General Exclusion Orders under Section 337

Gary M. Hnath

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Your company, Widgets Unlimited, imports foreign-made widgets into the United States. One day, you’re informed that U.S. Customs & Border Protection (Customs) has detained your goods and is determining whether they infringe a patent owned by The American Widget Corporation, based on an exclusion order issued by the International Trade Commission (ITC) after a recent ITC investigation, titled Certain Widgets with Extra Shiny Surfaces. Since you were never a party to any proceeding at the ITC, and indeed, you never even knew American Widget had patents on its widgets, you conclude that there must be some mistake and wait for the goods to be released by Customs. The following week, however, you’re told that the goods infringe American Widget’s patent and, based on the exclusion order, your widgets will not be allowed to enter the United States. You’re told you can ship them back or, if you fail to do so, Customs will destroy them.

What do you do now? How is it possible that you cannot import and sell your widgets in the United States, when there is no ruling by a court that your products infringe? Aren’t you entitled to some kind of due process? This article will explore general exclusion orders issued by the ITC, the legal basis for those orders, how a company can obtain a general exclusion order, and what options are available to a company faced with exclusion of its goods.

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I. THE ROLE OF SECTION 337 IN PROTECTING U.S. INTELLECTUAL PROPERTY RIGHTS

Section 337\(^1\) was enacted to protect U.S. domestic industries from unfair competition in the importation into the United States of goods made by foreign companies, including goods that infringe U.S. patents.\(^2\) Over the years, Section 337 has developed into one of the primary means for U.S. companies to protect their intellectual property rights, including patents, trademarks, and copyrights, from infringing imports. Over 90% of the cases recently brought under Section 337 involve alleged infringement of U.S. patents.\(^3\) In fact, when Section 337 was amended in 1988,\(^4\) infringements of U.S. patents and registered trademarks, copyrights, and mask works were expressly referenced as a basis for a violation of the statute, and complainants no longer had to prove injury to a domestic industry in such cases.\(^5\) The ITC is currently charged with responsibility for administering Section 337 investigations.

Why is Section 337 most often used to protect U.S. patent holders? The answer lies in the unique remedies available under Section 337. As a trade statute, Section 337 remedies are in rem; they are directed to the goods themselves. The primary remedy under Section 337 is an exclusion order which prevents the goods at issue (for example, goods that infringe on a U.S. patent) from entering the United States.\(^6\) Exclusion orders are issued by the ITC and enforced by Customs, which has the power to inspect and deny entry to goods within the scope of the order. Thus, exclusion orders are ideally suited to protect U.S. patents by enforcing intellectual property rights at the border.

Damages are not available under Section 337. However, by statute, Section 337 remedies are “in addition to” other remedies available under

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\(^2\) See, e.g., In re Orion Co., 71 F.2d 458, 466 (C.C.P.A. 1934).
\(^3\) Empirical analysis of Section 337 investigations since Jan. 1, 1996, on file with author.
\(^5\) Id.
\(^6\) The Commission may also issue cease and desist orders directing named respondents to “cease and desist from engaging in the unfair methods or acts involved.” 19 U.S.C. § 1337(f) (2004). Such orders, for example, are issued to prevent a U.S. respondent from selling significant inventories of the involved articles after a violation of Section 337 has been found. One complainant recently argued that the Commission’s practice of not issuing cease and desist orders against respondents who have no domestic inventory is too narrow and an abuse of discretion, given Customs’ difficulties in enforcing general exclusion orders and Customs’ “new responsibilities in combating terrorism.” Fuji Photo Film Co., Ltd. v. Int’l Trade Comm’n, 386 F.3d 1095, 1107 (Fed. Cir. 2004). The Federal Circuit rejected this argument, finding no evidence that Customs was “incapable of performing the duties Congress assigned to it.” Id.
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the law, including a district court action for damages.\(^7\) Therefore, Section 337, whether used alone or in conjunction with a parallel action for damages in district court, has developed as a vital tool in the arsenal of U.S. companies (as well as foreign companies holding U.S. patents) to prevent infringement of patents in cases involving goods imported into the United States.

Exclusion orders are issued only after a proceeding before the ITC which includes notice and an opportunity to be heard by named respondents. Once the Commission initiates an investigation, the case is assigned to an administrative law judge and the respondents are permitted to take discovery on the complainant's claims as well as any defenses raised by the respondents. Any party may file motions, including summary determination motions (the equivalent of summary judgment motions under the Federal Rules of Civil Procedure). Following submissions of prehearing briefs and statements, the case proceeds to a hearing in which all parties have an opportunity to call witnesses to testify and to submit exhibits in support of their positions.\(^8\)

After the conclusion of the hearing, the parties submit post hearing briefs and proposed findings of fact. The administrative law judge then issues an initial determination on the issues relating to the violation, and a recommended determination on issues of remedy and bonding. Any party may petition the Commission to review the initial determination. The Commission may choose to review the initial determination and may, in the course of its review, seek additional briefs from the parties. The Commission then issues its final determination as to whether there has been a violation of Section 337 and, if so, the appropriate remedy. The Commission's final determinations are subject to Presidential review for policy reasons, and ultimately can be appealed to the United States Court of Appeals for the Federal Circuit.\(^9\)

There are two types of exclusion orders available under Section 337: limited exclusion orders and general exclusion orders. A limited exclusion order applies to goods manufactured, imported, and sold by the parties actually named as respondents in the ITC proceeding. A general exclusion order is broader, and prevents any infringing articles from entering the United States, regardless of source. Thus, a general exclusion order is not limited to the parties named as respondents at the ITC, and is the strongest and most effective remedy available under Section 337. As stated by the Commission in *Certain Airless Paint Spray Pumps*,\(^10\) general exclusion

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\(^9\) Id.
orders are available as remedies because a complainant:

should not be compelled to file a series of separate complaints against several individual foreign manufacturers as it becomes aware of their products in the U.S. market. Such a practice would not only waste the resources of the complainant, it would also burden the Commission with redundant investigations.\(^\text{11}\)

In order to strengthen ITC exclusion orders and provide additional disincentives for their evasion, the 1988 amendments to Section 337 also included a provision allowing the Commission to order seizure and forfeiture of an article subject to an exclusion order. This can occur if the owner, importer, or consignee previously attempted to import the article, it was denied entry, and the Secretary of the Treasury provided notice that a further attempt to import the article would result in seizure and forfeiture.\(^\text{12}\) This provision was enacted in response to reports that despite the issuance of exclusion orders, infringing imports continued to enter the United States.\(^\text{13}\) For example, some importers would engage in “port shopping” by attempting to try to bring infringing goods into different ports, or import articles on multiple occasions, hoping to evade an exclusion order with the knowledge that an unsuccessful attempt would merely result in refusal to enter the goods and their return to the owner.\(^\text{14}\)

II. THE LEGAL BASIS FOR GENERAL EXCLUSION ORDERS

In *Certain Coin-Operated Audio-Visual Games*,\(^\text{15}\) the Commission, citing *Sealed Air Corp. v. U.S. International Trade Commission*,\(^\text{16}\) stated that:

the purpose of the exclusion remedy was to get away from *in personam* procedures, which United States business found unsatisfactory. Being unable in most cases to sue a foreign supplier, a U.S. business faced with infringing products from abroad was forced to pursue a multiplicity of individual importers, and if a court enjoined one, another could be found to take his place. Thus, the exclusion remedy was conceived.\(^\text{17}\)

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\(^\text{11}\) *Id.* at 18.


\(^\text{14}\) *Id.*


\(^\text{16}\) 645 F.2d 976 (C.C.P.A. 1981).

\(^\text{17}\) *Certain Coin-Operated Audio-Visual Games*, USITC Pub. 1160, Inv. No. 337-TA-87
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A general exclusion order, however, may prohibit the importation of goods by companies that were never parties to a Section 337 investigation. How can the Commission do so without violating due process?

The answer lies in the unique *in rem* nature of Section 337 exclusion orders. The Commission's jurisdiction to issue exclusion orders is based upon its power over property (imported goods) and therefore does not require personal jurisdiction. The United States Supreme Court has held that "[t]he power to regulate commerce with foreign nations is expressly conferred upon Congress, and being an enumerated power is complete in itself, acknowledging no limitations other than those prescribed in the Constitution." Further, importers have no right to import goods into the United States:

As a result of the complete power of Congress over foreign commerce, it necessarily follows that no individual has a vested right to trade with foreign nations, which is so broad in character as to limit and restrict the power of Congress to determine what articles of merchandise may be imported into this country and the terms upon which a right to import may be exercised. This being true, it results that a statute which restrains the introduction of particular goods into the United States from considerations of public policy does not violate the due process clause of the Constitution.

As explained by the Commission, its subject matter jurisdiction was delegated by Congress pursuant to the foreign commerce clause’s “broad comprehensive powers [to] regulate Commerce with foreign nations.”

As such, there is no such thing as a ‘vested right’ to import goods into the United States; importation is a privilege granted by Congress. Hence, Congress may exclude goods from the United States, or empower the Commission to do so, for ‘importation, even to our own citizens, is not a vested right, but an act of grace.’

That subject matter jurisdiction provides the Commission’s power to issue exclusion orders. As explained by the Court of Customs and Patent Appeals (C.C.P.A.):

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20 Id. at 493.
22 Id. (quoting *In re Orion Co.*, 71 F.2d 458, 465 (C.C.P.A. 1934)).
23 The C.C.P.A. is the predecessor to the modern Federal Circuit Court of Appeals.
The subject matter jurisdiction of the ITC over "the importation of articles into the United States," § 1337(a), and its authority to exclude "the articles concerned," § 1337(d), are fully adequate... Hence the ITC, upon investigation and determination of a violation, could exclude products sold by a domestic owner/importer/consignee, under its subject matter jurisdiction, whether or not it named the foreign manufacturer as a respondent or gave notice to that foreign manufacturer. Though its subject matter jurisdiction is sufficient, the ITC is a creature of statute. Hence it must follow established procedures in making a determination that a violation of the Act has occurred, and may exclude a product only after completion of such procedures.24

Thus, the Commission has held that although it

may act on the strength of the in rem nature of its jurisdiction in the absence of in personam jurisdiction, due process requires that it provide notice to persons with an interest in property reasonably calculated to inform them of the pendency of an action affecting that property so that they may have the opportunity to appear and defend their interests.25

The jurisdictional basis for the Commission to issue general exclusion orders that can affect the importation of goods by persons not a party to a Section 337 investigation is therefore firmly established.

III. THE STANDARDS FOR OBTAINING GENERAL EXCLUSION ORDERS

As the Commission noted in Certain Cigarettes and Packaging Thereof,26 because of a general exclusion order’s "considerable impact on international trade, potentially extending beyond the parties and articles involved in the investigation, more than just the interest of the parties is involved. Therefore, the Commission exercises caution in issuing general exclusion orders. . ."27

Because of the broad sweep of general exclusion orders, they are available only if certain conditions can be met. In Certain Airless Spray Pumps,28 the Commission enunciated the standard for general exclusion orders as follows:

27 Id. at 5.
it is incumbent upon the Commission to balance a complainant's interest in obtaining complete protection from all potential foreign infringers through a single investigation with the inherent potential of a general exclusion order to disrupt legitimate trade. We therefore require that a complainant seeking a general exclusion order show both a widespread pattern of unauthorized use of its patented invention and certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles.\(^29\)

The Commission held that evidence establishing the first prong of this test—"a widespread pattern of unauthorized use of [the] patented invention"—could include (1) a Commission determination of unauthorized importation into the United States of infringing articles by numerous foreign manufacturers; (2) the pendency of foreign infringement suits based upon foreign patents which correspond to the domestic patent at issue; and (3) other evidence which demonstrates a history of unauthorized foreign use of the patented invention.\(^30\)

The Commission further held in Spray Pumps that evidence relating to the second prong of the test for a general exclusion order—"certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles"—includes (1) an established demand for the patented product in the U.S. market and conditions in the world market; (2) the availability of marketing and distribution networks in the United States for potential foreign manufacturers; (3) the cost to foreign entrepreneurs of building a facility capable of producing the patented article; (4) the number of foreign manufacturers whose facilities could be retooled to produce the patented article; and (5) the cost to foreign manufacturers of retooling their facility to produce the patented articles.\(^31\)

In 1989, a GATT panel issued a report that found certain aspects of Section 337 inconsistent with the national treatment provisions of GATT, Article III:4, insofar as foreign goods were subject to restrictions not applicable to domestically-produced articles.\(^32\) In response to this report, a number of amendments were made to Section 337 as part of the Uruguay Round Amendments Act (URAA), enacted on December 8, 1994.\(^33\) The GATT panel found, *inter alia*, that general exclusion orders should be

\(^{29}\) Id. at 18.

\(^{30}\) Id.

\(^{31}\) Id.


limited to circumstances in which they are "necessary" to protect intellectual property rights. In response, Congress incorporated into the text of the statute the following standard for obtaining general exclusion orders:

(2) The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that –

(A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or

(B) there is a pattern of violation of this section and it is difficult to identify the source of infringing articles.

The Commission, citing the legislative history of the URAA, has held that these statutory standards "do not differ significantly" from the Spray Pumps criteria.

In the ten years between January 1, 1995 (when the amendments to the statute became effective) and December 31, 2004, a total of 158 complaints in Section 337 investigations were filed. In those investigations, according to information compiled by the ITC’s Office of Unfair Import Investigations, seven general exclusion orders issued between 1994 and 2002, compared to thirteen limited exclusion orders during the same time period. According to a review conducted by the author, four additional general exclusion orders were issued between January 1, 2003 and December 31, 2004, for a total of eleven general exclusion orders since the statute was amended in 1994.

34 Mittelberger & Hnath, supra note 32.

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Complainants seeking a general exclusion order should marshal their evidence, specifically address each of the statutory criteria, and present it in the most persuasive manner possible. This would include discovery from parties to the investigation, discovery from third parties, and even expert testimony bearing on each of the Spray Pumps factors. Interestingly, such evidence is often not contested by the named respondents to an investigation, since if their products are to be excluded, they may have some incentive in having their competitors’ products excluded as well. Note, however, that the Office of Unfair Import Investigations represents the public interest in a Section 337 investigation and may, in appropriate cases, independently challenge the evidence in support of a general exclusion order, even where the named respondents do not oppose the evidence.

IV. OBTAINING GENERAL EXCLUSION ORDERS WHERE RESPONDENTS DEFAULT OR SETTLE

Section 1337(d) provides that the Commission may issue a general exclusion order if it determines that there has been a violation of the statute and that the requirements of subsection (d)(2) are satisfied.\(^3\) The statute further provides that in “addition to the authority of the Commission to issue a general exclusion from entry of articles when a respondent appears to contest an investigation,” a general exclusion order may also be issued if (A) no person appears to contest an investigation concerning a violation of Section 337, (B) such a violation is established by “substantial, reliable, and probative evidence,” and (C) the requirements of subsection (d)(2) are satisfied.\(^4\)

What if all of the respondents settle? Can a complainant still pursue a general exclusion order? The Commission addressed this issue in Certain Plastic Molding Machines, where the complainant, Milacron, settled with all eleven respondents in the investigation.\(^4\) It then moved for summary determination of a violation of Section 337 and requested a general exclusion order pursuant to subsection 337(g)(2).\(^4\) As noted above, that subsection provides that in addition to the Commission’s authority to issue a general exclusion order when a respondent appears to contest an

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\(^3\) See supra note 35 and accompanying text.


investigation, a general exclusion order may also be issued if "no person appears to contest an investigation concerning a violation of the provisions of this section." 4

The administrative law judge ruled that subsection 337(g)(2) provides authority to issue a general exclusion order where all respondents have settled. 4 The Commission reversed, finding that since the settled respondents had "appeared" and "contested the investigation," it had no statutory authority under subsection (g)(2) to issue a general exclusion order. 4

The Commission held that "[a] general exclusion order is an extraordinary trade remedy in that it completely excludes from entry all articles that infringe the intellectual property right involved, without regard to the source of the articles. Consequently, we closely adhere to expressed Congressional intent in implementing this remedy." 4

The Commission noted that subsection (g)(2) was added to the statute in 1988 as part of the Omnibus Trade and Competitiveness Act. 4 The legislative history of that Act explains that the amendment:

was motivated by the fact that discovery is usually difficult or impossible to obtain from respondents who have chosen not to participate in a Section 337 investigation. For this reason, the bill authorizes the Commission to presume the facts alleged in the complaint to be true insofar as they involve a defaulting respondent, and to then issue relief limited to that respondent. This amendment will not affect participating respondents. 4

The Commission found nothing in the legislative history to support Milacron's argument that respondents that initially participated in the investigation but later settled were not "participating respondents." 4

Milacron also attempted to obtain a general exclusion order pursuant to subsection 337(d) by moving for a summary determination that the settling respondents had violated the statute. 5 The Commission held that it would not consider whether there had been a violation of Section 337 by the settling respondents:

42 U.S.C. § 1337(g)(2).
44 Id. at 14.
45 Id. at 22.
46 Id. at 7.
47 See id. at 8 (quoting H.R. REP. No. 100-40, at 160-61 (1988)).
48 Id. at 9.
[a]lthough Section 337 arguably grants the Commission the authority to make a finding on the issue of violation when it terminates an investigation based on a settlement agreement or consent order, it is less clear that the Commission has the authority to make a determination of violation for purposes of subsection 337(d) after all named respondents have settled and been terminated from the investigation because subsection 337(c) requires that each determination under subsection 337(d) be “on the record after notice and opportunity for a hearing” in conformance with the APA.\(^5\)

In any event, the Commission found it “unnecessary” to decide whether it had the authority to make a finding on the issue of violation under the circumstances presented in that investigation, because it decided to adhere to its “long-standing policy of not reaching the issue of violation when terminating investigations on the basis of settlement agreements.”\(^5\) It held that Milacron voluntarily settled with each respondent, resulting in their termination from the investigation, and that “either by design or inadvertence, Milacron placed itself in the position that it now finds itself.”\(^5\) Milacron argued that the Commission’s interpretation would make it harder to obtain settlements.\(^5\) The Commission rejected this argument, holding that to the contrary, allowing Milacron to obtain a general exclusion order where all parties had settled would be likely to “undercut the Commission’s policy of encouraging settlement by disrupting the reasonable expectations of respondents that they would not be found in violation of Section 337 once they had settled with complainant.”\(^5\)

The Commission held that its decision did not prevent complainants such as Milacron from attempting to obtain general exclusion orders. It explained that Milacron could have attempted to obtain a finding of violation and pursued a general exclusion order under subsection 337(d) by moving for summary determination before moving to terminate respondents based on settlement agreements. Milacron chose not to pursue that route. Notwithstanding the instant case, the Commission noted, Milacron could file another complaint under Section 337 and attempt to obtain a general exclusion order under subsection 337(d) or, if applicable, subsection 337(g)(2).\(^5\)

Finally, what if, unlike the situation in *Certain Plastic Molding Machines*, only some of the respondents settle based on a consent order or

\(^{51}\) *Id.* at 17.

\(^{52}\) *Id.* at 18.

\(^{53}\) *Id.* at 20.

\(^{54}\) *Id.* at 21.

\(^{55}\) *Id.*

settlement agreement and others default? This is, in fact, a common scenario in Section 337 investigations. The Commission in Certain Plastic Molding Machines expressly declined to decide this issue:

The Commission does not decide here whether subsection 337(g)(2) applies when some respondents fail to appear in an investigation. Rather, it decides only that subsection 337(g)(2) does not apply where all respondents participated in the investigation before entering settlement agreements with complainant. Depending on the particular circumstances of the case, the rationale that a general exclusion under subsection 337(g)(2) is appropriate where complainant has difficulty in getting discovery may or may not apply in an investigation in which some named respondents fail to appear.57

The Commission was soon to confront this very issue in Certain Sildenafil or any Pharmaceutically Acceptable Salt Thereof.58 The complainant in that investigation, Pfizer, filed a complaint alleging that the respondents were involved in the sale for importation, actual importation, and sale after importation of sildenafil compounds that infringed Pfizer’s patent.59 Pfizer sells sildenafil under the trade name “Viagra.”

Of the fifteen named respondents, eleven were found to be in default, two were never served with the complaint and notice of investigation, and the other two were terminated based on settlement agreements.60 Pfizer moved for summary determination of a Section 337 violation and the existence of a domestic industry, as well as the entry of a general exclusion order against all infringing imports of the accused sildenafil products and the entry of a cease and desist order against the only defaulting domestic respondent.61 In seeking a general exclusion order, Pfizer relied both on subsection (d)(2) and subsection (g)(2).62

More specifically, Pfizer argued that it established a violation of Section 337 through its motion for summary determination and further satisfied the requirements of subsection (d)(2), and therefore the Commission did not need to reach subsection (g)(2).63 In fact, Pfizer argued that the requirements of subsection (d)(2) are more stringent since it could obtain summary determination only if it demonstrated “no dispute as to any material fact” and “entitlement to summary determination as a matter

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57 Id. at 13-14.
59 See id. at 1.
60 Id. at 2.
61 Id.
62 Id. at 3-4.
63 Id. at 6.
of law,” whereas under subsection (g)(2) it needed to show a violation only through “substantial, reliable, and probative evidence.”64

The administrative law judge held that the Commission’s interpretation of the legislative history in Plastic Molding Machines implied that “Congress intended Section 337(g)(2) to be the exclusive avenue for issuing general exclusion orders in cases involving defaulting respondents, not merely an alternative to elect in lieu of the route prescribed for contested cases under Section 337(d)(2), as Pfizer and the Staff maintain.”65 He further explained:

If cases involving defaulting respondents could reach a general exclusion order by an election of either Section 337(g)(2) or Section 337(d)(2), as Pfizer and the Staff suggest, then the third condition would render Section 337(g)(2) superfluous in view of the choice available to elect Section (d)(2) as a route by itself. No one would “elect” to satisfy the extra conditions of Section 337(g)(2) to obtain a general exclusion order when the conditions of Section 337(d)(2) alone would achieve the same remedy. More logically, it must be the case that, where there are defaulting respondents, Section 337(g)(2) is the only way to reach a general exclusion order.66

The administrative law judge therefore held that Pfizer was required to come forward with “substantial, reliable, and probative evidence” of a violation of Section 337 as required by subsection (g)(2)(B) in addition to meeting the requirements of subsection 337(d)(2).67 He found that the requirements for granting summary determination did not take the place of those requirements, since Pfizer’s motion was uncontested.68 However, examining the record, including the evidence supporting Pfizer’s motion, he found that Pfizer had indeed met the requirements of demonstrating a violation by “substantial, reliable, and probative evidence” as well as the requirements of subsection (d)(2), and accordingly recommended the issuance of a general exclusion order.69

On February 6, 2004, the Commission announced that it was issuing a general exclusion, but based on subsection (d)(2), not subsection (g)(2).70

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64 Certain Sildenafil or any Pharmaceutically Acceptable Salt Thereof, USTIC, Inv. No. 337-TA-489 at 5-6 (Oct. 27, 2003) (Order No. 19 Initial Determination).
65 Id. at 7.
66 Id. at 7-8.
67 Id. at 9.
68 Id.
69 Id. at 17.
The Commission held that subsection (g)(2) did not apply because it expressly requires that no respondent can appear to contest the investigation, but two of the respondents (Ezee and Biovea) did appear. The fact that no discovery was taken from these respondents and that they were terminated based on settlement agreements did not change the fact that they did appear.\(^1\) The Commission held, however, that the adjudicative provisions of the Administrative Procedure Act, which apply to Section 337 investigations, provide that a sanction or order may not be issued unless supported by “reliable, probative, and substantial evidence.”\(^2\) Accordingly, the Commission found that there was no difference between the standards for issuing general exclusion orders under subsections (d)(2) and (g)(2), that Pfizer had in fact demonstrated a violation of Section 337 under this standard, and that since the other requirements of subsection (d)(2) were satisfied, a general exclusion order was appropriate.\(^3\)

Complainants should therefore be prepared to make as complete a record as possible of a violation of Section 377, whether by summary determination or otherwise, in order to obtain a general exclusion order.

**V. ENFORCEMENT OF GENERAL EXCLUSION ORDERS**

As noted above, general exclusion orders are enforced in the first instance by the Bureau of Customs and Border Protection in the Department of Homeland Security. If Customs allows importation, by a company not previously a party to a Section 337 investigation, of a product that a complainant believes infringes its patent, the complainant can attempt to enforce the order at the ITC. In that event, what defenses can the company raise?

The Federal Circuit addressed this issue recently in *VastFame Camera, Ltd. v. International Trade Commission*.\(^4\) After the Commission issued a general exclusion order in *Certain Lens-Fitted Film Packages*,\(^5\) VastFame, not a party to the original investigation, obtained a ruling from Customs that its cameras did not violate the order and allowed importation of the cameras.\(^6\) The complainant, Fuji, then filed a complaint with the Commission requesting enforcement of the general exclusion order and advisory proceedings to determine whether VastFame and others had violated the order. VastFame asserted as a defense that claim 15 of one of

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\(^1\) Certain Sildenafil or any Pharmaceutically Acceptable Salt Thereof, USITC, Inv. No. 337-TA-489 at 4 (July 26, 2004) (Commission Opinion on Remedy).

\(^2\) *Id.* (quoting 5 U.S.C. § 556 (2004)).

\(^3\) *Id.* at 4-8.

\(^4\) 386 F.3d 1108 (Fed. Cir. 2004).


\(^6\) See *VastFame Camera, Ltd. v. Int’l Trade Comm’n*, 386 F.3d 1108, 1110 (Fed. Cir. 2004).

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the patents at issue (the ‘087 patent) was invalid.\footnote{See id.}

The administrative law judge ruled that the defense of invalidity could not be raised by VastFame, and found that VastFame infringed claim 15 of the ‘087 patent and that its cameras were in violation of the general exclusion order.\footnote{See id.} The Commission affirmed,\footnote{Certain Lens-Fitted Film Packages, USITC, Inv. No. 337-TA-406 at 8-9 (June 28, 1999) (Commission Opinion).} and VastFame appealed to the Federal Circuit.\footnote{VastFame Camera, Ltd. v. Int'l Trade Comm'n, 386 F.3d 1108, 1111 (Fed. Cir. 2004).}

The Federal Circuit held that the Commission, as the agency charged with the administration of Section 337, is entitled to appropriate deference in its interpretation of the statute.\footnote{Id.} However, the Commission is also a “creature of statute” and “it must find authority for its actions in the enabling statute.”\footnote{Id. at 1111-12.}

The Federal Circuit found no express statutory authority to conduct enforcement proceedings.\footnote{Id. at 1112.} Instead, the court found that the Commission’s authority to conduct such proceedings arises under and is subject to the provisions of § 1337(b), which provides that the “Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative.”\footnote{Id. (quoting § 1337(b)).} “Investigations” in turn are governed by § 1337(c), which permits a respondent to present “[a]ll legal and equitable defenses.”\footnote{Id. at 1115.}

Therefore, the Federal Circuit held that VastFame was entitled to raise validity as a defense in the enforcement proceeding, and remanded to the Commission for consideration of that defense. The Court rejected the Commission’s argument that a general exclusion order is like a district court injunction, and should not be subject to collateral attack.\footnote{VastFame, 386 F.3d at 1114-15.} The Court noted that district court injunctions are generally limited to parties entering appearances before the court, or those aiding or abetting or acting in concert or participation with parties before the court.\footnote{Id. at 1114.} In contrast, general exclusion orders apply whether or not the persons importing the articles were parties to the investigation. Therefore, the justification for prohibiting collateral challenges to district court injunctions does not apply to general exclusion orders.\footnote{Id. at 1114-15.}
The Federal Circuit also rejected the Commission’s policy-based arguments based on “(1) the difficulty in administering the statute if general exclusion orders are subject to repeated challenges, (2) the necessity of preserving the original complainant’s remedy once it has been issued, and (3) the public interest in avoiding uncertainty in the market place.” The Court noted that the same policies would be served by preventing accused infringers from challenging the validity of a patent that had been previously found to be invalid, but “that is not the law.” In any event, these policies did not justify the Commission’s interpretation in the absence of a showing that the statute could be “fairly read the way the Commission interprets it. To the contrary, the intent of Congress with respect to this issue is quite clear.”

In view of its finding that VastFame was entitled to present its invalidity defense under § 1337(c), the Federal Circuit did not reach the issue of whether VastFame’s due process rights had been violated.

In light of the Federal Circuit’s opinion in VastFame, complainants in Section 337 investigations, before seeking enforcement of a general exclusion order, need to consider carefully the risk that pursuing enforcement could possibly open up the order to collateral attack on grounds of invalidity or unenforceability that were never raised or considered during the original investigation.

VI. WHAT TO DO IF FACED WITH EXCLUSION OF GOODS BASED ON A GENERAL EXCLUSION ORDER

What then does a company do if, even though never named as a party to an ITC investigation, it faces rejection of its products at the border based on a general exclusion order? Discussed below are a number of options that may be considered.

A. Intervention

If the ITC investigation is still pending, a company may attempt to intervene in the ongoing investigation to protect its interests. The Commission’s Rules specifically provide for intervention by interested parties by filing a motion with the Commission. The standards for intervention applied by the ITC are similar to those set forth in Rule 24 of the Federal Rules of Civil Procedure. In addressing a motion to intervene by a party, the Commission will consider (1) whether the motion to

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89 Id. at 1114.
90 Id.
91 Id.
92 VastFame, 386 F.3d at 1115-16.

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intervene is timely; (2) whether the moving party has an interest relating to the property or transaction which is the subject of the action; (3) whether disposition of the action may as a practical matter impair or impede its ability to protect that interest; and (4) whether the moving party’s interests are adequately represented by the existing parties.94

A company whose imported goods could be affected by a Section 337 general exclusion order clearly has an interest in the outcome of the proceeding. If a motion is filed in a timely manner, preferably early in the investigation, a company may be permitted to intervene in the ongoing investigation in order to protect its interests, rather than having to wait until an investigation is completed and a general exclusion order has already issued.

B. Comments to the Commission

The ITC’s Rules also provide that any “interested persons” can submit comments during the Commission review stage concerning the issues of remedy, bonding and the public interest.95 There is no limitation on who can submit comments; “interested persons” could include, for example, companies not parties to the investigation or trade associations. However, at that point, there has already been an initial determination on the substantive issues (such as patent infringement, validity and enforceability) in the investigation, and the ability to introduce new evidence or arguments bearing on those issues through comments may be limited.

C. Administrative Remedies Through Customs

A different situation is presented if an exclusion order has already issued. One option available is to seek relief, formally or informally, through Customs. A typical general exclusion order will prevent the importation of any articles that are “covered by” a valid and enforceable U.S. patent.96 Complainants can, and often do, provide input to Customs concerning the scope of an exclusion order and what products fall within its scope. For example, American Widget may provide test results and other information to Customs in an attempt to persuade Customs that products imported by Widgets Unlimited are “covered by” the general exclusion order. Widgets Unlimited may wish to take the initiative and provide information establishing that its products are not covered by the patent. This could be done informally or, if the goods have not been imported yet,

Widgets Unlimited could request a ruling from Customs that its goods are not covered by an exclusion order by submitting a letter to Customs. An adverse decision from Customs could be reviewed by bringing a declaratory judgment action in the U.S. Court of International Trade (CIT) pursuant to 28 U.S.C. § 1581(h). If there has already been an attempt to import the goods and Customs has denied entry, then Widgets Unlimited could file a protest with Customs pursuant to 19 C.F.R. § 174. If the protest is denied, Widgets Unlimited could then appeal the denial by filing a civil action in the CIT.

D. A Declaratory Judgment Action in District Court

If Widgets Unlimited believes that American Widget’s patent is invalid or unenforceable, this is likely not an argument that can be made to Customs, since Customs will generally take the validity and enforceability of the patent as already established in the underlying ITC proceeding. In that case, Widgets Unlimited may wish to consider going to a district court and filing a declaratory judgment action, seeking a declaration that American Widget’s patent is invalid or unenforceable. Arguably, the exclusion of goods by Customs (possibly with American Widget’s participation and/or consent) could establish that a “case or controversy” exists and satisfy the jurisdictional requirements for a declaratory judgment action. The same procedure could be used in an attempt to establish that Widgets Unlimited’s product does not infringe. If successful in federal court, Widgets Unlimited could then seek modification or rescission of the ITC’s exclusion order according to procedures discussed below. The Commission will generally follow district court decisions on the validity, enforceability or infringement of intellectual property rights.

E. Petition for Modification or Rescission

Alternatively, Widgets Unlimited could seek relief directly from the ITC. For example, a party may seek modification or rescission of a Commission order, including an exclusion order, under 19 C.F.R. § 210.76 by filing a petition with the Commission setting forth “changed conditions of fact or law, or the public interest” that require that a Commission order be modified or set aside, in whole or in part. The Commission may also

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consider such action on its own initiative. If a party has previously been found in violation of Section 337, the burden of proof by statute is on the petitioner to show that modification or rescission is appropriate. The statute further provides that relief may be granted by the Commission on the basis of “new evidence or evidence that could not have been presented at the prior proceeding,” or “on grounds which would permit relief from a judgment or order under the Federal Rules of Civil Procedure.”

For example, in *Certain Miniature Plug-in Blade Fuses*, the Commission, on its own initiative, requested submissions from the complainant and Office of Unfair Import Investigations as to whether a general exclusion order issued more than fifteen years previously should be modified because of a recent appellate decision calling into question the validity of the trade dress on which the order was based. In February 2001, after receiving the submissions, the Commission instituted a modification proceeding.

Both the statute and the Commission’s Rules are silent as to the standard to be applied if modification or rescission is sought by a company not previously found to be in violation of Section 337. Arguably, for example, such a company could seek rescission based on evidence that a patent is invalid or unenforceable, based on evidence not previously before the Commission. By definition, such evidence could not have been previously submitted by the company since it was not a party to the original investigation. As discussed above, the Federal Circuit recently held in *VastFame* that a company not previously a party to the original investigation could assert invalidity or unenforceability as a defense to an attempt to enforce the Commission’s general exclusion order. It is unclear whether the same rationale would apply to a company adversely affected by a general exclusion order, and affirmatively seeking modification or rescission of a Commission general exclusion order based on invalidity or unenforceability of a patent.

The Commission, in considering a petition under 19 C.F.R. § 210.76, may institute a proceeding to modify or rescind the exclusion order by issuing a notice. The Commission may hold a public hearing and afford interested persons the opportunity to appear and be heard. After considering the petition, any responses thereto, and any other information in the record, the Commission may then take such action as it deems appropriate. The Commission may also delegate a hearing to be

104 *VastFame Camera, Ltd. v. Int’l Trade Comm’n*, 386 F.3d 1108 (Fed. Cir. 2004).
106 *Id.*
107 *Id.*
conducted by an administrative law judge, who would then issue a recommended determination that is reviewed by the Commission. A Commission decision modifying an exclusion order is a “final determination” that may be appealed to the Federal Circuit.

F. Request for an Advisory Opinion

Widgets Unlimited could also seek an advisory opinion from the Commission pursuant to 19 C.F.R. § 210.79. Under this provision, any person (whether or not a party to the original investigation) may request that the Commission issue an advisory opinion “as to whether the person’s proposed course of action or conduct would violate a Commission exclusion order, cease and desist order, or consent order.” In considering such a request, the Commission:

will consider whether the issuance of such an advisory opinion would facilitate the enforcement of Section 337 of the Tariff Act of 1930, would be in the public interest, and would benefit consumers and competitive conditions in the United States, and whether the person has a compelling business need for the advice and has framed his request as fully and accurately as possible.

Advisory opinion proceedings are not subject to some of the procedural rules normally found in administrative procedures (including the due process hearing provisions of the Administrative Procedure Act), although the Commission or administrative law judge may, and often does, choose to conduct a hearing and take evidence in connection with such proceedings. Furthermore, advisory opinions are not “final determinations” of the Commission and therefore are not appealable to the Federal Circuit. In addition, there are no deadlines (other than perhaps those established by the Commission in its notice) that apply to advisory opinion proceedings, and therefore a company may be prevented from importing its goods for some time while waiting for a Commission decision.

108 Id.
111 Id.
112 See id. (exempting these advisory opinion proceedings from the rules of 5 U.S.C. §§ 554-57, 702).
113 Allied Corp., 850 F.2d at 1578.
114 See Sealed Air Corp. v. U.S. Int’l Trade Comm’n, 645 F.2d 976, 989 (Fed. Cir. 1981) (upholding a Commission exclusion order that effectively required a company seeking to import goods to file a petition with the ITC to determine whether entry should be allowed; as a result, the company would be denied importation “for the period necessary to make that finding”).
Moreover, a company seeking an advisory opinion may have the burden of proof of showing that its product does not infringe the complainant's patent, whereas in the original investigation (or in district court), the burden of proof would clearly be on the complainant to prove infringement.\textsuperscript{115}

Therefore, while advisory opinions may be useful to a company seeking guidance as to whether its product is within the scope of a general exclusion order, they are not a substitute for the due process protections afforded to parties to the original investigation.

In sum, there are several options that Widgets Unlimited might consider if it is concerned that its products may be affected by a general exclusion order. Each option has its own advantages and limitations that must be carefully considered and weighed in determining the course of action that will best serve a company's business needs.

VII. CONCLUSION

A general exclusion order is a powerful remedy. The Commission’s authority to issue general exclusion orders is well-established. A company's products may be excluded from entry into the United States even in the absence of notice and an opportunity to be heard. However, several procedural options are available to companies that find their products have been or may be excluded from entry into the United States by a general exclusion order.

\textsuperscript{115} See Certain Condensers, Parts Thereof & Products Containing Same, USITC, Inv. No. 337-TA-334(R) at 3 (Apr. 13, 2000) (Initial Advisory Opinion) (stating that, in an advisory opinion proceeding, the petitioner has the burden of proving that its products do not infringe the complainant's patents).