evidence that Respondent lacks a license issued by the Board of Pharmacy, even though in its pre-hearing statement, it represented that a Diversion Investigator would testify that ''the Respondent is required to have a valid California Board of Pharmacy license . . . or a California Bureau of Narcotic Enforcement permit.'' *Id.* (quoting Gov. Pre-Hearing Statement, at 6).[1] Likewise, the ALJ did not address the applicability of this provision and explain why summary disposition would be appropriate given the Government's failure to present any evidence that Respondent does not hold a license from the pharmacy board.[2]

See ALJ I. Because under settled principles, a party moving for summary disposition ''must show, with materials of appropriate evidentiary quality, that

[1] I further explained that this representation of anticipated testimony is not evidence and thus did not support a motion for summary disposition. *Cf. Insoftvision, LLC,* v. *MB Financial Bank, N.A.,* 2011 WL 4036134, *5 (N.D. Ill., Sept. 12, 2011) (''In order to establish a fact in support of summary judgment . . . a party must present competent evidence . . . . A] party's expectation of how [a witness] would testify at trial'' does not suffice.).

[2] As explained above, in his memorandum to the parties, the ALJ directed both parties to address the issue of whether the ''Respondent presently possess[es] a valid, unrevoked and unrestricted state license, registration or other authority to handle listed chemicals, to include List I chemicals, from the State of California or any other State, territory or U.S. jurisdiction in which Respondent proposes to do business,'' as well as to produce supporting evidence. Memorandum To Parties And Order, at 1. In response, Respondent acknowledged that his state permit for controlled chemical substances had expired. Moreover, Respondent did not make any claim that he possessed a license issued by the pharmacy board.

However, in the remand order, I held that the Government had the burden of proof on the issue of whether Respondent has authority under California law, and on summary disposition, it was required to show, ''with materials of appropriate evidentiary quality, that every state of facts is excluded save that which entitles [it] to relief.'' *Sword* v. *Fox,* 317 F. Supp. 1055, 1057 (W.D. Va. 1970). I further held that while to defeat the motion, Respondent was required to show a genuine dispute over the material facts, it was not required to do so when no evidence was put forward by the Government on a material fact as to which the Government had the burden of proof. To the extent the ALJ deemed summary disposition appropriate because Respondent produced no evidence that it held a state pharmacy license, this improperly shifted the burden of proof from the Government to Respondent.

every state of facts is excluded save that which entitles [it] to relief,'' *Sword* v. *Fox,* 317 F. Supp. 1055, 1057 (W.D. Va. 1970) (quoted in in Charles Alan Wright, *et al.,* 10B *Federal Practice & Procedure* § 2727 n.1), and the non-moving party has no obligation to come forward with evidence disputing the motion ''if the movant fails to meet [its] burden of showing the absence of any genuine issue of material fact,'' *Federal Practice & Procedure,* at § 2739; I concluded that summary disposition was inappropriate. Accordingly, I remanded the matter to the ALJ for further proceedings.[3]

On remand, the ALJ issued a second Memorandum to Parties and Order (Memorandum II, Oct. 26, 2011). Therein, the ALJ directed the Government to address ''whether Respondent presently possesses a valid, unrevoked and unrestricted state license, registration or other authority, including a license from the California Board of Pharmacy, to handle listed chemicals, including list I chemicals,'' as well as ''whether Respondent's application for a DEA Certificate of Registration . . . to distribute list I chemicals should be summarily resolved without a plenary administrative hearing.'' Memorandum II, at 2.

On November 2, the Government filed a new Motion for Summary Disposition. Therein, the Government stated that it had contacted the California Department of Justice Bureau of Narcotic Enforcement and determined that Respondent's Controlled Chemical Substances Permit had expired on June 11, 2011 and had not been renewed. Motion for Summary Disp (II), at 4. The Government further stated that it had contacted the California State Board of Pharmacy and determined that neither Respondent, nor its owner, holds a license issued by the Board. *Id.* As support for these assertions, the Government attached the affidavit of a Diversion Investigator.

In its motion, the Government reiterated its position that because ''Respondent is currently without authority to handle list I chemicals in the State of California, the state in which [it] seeks registration with the DEA, [it] is not eligible to possess a DEA registration in that state'' and that the CSA ''requires that a list I chemical manufacturer and distributor must be currently authorized to handle list I chemicals in the jurisdiction in which it seeks to maintain a DEA registration.'' *Id.* at 5. The Government also argued that ''because 'possessing authority under state law to handle listed chemicals is an essential condition for holding a DEA registration,' the DEA has consistently held that 'the CSA requires the revocation [denial] of a registration issued to a [registrant] who lacks [such authority].''' *Id.* (brackets and bracketed text in original) (citing *Jack's Sales, Inc.,* and numerous practitioner cases). The Government also reiterated its position that summary disposition was warranted even if ''there is the potential that the Respondent's listed chemical privileges may be reinstated.'' *Id.* at 6 (citing, *inter alia, Roger A. Rodriguez, M.D.,* 70 FR 33206, 33207 (2005)).

On November 9, the ALJ granted the Government's motion. Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the ALJ (Nov. 9, 2011) (hereinafter, ALJ II). As a preliminary matter, the ALJ noted that Respondent had failed to ''respond to the Government's November 2, 2011 motion for summary disposition, or seek an extension within the deadline for response,[4] and is therefore deemed to waive objection.'' ALJ II at 4–5.

Turning to the merits, the ALJ found that it was undisputed that Respondent did not renew his state Permit for Controlled Chemical Substances and that Respondent is not exempt from this requirement because it does not hold a license issued by the California State Board of Pharmacy. ALJ at 6. Noting that under 21 U.S.C. 824(a)(3), the loss of state authority to manufacture or distribute a list I chemical ''is grounds to revoke a practitioner's registration,'' *id.,* the ALJ further explained that ''this Agency has consistently held that a registrant or prospective registrant may not hold a DEA registration if the registrant is without appropriate authority under the laws of the state in which it does business.'' *Id.* (citing *Jack's Sales,* 66 FR at 52939; also citing five cases involving practitioners). Reasoning that ''[s]ummary disposition is warranted even if the respondent's lack of state authority is temporary, because 'revocation is also appropriate when a state license had been suspended, but with the possibility of future reinstatement,''' *id.* (citing *Bergman,* 70 FR at 33193; *Rodriguez,* 70 FR at 33206), the ALJ granted the Government's motion and recommended that Respondent's application be denied.[5] *Id.* at 6–7. Alternatively, the ALJ found that Respondent had waived its right to a hearing by failing to comply with his Order for Pre-Hearing Conference and/or failing respond to Government's motion. *Id.* at 7, n.4.

Neither party filed exceptions to the ALJ's recommended decision. Thereafter, the ALJ re-forwarded the record to me for final agency action.

Having considered the entire record, I adopt the ALJ's factual findings that Respondent does not possess either a California Bureau of Narcotic Enforcement Permit for Controlled Chemical Substances or a license from the California Board of Pharmacy, as well as his legal conclusion that Respondent does not currently possess authority under California law to handle list I chemicals in California. While I also adopt the ALJ's recommendation that Respondent's application be denied, for reasons explained below, I do not adopt the ALJ's reasoning that the Government was entitled to summary disposition on the basis that Respondent lacks state authority. However, I find that two alternative grounds exist to deny Respondent's application: (1) That Respondent has waived his right to a hearing to contest whether granting his application would be inconsistent with the public interest, and (2) Respondent did not apply for the correct registration and thus would not be in compliance with applicable laws.

As discussed above, the Government maintains that because ''Respondent is currently without authority to handle list I chemicals in . . . California, the state in which [it] seeks registration . . . [it] is not eligible to possess a DEA registration in that State'' and that the CSA ''requires that a list I chemical

[3] This Office served a copy of the Remand Order by First Class Mail on Respondent.

[4] The ALJ also noted that on October 20, 2011, he issued an Order for Prehearing Conference which scheduled a pre-hearing conference for October 26, 2011 and also ordered the parties to contact the Office of Administrative Law Judges no later than 4 p.m. on October 25, 2011 to confirm their participation. The ALJ found that ''Respondent failed to comply with this order.'' ALJ II, at 3. The ALJ further noted that when his office attempted to contact Respondent's owner by phone, it ''was unable to reach him or any other representative for Respondent.'' *Id.*at 3–4.

[5] In a footnote, the ALJ quoted Cal. Health & Safety Code § 11106(a)(1)(C) and suggested that Respondent was not exempt from the permit requirement, because to be exempt it was required to be both licensed by the Pharmacy Board and hold a DEA registration. *See* ALJ II, at 3 n.1. The ALJ then reasoned: ''Thus, it appears that even if Respondent was licensed by the . . . State Board of Pharmacy, [it] would nonetheless lack state authority to handle list I chemicals because [it] does not maintain any DEA registration.'' ALJ II, at 3 n.1. Under the ALJ's logic, Respondent would not be entitled to a DEA registration because it does not have a DEA registration.

On the other hand, if Respondent did hold the requisite Pharmacy Board license and were the Agency to grant its application, it would immediately have state authority. And as explained in this decision, the CSA does not make possession of state authority a condition precedent to granting a registration for a list I chemical distributor.

manufacturer and distributor must be currently authorized to handle list I chemicals in the jurisdiction in which it seeks to maintain a DEA registration.'' Mot. for Summary Disp. (II) at 4. The Government further maintains that ''because 'possessing authority under state law to handle listed chemicals is an essential condition for holding a DEA registration,' [the Agency] has consistently held that 'the CSA requires the revocation . . . of a registration issued to a registrant [, and the denial of an application for registration submitted by an applicant,] who lacks''' state authority. *Id.* at 5. As noted above, in support of these propositions, the Government cited *Jack's Sales* and numerous cases involving practitioners. The ALJ adopted the Government's reasoning. ALJ II at 6.

Contrary to both the Government's and the ALJ's understanding, the CSA neither makes the current possession of state authority an essential condition for holding a DEA registration, nor requires that the Agency revoke an existing registration held by, or deny an application submitted by, a list I chemical handler because it is not currently authorized by the State to handle list I chemicals. Indeed, *Jack's Sales,* the case cited for these propositions, itself acknowledged that the CSA ''does not specify that state licensure is a condition precedent to registration as a distributor of lists I chemicals.'' 66 FR at 52939. Moreover, while *Jack's Sales* did uphold the use of summary disposition to deny an application for a list I chemical distributor's registration, on the ground that the applicant lacked a required state license, as explained below I conclude that its reasoning is flawed for two reasons: (1) It relied on provisions of the CSA which are specifically applicable to practitioners and not to list I chemical distributors, and (2) its reasoning cannot be squared with intervening judicial precedent. *See Penick Corp.* v. *DEA,* 491 F.3d 483, 490 (D.C. Cir. 2007).

To be sure, in numerous cases involving practitioners, this Agency has held that ''a practitioner must be currently authorized to handle controlled substances in the 'jurisdiction in which [it] practices' in order to [obtain and] maintain a DEA registration.'' *Roots Pharmaceuticals, Inc.,* 76 FR 51430 (2011); *see also Robert Wayne Mosier,* 75 FR 49950 (2010). However, this rule is grounded in the CSA's specific textual provisions which are applicable to this category of registrant. More specifically, Congress defined the term ''practitioner'' to ''mean[] a physician . . . *licensed, registered, or otherwise permitted, by the . . . jurisdiction in which he practices . . .* to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21) (emphasis added). Likewise, Congress, in setting forth the requirements for obtaining a practitioner's registration, directed that ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . *if the applicant is authorized* to dispense . . . controlled substances under the laws of the State in which he practices.''' 21 U.S.C. 823(f) (emphasis added). As these provisions make plain, a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances.

Accordingly, DEA has uniformly denied the applications of practitioners who lack state authority. Moreover, notwithstanding that 21 U.S.C. 824(a)(3), grants the Agency the authority to either suspend or revoke ''[a] registration pursuant to section 823,'' based on the CSA's clear requirement that a practitioner must possess state authority to hold a registration, DEA has uniformly revoked the registrations of practitioners who no longer possess state authority to dispense controlled substances and done so without regard to the underlying reason why the practitioner no longer possesses the requisite authority.[6]

By contrast, in defining the term ''distributor,'' Congress did not impose a requirement that the person engaged in this activity hold state authority. *See id.* § 802(11). Rather, it simply defined the term to ''mean[] a person who so delivers [other than by administering or dispensing] a controlled substance or listed chemical.'' *Id.* Likewise, Congress did not condition the registration of list I chemical distributors by requiring that they possess state authority. *See id.* § 823(h) (''The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest.''). If Congress had intended to condition the registration of list I chemical distributors on their possession of a state license, it had only to adopt language similar to that it employed in the provisions applicable to practitioners. *See Dean* v. *United States,* 556 U.S. 568, 573 (2009) (quoting *Russello* v. *United States,* 464 U.S. 16, 23 (1983) (''[W]here Congress includes particular language in one section of a statute but omits it in another section of the same enactment, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'')).

To be sure, in section 823(h), Congress directed that ''[i]n determining the public interest,'' the Agency ''shall consider,'' *inter alia,* ''compliance by the applicant with applicable Federal, State, and local law[.]'' *Id.* Thus, where state law requires that an applicant obtain a license to engage in list I chemical activities, DEA can consider an applicant's compliance (or lack thereof) with such a requirement in the public interest determination. However, as the D.C. Circuit has explained in discussing the public interest determination under section 823, the ''enumerated factors represent components of the public interest rather than independent requirements for registration and thus, the . . . Administrator may find a given registration consistent with the public interest even if one (or possibly more) of the public interest factors is not satisfied.'' *Penick Corp., Inc.,* v. *DEA,* 491 F.3d 483, 490 (D.C. Cir. 2007) (citing *Johnson Matthey, Inc.,* 60 FR 26050, 26052 (1995) (''It is well established that the . . . Administrator is not required to make findings with respect to each of the . . . factors, but has discretion to give each factor the weight [she] deems appropriate, depending upon the facts and circumstances in each case.'')).

This is not to say that DEA will grant an application for registration notwithstanding an applicant's failure to obtain a required state license. Indeed, as it does here, an applicant's failure to obtain a required state license will likely warrant an adverse finding under the compliance factor, *see* 21 U.S.C. 823(h)(2), and a finding under a single factor can support the conclusion that granting an application for registration would be inconsistent with the public interest and the consequent denial of an application. *See MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009).

What it is to say is that summary disposition may not be an appropriate mechanism for resolving such a case

[6] As explained below, that section 824(a)(3) authorizes revocation where a registrant ''has had [its] State license or registration suspended, revoked, or denied by competent state authority and is no longer authorized by State law to engage in the manufacturing [or] distribution of . . . list I chemicals'' does not mean that revocation is warranted in all instances. This provision grants the Agency discretionary authority to impose an appropriate sanction; the failure to consider factors such as the egregiousness of the misconduct and mitigating factors in imposing the sanction would render the sanction arbitrary and capricious.

because the applicant/registrant may have a valid explanation for why it is not currently licensed by the state, which would not necessarily support either revocation of an existing registration or the denial of an application. For example, the state licensing authority may have a large backlog in issuing its licenses, the applicant/registrant's application may have been lost or misplaced, there may be minor compliance issues which the applicant/registrant is in the process of correcting and which have delayed the issuance of the license but which would not necessarily warrant a denial or revocation (as the case may be) by DEA, or the applicant/registrant may have simply forgotten to renew its license on time. However, because other than in the case of practitioners, the possession of state authority is not an independent requirement for registration, what is clear is that an applicant/registrant is entitled to rebut the Government's *prima facie* case by showing that its conduct is not sufficiently egregious to warrant denial or revocation and what remedial measures it has undertaken to correct the problem. Thus, upon a proper showing by a respondent, summary disposition would be unwarranted and the respondent would be entitled to put on evidence.

In this matter, it is noted that in his July 14, 2011 filing, Respondent's owner claimed that it had filed for a renewal of its state license. However, since then, Respondent has produced no evidence that it has obtained a new state license. In addition, Respondent failed to comply with the ALJ's order for prehearing conference and failed to respond to the Government's renewed motion for summary disposition. As the First Circuit has noted in language that applies with equal force to administrative proceedings, '''[l]itigants must act punctually and not casually or indifferently if a judicial system is to function effectively.''' *McKinnon* v. *Kwong Wah Restaurant,* 83 F.3d 498, 504 (1st Cir. 1996) (quoted in *Kamir Garces-Mejias,* 72 FR 54931, 54933 (2007) (holding that registrant's failure to respond to ALJ's orders constituted waiver of her right to a hearing)). I therefore conclude that Respondent has waived its right to present evidence regarding its compliance with applicable laws. *See Garces-Mejias,* 72 FR at 54932–33; *see also Pamela Monterosso,* 73 FR 11146, 11147 (2008).

In addition, as I noted in the remand order, Respondent applied for a distributor's registration, and paid the fee for this category of registration (and not the fee for a manufacturer's registration).[7] However, it is clear from Respondent's application that it sought to engage in the ''Preparation 5% Solution (Lugol's Solution)'' and then noted that it intended to manufacture iodine in the dosage formulation of ''8 ml each.'' This constitutes manufacturing activity under the CSA. *See* 21 U.S.C. 802(15) (defining manufacturing to include ''the production, preparation . . . or processing of a drug or other substance, either directly or indirectly . . . and includes any packaging or repackaging of such substances or labeling or relabeling of its container'').

Under the CSA, ''[p]ersons registered . . . to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration.'' *Id.* § 822(b). Under DEA regulations, the manufacturing and distribution of list I chemicals are activities which ''are deemed to be independent of each other'' and while the holder of a manufacturer's registration can engage in the distribution of a list I chemical, the holder of a distributor's registration cannot engage in manufacturing. 21 CFR 1309.21(c); *id.* 1309.22(b) & (d). Accordingly, Respondent's proposed activity would not be lawful under the registration it seeks.

Based on Respondent's failure to obtain the required state permit or license, as well as that its proposed activity would not be lawful under the registration for which it applied, I find that the record supports a finding under factor two that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(h). Accordingly, Respondent's application will be denied.[8]

[7] In his letter requesting a hearing, Respondent's owner stated that it required a DEA registration ''to manufacture iodine 5% solution, called Lugol Solution.'' Letter of Paul Anand, Ph.D., to Administrator (June 23, 2011). However, according to Respondent's application, it sought registration as a Chemical Distributor and not as a Chemical Manufacturer; consistent with this, it paid the fee for the former and not the latter. Respondent's Application, at 1, 3. Moreover, in Section 3B of the application, which applies to ''Manufacturers Only,'' Dr. Anand wrote: ''Preparation 5% Solution (Lugol's Solution),'' and in Section 3C, he checked the box for bulk iodine. *Id.* at 1–2.

Under DEA's regulation, the manufacturing of list I chemicals is deemed to be an activity which is independent of distribution (although a registered manufacturer can lawfully engage in distribution), and thus requires a manufacturer's registration. *See* 21 CFR 1309.22. Because Respondent did not apply for the required registration, its application should have been rejected as defective. *See id.* § 1309.34(a).

[8] As found above, on November 2, the Government filed its second motion for summary disposition by mailing it to Respondent's owner, at its address in Brea, California; on November 9, the ALJ issued his recommended decision noting that ''Respondent had 'until 4:00 p.m. EDT three business days after the date of service of any motion to file a responsive pleading' and that '[i]n the absence of good cause, failure to file a written response to the moving party's motion after three business days will be deemed a waiver of objection.''' ALJ II, at 4. The ALJ apparently deemed service to have been effectuated with mailing. *See id.* (noting that ''[a]s of November 9, 2011, five business days after service of the Government's [motion], Respondent had not yet filed a response''). While courts frequently deem service of a pleading to have occurred on mailing and not upon receipt by the opposing party, *see, e.g.,* F.R.C.P. r. 5(b)(2)(C), due regard must be given to the respective locations of the parties and the vagaries of the mail. While an ALJ is entitled to substantial discretion in managing his/her docket, the amount of time the ALJ allowed here for Respondent to file its responsive pleading was unduly limited and potentially a violation of Due Process.

However, because following issuance of the remand order, Respondent has not filed any pleadings including exceptions, I deem any such error harmless.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) and 28 CFR 0.100(b), I order that the application of Bio Diagnostic International, Inc., for a DEA Certificate of Registration as a distributor of list I chemicals, be, and it hereby is, denied. This Order is effective July 31, 2013.

Dated: June 21, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–15704 Filed 6–28–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sigrid Sanchez, M.D.; Decision and Order

On February 4, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Sigrid A. Sanchez, M.D. (Respondent), of Sunrise, Florida. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration as a practitioner, on the ground that her ''registration would be inconsistent with the public interest.'' GX 7, at 1 (citing 21 U.S.C. 823(f)).

More specifically, the Show Cause Order alleged that on May 19, 2010, Respondent had surrendered her previous DEA registration, and that on July 29, 2010, she had applied for a new registration. *Id.* The Show Cause Order further alleged that on April 30, 2010, the Florida Department of Health had conducted ''a dispensing practitioner's