UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ROCHE DIABETES CARE, INC., ROCHE DIABETES CARE GmbH, and HOFFMANN-LA ROCHE, INC.,	:	Case No. _____
Plaintiffs,	:	**FILED *EX PARTE* AND UNDER SEAL PURSUANT TO 15 U.S.C. § 1116**
v.	:	
JMD ENTERPRISES d/b/a DKY STORE USA, JMD INTERNATIONAL, DILEEP KUMAR YADAV, ABHISHEK JAIN, MEDICAL HUB_USA STORE, RATNAKAR SHARMA, AUTHENTIC INDIAN STORE, and ATIKUR RAHMAN,	:	
Defendants.	:	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF EMERGENCY MOTION FOR A LETTER OF REQUEST DIRECTED TO THE HONORABLE HIGH COURT OF DELHI FOR AN *EX PARTE* SEIZURE ORDER; FOR AN *EX PARTE* TEMPORARY RESTRAINING ORDER; FOR AN EXPEDITED DISCOVERY ORDER; FOR AN ASSET FREEZE ORDER; AND FOR ALTERNATIVE SERVICE

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PRELIMINARY STATEMENT

Plaintiffs Roche Diabetes Care, Inc., Roche Diabetes Care GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche" or "Plaintiffs") submit this memorandum of law in support of their application for emergency, *ex parte* preliminary relief against sellers and distributors of dangerous counterfeit and infringing medical devices to American patients. The Defendants in this action are India-based companies and their principals who are selling into the United States – and likely manufacturing – counterfeit versions of multiple Roche diabetes care medical devices that millions of American patients rely upon to manage their disease. These include counterfeit Accu-Chek Softclix® lancets, which patients use to puncture their skin and draw blood for testing, and counterfeit Accu-Chek® blood glucose test strips, which patients use daily to monitor their blood sugar levels.

The Defendants' counterfeits are either complete fakes – low-quality, defective knockoffs meant to imitate Roche products that may not even be sterile – or are products at or near their expiration date that have been removed from their original packaging, exposed to unknown conditions, given fake expiration dates and serial numbers, and falsely sold as factory-new, unexpired product. These counterfeit goods are then placed in counterfeit packaging meant to imitate Roche's authentic U.S. packaging, including fake and inaccurate patient instructional inserts.

The defendants falsely advertise these dangerous counterfeit medical devices as authentic Roche U.S. products, and sell them to American patients through Amazon and other online retailers. Untold quantities of these dangerous counterfeit medical devices are currently sitting in Amazon warehouses in this District and nationwide, ready for Amazon to deliver to U.S. patients at the click of a button. These counterfeit medical devices pose an immediate and

ongoing threat to the health and safety of American patients, and their sale and distribution in the United States must be stopped.

In this *ex parte* motion, Roche seeks a Temporary Restraining Order putting a stop to these ongoing sales of counterfeits in U.S. commerce, and an Asset Freeze Order preventing the Defendants from absconding with their ill-gotten gains. Roche also seeks an Expedited Discovery Order so that Roche may quickly obtain information about the distribution of these counterfeit medical devices, including the patients to whom they have been delivered by Amazon and others, as well an order authorizing alternative service under the Federal Rules of Civil Procedure.

Finally, Roche seeks a Letter of Request from this Court directed to the appropriate Indian judicial authorities to seek documents and information vital to this litigation. Under the Lanham Act as amended by the Trademark Counterfeiting Act of 1984, Roche is entitled to an *ex parte* Seizure Order against these Defendants, who are willfully manufacturing and selling dangerous counterfeit medical devices and are taking steps to conceal their illegal activity. This Court unquestionably has jurisdiction over the Defendants, who have purposefully sold counterfeits into New York, including this District. However, the seizure target locations currently known to Roche are all located in India, and Seizure Orders under the Lanham Act are for obvious reasons limited to locations on U.S. soil. Roche therefore respectfully requests that this Court issue a Letter of Request directed to the Honorable High Court of Delhi at New Delhi, India, supporting the issuance of an *ex parte* seizure order against the Defendants by the Indian courts. Roche will use that Letter of Request to promptly submit an application, through Indian counsel, in New Delhi seeking a seizure under Indian law, known as an *Anton Piller* Order, through the Delhi court's proper and usual process. Both American and Indian law permit such

seizures in recognition of the fact that counterfeiters like the Defendants here will, if served with normal legal process, simply close up shop, abscond with the evidence, and shortly reopen their counterfeiting business under another name.

The undersigned counsel has used Letters of Request from U.S. district courts to successfully obtain seizure orders against counterfeiters overseas on numerous occasions in several foreign courts – including, recently, to obtain a very successful seizure order from the same New Delhi court against different counterfeiters of medical devices who were selling their dangerous counterfeits into the United States. A Letter of Request from this Court will allow Roche to use the information and documents from the Indian seizures in support of its claims in this action. A Letter of Request will also expedite processing and ruling upon Roche's application to the New Delhi – in our experience and in the estimation of experienced Indian counsel, down to a matter of two or three days – allowing Roche to complete the seizures and obtain crucial evidence while the requested Temporary Restraining Order from this Court remains in effect.

In support of its motion, Roche relies on this memorandum of law; the declarations of Geoffrey Potter, Hannah Coleman, Kerri McAleavey, Debra Robinson, Patrick Barron, Keith Verner, Connor Brooks, and Chandan Sharma, and the exhibits attached thereto; the Complaint; and any other matter the Court may wish to consider. The declarations and documentary evidence before this Court establish that the Defendants are selling and distributing in the United States dangerous counterfeit and infringing Roche medical devices, and that an *ex parte* seizure is necessary because these Defendants are likely to destroy evidence and disappear with their ill-gotten gains if given prior notice.

STATEMENT OF FACTS

A. Roche's Accu-Chek® Diabetes Care Products

Roche has been selling Accu-Chek® products for over 40 years. (Decl. of Keith Verner, dated May 13, 2024 ("Verner Decl.") ¶ 5.) Accu-Chek® products are diabetes care medical devices that allow patients to monitor their blood sugar and manage their disease. (*Id.* ¶ 4.) The Accu-Chek® family of products includes glucometers, blood glucose test strips, lancets, and other diabetes care medical devices. (Decl. of Debra Robinson, dated May 13, 2024 ("Robinson Decl.") ¶ 2.) Roche manufactures and sells several different lines of blood glucose test strips under the Accu-Chek® brand, including Accu-Chek SmartView®, Accu-Chek Guide®, Accu-Chek Nano®, Accu-Chek Aviva®, and Accu-Chek Instant®. (*Id.* ¶ 3). Roche also manufactures several different lines of lancets – specialized disposable needles used to draw blood for testing – under the Accu-Chek® brand, including Accu-Chek Softclix®. (Decl. of Patrick Barron, dated May 16, 2024 ("Barron Decl.") ¶ 5). Accu-Chek® is one of the top two leading brands for blood glucose monitoring products in the United States. (Verner Decl. ¶ 7).

All authentic Roche Accu-Chek® blood glucose test strips distributed in the United States are manufactured, according to strict and consistent specifications, in a factory on Roche's campus in Indianapolis. (Barron Decl. ¶ 5). And all Roche Accu-Chek® products are manufactured in facilities with rigorous quality controls, specialized equipment, and consistent processes to produce products that patients can rely upon to be high quality and uniform in each package. (*Id.* ¶¶ 4, 9, 16). Roche has for over four decades earned and safeguarded a reputation of quality, safety, and reliability for its Accu-Chek® brand products. (Verner Decl. ¶¶ 5-10).

B. Trademarks Used on Accu-Chek® Products

Roche is the owner of a number of well-established and well-known trademarks, all duly registered and active with the U.S. Patent and Trademark Office, that appear on the

packaging of genuine Accu-Chek® products (collectively, the "Accu-Chek Marks"). (Robinson Decl. ¶ 3). Those trademarks, including their U.S. registration numbers and dates, are set forth in the accompanying Declaration of Debra Robinson ("Robinson Decl."). (Robinson Decl. ¶¶ 4-15). In addition, Roche owns and uses distinctive packaging (the "Accu-Chek Trade Dress") to distinguish Accu-Chek® products in the marketplace. (*Id.* ¶ 16).

Roche has used and is currently using the Accu-Chek Marks and the Accu-Chek Trade Dress in commerce and in connection with its sale of Accu-Chek® products, and plans to continue such use in the future. (*Id.* ¶ 17). Roche prominently displays the Accu-Chek Marks and the Accu-Chek Trade Dress in its advertising and promotional materials. (Verner Decl. ¶¶ 9-10). Roche has engaged and continues to engage in activities designed to promote the Accu-Chek® brand and the business and goodwill associated with its trademarks, and to expand the use and reputation of its trademarks, trade dress, logos, copyrights, and property throughout the United States. (Robinson Decl. ¶ 18). The Accu-Chek Marks and Trade Dress are embodiments of Roche's business goodwill and are invaluable assets to Roche. (*Id.* ¶ 19).

C. Roche Discovers the Counterfeits Being Sold on Amazon and Makes Test Buys

In late March 2024, Roche received a whistleblower complaint that India-based companies, including defendants JMD Enterprises d/b/a DKY Store USA ("JMD Enterprises),[1] JMD International, and Medical Hub_USA Store ("Medical Hub") were selling on Amazon, to U.S. consumers, counterfeit versions of Roche Accu-Chek SmartView® test strips. (Decl. of Kerri McAleavey, dated May 17, 2024 ("McAleavey Decl.") ¶ 13.) In April and May 2024,

[1] JMD Enterprises owns and operates the Amazon.com storefront for DKY Store USA ("DKY"). (Decl. of Hannah Coleman, dated May 18, 2024 ("Coleman Decl.") ¶¶ 10-14.). For example, on the DKY storefront "detailed seller information" page, JMD Enterprises appears as the "business name" for DKY. (Coleman Decl. ¶ 10).

Roche and its investigators, acting under the direction and control of counsel, conducted an investigation into the counterfeit strips. (Decl. of Hannah Coleman, dated May 18, 2024 ("Coleman Decl.") ¶ 6.) Roche and its investigators made numerous test buys of Accu-Chek® products from India-based sellers from a number of sources, including Amazon.com. (*Id.*). From its test purchases on Amazon, Roche (through its investigators) received from JMD Enterprises, JMD International, and Medical Hub counterfeit versions of its Accu-Chek SmartView® test strips. (McAleavey Decl. ¶ 13). Roche also received from Defendants JMD Enterprises and JMD International counterfeit versions of Accu-Chek Softclix® lancets. (*Id.* ¶ 29). Most of these counterfeits were sold by the Defendants but "fulfilled by Amazon," meaning the counterfeits were being stored in Amazon's U.S. warehouses and delivered to consumers directly by Amazon. (Coleman Decl. ¶¶ 14, 18, 21). The Defendants, through Amazon, delivered counterfeits to Roche's investigators in this District, from multiple Amazon warehouses located in this District. (McAleavey Decl. ¶ 7). In addition to the sales delivered by Amazon, the Defendants also shipped certain counterfeit and infringing products directly from India to Roche's investigators in this District. (Coleman Decl. ¶¶ 18, 24).

D. Roche Also Receives Non-Counterfeit, but Unlawfully Diverted, Accu-Chek® Test Strips

In addition to the counterfeit Accu-Chek SmartView® and Accu-Chek Softclix® medical devices, Roche's investigators received from each corporate Defendant multiple boxes of international Accu-Chek® test strips: i.e., Accu-Chek® test strips that are packaged for and intended for sale outside the United States. (*Id.* ¶ 8). However, because these international test strips are not intended for sale in the United States, they do not comply with FDA regulations – rather, they comply with the requirements of the applicable regulatory regime for which they were packaged and into which they were sold. (Barron Decl. ¶ 21). As set forth in more detail

below, these unlawfully diverted international test strips are not counterfeits, but also infringe Roche's trademark rights under the Lanham Act, and are illegal, misbranded medical devices when sold in the United States.

E. Roche's Investigators Identify the Locations of Counterfeiters in India

After Roche confirmed that Accu-Chek® products sold by the Defendants were counterfeit, Roche, at the direction and under the supervision of counsel, expanded its investigation to include local investigators in India. (Coleman Decl. ¶ 26). These investigators conducted public-record searches as well as extensive in-person surveillance of the individual Defendants and their associates in order to identify the sites of their counterfeiting operations. (*Id.* ¶ 27). As set forth in more detail below, those investigators were able to identify the multiple locations in India in which the counterfeiters were operating, including back-alley apartments in New Delhi. (*Id.* ¶¶ 28, 29, 46).

F. Roche's Initial Analysis of the Counterfeit Accu-Chek Softclix® Lancets

Roche experts examined the Accu-Chek Softclix® lancets purchased from JMD Enterprises and JMD International and conclusively determined that both the lancets themselves and their packaging was counterfeit. (Decl. of Connor Brooks, dated May 16, 2024 ("Brooks Decl.") ¶ 2; Barron Decl. ¶¶ 7-8).

The Counterfeit Softclix Packaging. All Softclix products that Roche received from the Defendants had identical or near-identical counterfeit packaging that clearly attempted to replicate Roche's authentic Softclix packaging, but did so imperfectly. (McAleavey Decl. ¶ 30). Perhaps most obviously, the Softclix boxes sold by the Defendants misspell the name of the product: the boxes state "Accu-Chek Softclick," whereas the real product name is "Accu-Chek Softclix." (*Id.* ¶ 31). The counterfeits also erroneously use the ™ symbol after these brand

names, whereas authentic Roche packaging uses the ® symbol for its registered marks. (*Id.*).

Authentic Packaging

Counterfeit Packaging

Moreover, the counterfeit Softclix lancets arrive sealed in a cloudy plastic bag inside the carton. There is no such plastic bag in authentic Softclix lancet packaging. (Brooks Decl. ¶ 8). And there are other, subtler differences in font, spacing, and design between authentic Softclix packaging and the Defendants' packaging that demonstrate the Defendants' packaging is entirely counterfeit. (McAleavey Decl. ¶ 32).

The Counterfeit Softclix Lancets. Authentic Accu-Chek Softclix® lancets are premium, thin-gauge, bevel-cut lancets specially designed to ensure smooth entry into the skin and precision of insertion to minimize pain to the patient. (*Id.* ¶ 3). Softclix lancets are also specifically designed to work with Roche's Accu-Chek Softclix® lancing device, which contains precision guided technology also designed to reduce pain. (*Id.*). Roche warns patients to only use authentic Softclix lancets with its Softclix lancing devices, as other lancets may damage the lancing device and/or cause it to malfunction. (*Id.* ¶ 11).

The supposed Softclix lancets sold by Defendants are obvious fakes. Authentic Softclix lancets are encased in plastic, with a round cap that the patient removes prior to inserting it into the Softclix lancing device. (*Id.* ¶ 6). The plastic encasement for authentic Softclix lancets has two small round holes through which the needle is visible; the counterfeits have three such holes in their plastic encasement. (McAleavey Decl. ¶ 6.).

Moreover, upon removing the cap of the counterfeits, the needle is noticeably shorter than an authentic Softclix lancet. (*Id.* ¶ 15).

The counterfeit Softclix lancets also show several additional signs that they are cheaply and poorly made, especially as compared to authentic Softclix lancets. (*Id.* ¶ 8). There are small out-jutting pieces of plastic on the cap and bottom of the plastic encasement of the counterfeits, indicating where the fakes were removed or "broken out" from cheap plastic molding. (*Id.*). Indeed, the plastic bags containing the counterfeit lancets have loose plastic shards resting at the bottom that also appear to be remnants from the molding process. (*Id.*). And the cap of the counterfeit lancets is difficult to remove. (*Id.*).

Moreover, even within the same box, the coloring of the counterfeit lancets is inconsistent: some plastic encasements are various shades of white, while others have a noticeable blue tint. (McAleavey Decl. ¶ 33). Unlike authentic Accu-Chek® products, the counterfeit lancets are clearly not manufactured to a consistent, high-quality standard. (Brooks Decl. ¶¶ 9, 14).

Initial Functionality Testing of the Counterfeits. Unsurprisingly, the Defendants' counterfeit lancets do not function as intended. Using techniques that Roche uses to perform quality-assurance testing on samples of authentic Softclix lancets, Roche loaded the counterfeit lancets into an authentic Softclix lancing device and fired them into a silicone block covered with a thin layer of aluminum. (*Id.* ¶ 13-14). The Defendants' counterfeits failed this test in several ways. (*Id.*).

First, the counterfeits do not consistently "click" into the lancing device or rest securely in the device, as authentic Softclix lancets do. (Brooks Decl. ¶ 11). Next, when fired into the silicone block, authentic Softclix lancets puncture through the aluminum and into the

silicone at all depth settings, indicating they would puncture human skin. (*Id.* ¶ 14). For several depth settings, the counterfeit lancets failed to even make an indentation upon the aluminum cover, let alone puncture into the silicone. (*Id.*). And finally, whereas authentic Softclix lancets eject easily after use by pushing a plunger on the lancing devices, the counterfeits tended to get stuck in the device, needing to be pried out by hand with the needle exposed. (*Id.* ¶ 12).

The Counterfeit Lancets May Not Be Sterile. Even more concerningly, upon initial inspection there is good reason to believe the counterfeit lancets may not be sterile. It is, of course, extremely important that lancets are sterile: they are needles designed to puncture the blood-skin barrier and make contact with the patient's bloodstream. (Barron Decl. ¶¶ 5, 7). Authentic Softclix lancets are sterilized using gamma radiation, a process that is carefully documented and confirmed via a radiation dosimeter. (*Id.* ¶ 6). Roche's sterilization process ensures that authentic Softclix lancets remain sterile through their listed expiration date. (*Id.*).

Because the Defendants' counterfeit Accu-Chek Softclix® lancets are fakes that are not manufactured by Plaintiffs, Roche cannot vouch for the safety or sterility of the counterfeits. (*Id.* ¶ 7). Given the low and inconsistent quality of the counterfeits, their illicit nature, their failure to function as intended, and the apparent goal of the counterfeiters to create the counterfeits as cheaply as possible, there is strong reason to suspect that the counterfeit lancets are not sterile. (*Id.*). Any uncertainty as to whether lancets are sterile is unacceptable and puts American patients at risk. (*Id.* ¶ 8).

G. Roche's Initial Analysis of the Counterfeit Accu-Chek SmartView® Test Strips

Roche experts also examined the Accu-Chek SmartView® test strips purchased from the Defendants and conclusively determined the packaging, vial labels, and products inserts were counterfeit, and that the counterfeits bore fake serial numbers, lot numbers, and expiration

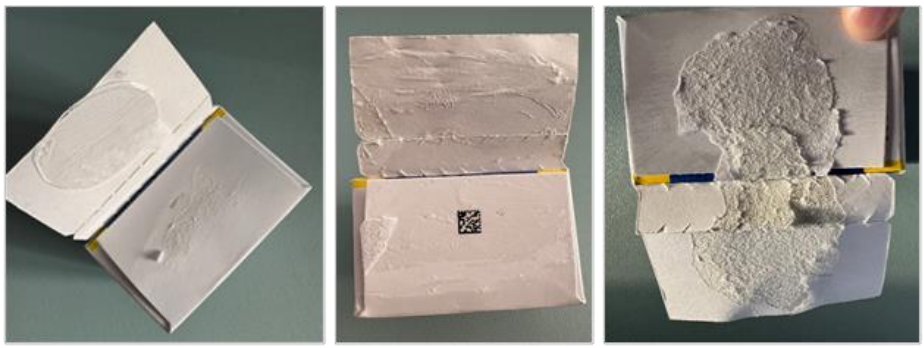
dates that concealed the fact that the strips are in fact expired or near-expired. (McAleavey Decl. ¶¶ 11-28). In addition, the vials containing the test strips have a strong, chemical-like odor. (*Id.* ¶ 21). That odor, combined with other information available to Roche, strongly suggests that the test strips have been tampered with or otherwise damaged and are not safe for use. (*Id.*; Barron Decl. ¶¶ 17,18).

The Counterfeit SmartView Packaging. The packaging of the purported SmartView test strips sold by Defendants is unquestionably counterfeit. (McAleavey Decl. ¶ 14). While clearly intended to duplicate authentic U.S. packaging for Accu-Chek SmartView® strips, the counterfeit boxes have several tell-tale errors. (*Id.*). In addition to subtler differences in font and layout, the counterfeit boxes misspell the name of the manufacturer as "Roche **Diabeter** Care, Inc." (emphasis added). (*Id.* ¶ 15).

Authentic Packaging

Counterfeit Packaging

The construction of the counterfeit SmartView boxes is also different and lower quality than authentic SmartView packaging. (*Id.* ¶ 16). For example, the top flap of authentic SmartView boxes is sealed by a machine that puts precise dots of adhesive on specified areas of the flap. (*Id.*). The counterfeits boxes, in contrast, appear to be glued together by hand, with globs of adhesive that sometimes extend beyond the top flap and that cause the box to tear upon opening. (*Id.*).



Counterfeit Packaging

Moreover, all of the counterfeit SmartView boxes purchased by Roche's investigators from JMD Enterprises, JMD International, and Medical Hub were identical or nearly identical, and all of them listed the same lot numbers, expiration dates, and serial numbers. (McAleavey Decl. ¶ 18). On authentic products, serial numbers are unique identifiers for that particular box of SmartView strips: the serial number are not repeated across boxes. (*Id*. ¶ 19). The repeated serial number on every box of SmartView strips sold by Defendants is an unmistakable sign that they are counterfeit – a sign that would have been obvious to any legitimate distributor. (*Id*.).

Counterfeit Accu-Chek SmartView® packaging with identical serial numbers

Moreover, on authentic product, the applicable lot number, serial number, and expiration date for the strips are etched onto the variable-print area of the packaging through laser ablation, which leaves a slight texture; all of the counterfeits had identical information that was printed onto the box with ink. (McAleavey Decl. ¶ 20). In sum, the evidence shows that the counterfeiters manufactured a large volume of a single counterfeit box, without changing the serial or lot numbers, and those counterfeits are now being distributed into the United States by multiple India-based sellers.

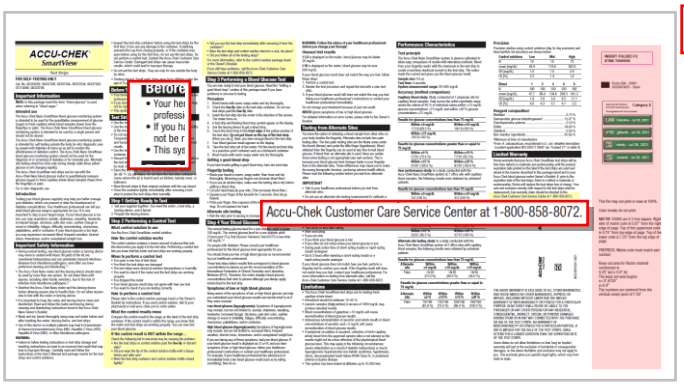
The Counterfeit SmartView Vial Labels. Accu-Chek SmartView® test strips are stored in airtight, desiccant-lined vials that protect the strips from exposure to air and moisture, with a label that lists the same lot number, serial number, and expiration date that appears on the box. (*Id.* ¶ 12). The vials in the counterfeit SmartView boxes appear to have once been authentic vials, but now have had their original labels removed and counterfeit labels applied in their place. (*Id.* ¶ 23). The counterfeit vial labels tend to be askew and show signs of

wrinkling and bubbling. (*Id*. ¶ 24). And as with the product boxes, all of the counterfeit labels have the same serial number, lot number, and expiration dates, and the text is applied by regular ink printing, not laser ablation. (*Id*. ¶ 22).

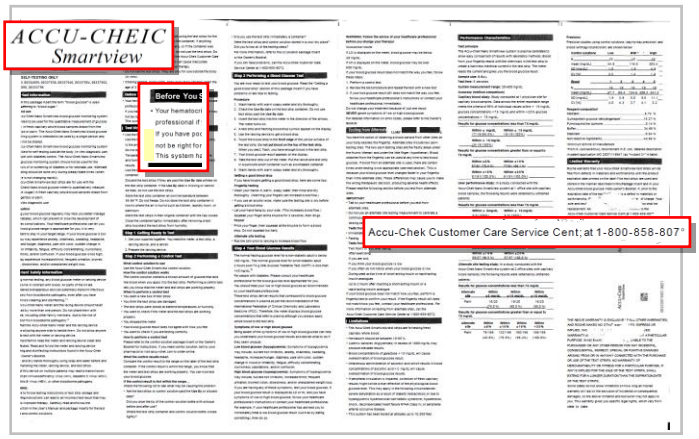
Upon opening the counterfeit SmartView boxes, a strong, chemical-like odor emanated from the vials; that odor does not exist in authentic product. (Id. ¶ 21). A likely explanation for that odor is that it is a byproduct of the removal of the original vial label by use of a harsh chemical. (Barron Decl. ¶ 17). Counterfeiters can also remove vial labels can via application of intense, focused heat, such as from a heat gun. (Id.). In either scenario, the process of removing the label has the potential to damage the test strips inside the vial, causing the strips to give an inaccurate reading or no reading at all. (Id. ¶¶ 17, 18).

The Counterfeit SmartView Instructional Inserts. The instructional inserts included in the Defendants' counterfeit SmartView boxes are also counterfeits, intended to replicate authentic U.S. SmartView inserts, but with several glaring errors – including misspelling the brand name of the product as "ACCU-CHEIC" and failing to include FDA-mandated warnings. (McAleavey Decl. ¶¶ 26-27). The counterfeit inserts also provide the wrong number for Roche's U.S. consumer hotline, which impairs patients' ability to ask questions and receive assistance from Roche, as well as to report issues to Roche; it evinces an attempt by the counterfeiters to prevent customer calls about the counterfeit products. (*Id*.). Some of differences between authentic inserts and the Defendants' counterfeit inserts are illustrated below:

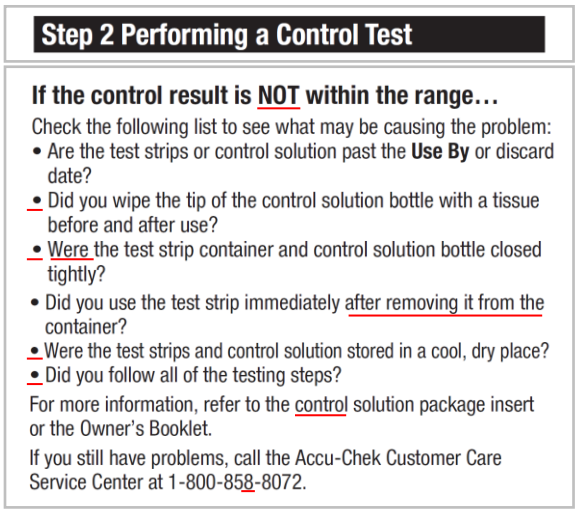
Authentic Patient Insert



Counterfeit Patient Insert



Authentic Patient Insert



Step 2 Performing a Control Test

If the control result is NOT within the range…

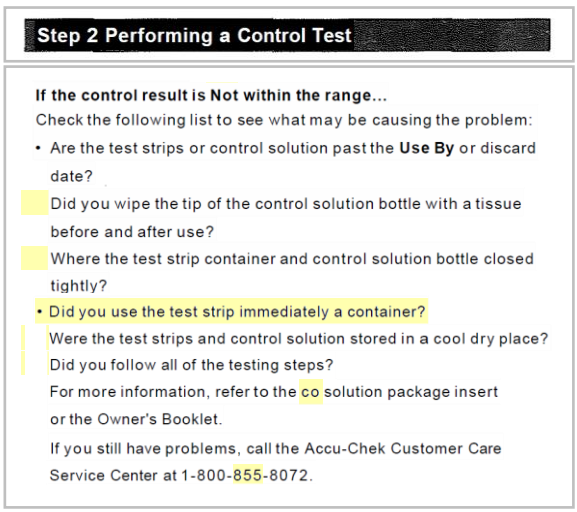
Check the following list to see what may be causing the problem:

- Are the test strips or control solution past the **Use By** or discard date?
- Did you wipe the tip of the control solution bottle with a tissue before and after use?
- Were the test strip container and control solution bottle closed tightly?
- Did you use the test strip immediately after removing it from the container?
- Were the test strips and control solution stored in a cool, dry place?
- Did you follow all of the testing steps?

For more information, refer to the control solution package insert or the Owner's Booklet.

If you still have problems, call the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Counterfeit Patient Insert



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- Did you use the test strip immediately a container?

Were the test strips and control solution stored in a cool dry place?

Did you follow all of the testing steps?

For more information, refer to the co solution package insert or the Owner's Booklet.

If you still have problems, call the Accu-Chek Customer Care Service Center at 1-800-855-8072.

Moreover, the counterfeit inserts are folded incorrectly: the counterfeiters were unable to replicate the manner in which authentic SmartView inserts are machine-folded using specialized equipment. (McAleavey Decl. ¶ 28).

The Counterfeit Accu-Chek SmartView® Test Strips Have Fake Expiration Dates and Pose a Danger to U.S. Patients. The lot numbers and expiration dates on that appear on the counterfeit boxes and vial labels are, unsurprisingly, fake. (Id. ¶ 25). Using markings that

appear on the bottom of once-authentic vials inside the Defendants' counterfeit SmartView boxes, Roche compared the lot and expiration information on the counterfeits to its internal records, and confirmed that the test strips that were originally placed inside those vials are either at or near their expiration dates. (McAleavey Decl. ¶ 25). The fake expiration dates on the counterfeits, however, claim that the strips will not expire for over year. (Id.).

The active ingredients in blood glucose test strips naturally degrade over time. (Barron Decl. ¶ 10). On authentic product, the expiration dates of SmartView test strips are based on data that show the time frame in which the test strips will continue to function within set parameters. (Id.). As the active ingredients in the test strips continue to naturally degrade beyond the expiration date, the blood glucose readings given by the test strips will become biased, and in particular tend to record higher levels of glucose in the blood samples than actually exist. (Id. ¶ 11). Diabetic patients rely on blood glucose readings to manage their disease, including by selecting when and how much insulin to self-inject. (Id. ¶ 12). A patient who receives an inaccurately high reading by unknowingly using expired test strips could give themselves an overdose of insulin. (Id.). Insulin overdose can have serious consequences for diabetic patients, including coma and death. (Id.). By putting fake expiration dates on expired or nearly expired test strips, the counterfeiters are putting American patients' health and safety at risk. (Id. ¶ 13).

Moreover, blood glucose test strips must be stored at certain temperatures. (Id. ¶ 14). Accu-Chek SmartView® test strips must be stored at temperatures at or below 86 degrees Fahrenheit, as stated on the box and in the instructional inserts. (Id.). Storage above that temperature can lead to premature degrading of the active ingredients in the strips, which again can cause the strips to give inaccurate and artificially high readings. (Id.). Roche employees

have seen the counterfeiters storing test strips in unairconditioned rooms in back-street New Delhi apartments, where temperatures in the summer regularly exceed 110 degrees Fahrenheit. (Decl. of Chandan Sharma, dated May 19, 2024 ("Sharma Decl.") ¶¶ 8, 12.)

Shipping test strips from India to the United States will also routinely expose the strips to temperatures exceeding 86 degrees Fahrenheit. (Barron Decl. ¶ 15). Roche ensures that its authentic Accu-Chek® test strips are shipped internationally in temperature-controlled shipments, at significant expense. (Id.). It is a virtual certainty that the counterfeiters do not pay for temperature-controlled shipping when they ship their counterfeit test strips from Delhi to the United States. (Id.).

Finally, as noted above, it appears that the counterfeiters removed the original labels from the test strip vials through means that are likely to cause damage to the test strips, which can also lead to inaccurate readings. (Id. ¶ 17).

In sum, the Defendants' counterfeit SmartView test strips are falsely advertised to U.S. consumers as factory-new U.S. product with a long shelf life, when in reality they are expired or nearly expired test strips whose vials have been tampered with and that have likely been stored and shipped in unsafe conditions. The Defendants' counterfeit test strips are thus, unknown to the American consumer, may either not work at all, or give inaccurate readings that pose a risk to patients' health.

H. The Defendants Also Sell Unlawfully Diverted International Test Strips

In addition to the counterfeit Softclix lancets and counterfeit SmartView test strips, Defendants also sold to Roche's investigators in this District unlawfully diverted international versions of different Accu-Chek® test strips, including Accu-Chek Guide®, Accu-Chek Aviva®, Accu-Chek Active®, and Accu-Chek Instant®. (McAleavey Decl. ¶ 8). These international Accu-Chek® test strips were manufactured by Roche and packaged for overseas

markets. (McAleavey Decl. ¶ 34). Because they are not intended for sale in the United States, these international Accu-Chek® test strips do not fully comply with FDA regulations – rather, they comply with the regulatory regimes applicable to the part of the world in which they are distributed. (*Id.* ¶ 34). As such, international Accu-Chek® test strips constitute misbranded medical devices under the Food & Drug Administration Act, and their sale or distribution in the United States is a strict-liability federal crime under 21 U.S.C § 333(a).

The boxes of international Accu-Chek® test strips sold by Defendants materially differ from boxes of U.S. Accu-Chek® test strips in numerous ways, and thus violate Roche's U.S. trademark rights. (*Id.* ¶ 35). For example, in contrast to authentic U.S. Accu-Chek® test strips, the boxes of international Accu-Chek® test strips that the Defendants have diverted into U.S. commerce:

- Contain languages other than English on the packaging, and in some cases do not contain any English at all;
- Do not list Roche's toll-free consumer hotline through which U.S. patients can ask questions or report adverse events;
- Feature non-U.S.-standard measurements (e.g., Celsius and millimoles) and foreign regulatory markings;
- Lack FDA-mandated warnings and instructions, including "Do not reuse" and "For *in vitro* diagnostic use"; and
- Feature significantly different trade dress that is likely to confuse regular users of U.S. Accu-Chek® test strips.

(*Id.* ¶¶ 36-39). Moreover, the international patient inserts also feature different languages, measurements, and regulatory markings, among other differences. (*Id.* ¶ 40). The international patient inserts also instruct patients that they may draw blood samples from parts of the body that do not appear in the FDA-approved U.S. patient insert instructions. (*Id.* ¶ 41).

Moreover, the diversion of international Accu-Chek® products into the United States interferes with Roche's ability to issue targeted recalls: Roche would focus its notice of such a recall on the market for which the product was packaged for sale and into which it was distributed, and the Defendants' unlawful diversion has removed the products from that market. (Barron Decl. ¶¶ 20-21).

ARGUMENT

I. THIS COURT HAS THE AUTHORITY TO ISSUE, AND SHOULD ISSUE, A LETTER OF REQUEST THAT THE JUDICIAL AUTHORITIES IN INDIA ISSUE AN *EX PARTE* SEIZURE ORDER AGAINST THE JMD DEFENDANTS

As demonstrated in detail below, Roche is entitled to an *ex parte* seizure order under the laws of the United States with respect to Defendants JMD International, JMD Enterprises, and Yadav (collectively, the "JMD Defendants"). However, all the currently known seizure target locations are in India. Therefore, Plaintiffs seek a letter of request from this Court directed to the judicial authorities in Delhi, India, requesting that such authorities issue an order, known in India (as elsewhere) as an *Anton Piller* Order, preserving relevant documents and information in the possession of the JMD Defendants so that they can be inspected by Plaintiffs in discovery and used as part of the record in this action.

A. This Court Has Clear Authority to Issue the Letter of Request

Pursuant to 28 U.S.C. § 1781(b)(2), this Court has the authority to issue letters of request, also known as letters rogatory, to seek the cooperation of a foreign court in discovery. *See Yellow Pages Photos, Inc. v. Ziplocal, LP* 795 F.3d 1255, 1273 (11th Cir. 2015) ("Federal courts have authority to issue letters rogatory in civil and criminal cases."). Courts routinely issue letters of request where "the movant makes a reasonable showing that the evidence sought may be material or may lead to the discovery of material evidence." *Netherby Ltd. v. Jones Apparel Group, Inc.*, No. 04-cv-7028, 2005 WL 1214345, at *1 (S.D.N.Y. May 18, 2005)

(granting Plaintiff's motion for the issuance of letters rogatory to take third-party discovery); *see also Yellow Pages Photos*, 795 F.3d at 1273 (collecting caselaw holding that "there must be 'good reason' to deny the request for the issuance of letters rogatory," but that "when a request to issue letters rogatory is overly broad or unlikely to lead to the discovery of relevant evidence, district courts retain discretion to refuse to issue them").

This Court is authorized to issue the letters of request sought; it need not determine whether an Indian court will, in fact, issue the *Anton Piller* Order—that is for the Indian court to determine by application of Indian law. Thus, in *Foden v. Aldunate*, 3 F.3d 54 (2d Cir. 1993), the Second Circuit rejected the argument that 28 U.S.C. § 1782, the companion statute which pertains to assistance courts in the United States give to foreign tribunals and litigants, requires that the district court "make a finding of discoverability under the laws of the foreign jurisdiction." *Id*. at 57. Similarly, in *Euromepa, S.A. v. R. Esmerian, Inc.*, 51 F.3d 1095 (2d Cir. 1995), the court explained that the drafters of Section 1782 "did not want to have a request for cooperation turn into an unduly expensive and time-consuming fight about foreign law . . . [i]t would . . . be wholly inappropriate for an American district court to try to obtain this understanding for the purpose of honoring a simple request for assistance." *Id*. at 1099; *see also In re Request From Canada Pursuant to the Treaty Between the United States of America and Canada on Mutual Legal Assistance in Criminal Matters*, 155 F. Supp. 2d 515, 520 (M.D.N.C. 2001) (enforcing subpoenas despite claims that they would not have been allowed under Canadian law).

B. The Letter of Request Will Provide Critical Discovery for This Action

This case is about protecting American patients and addressing the sale of counterfeit goods in the United States in violation of Roche's U.S. registered trademarks. The Defendants' counterfeits are designed to be sold to American patients: the counterfeit packaging

and counterfeit inserts are specifically designed to mimic Roche's FDA-compliant packaging and inserts for Accu-Chek® test strips sold in the United States, and not the international packaging that would be familiar to Indian consumers. Roche intends to fully pursue its claims against the Defendants in this Court.

As discussed in more detail below, Roche seeks a seizure against the Defendants because the evidence demonstrates that the Defendants will simply disappear with the counterfeits if given the opportunity to do so, only to resume their counterfeiting operations under another name. This Court has jurisdiction over the Defendants because they sold counterfeiting and infringing products into this District. *Chloe v. Queen Bee of Beverly Hills, LLC*, 616 F.3d 158, 170-71 (2d Cir. 2010) (affirming personal jurisdiction where defendant shipped a single counterfeit product to plaintiff's investigator in New York, who made the purchase as a test buy). The seizures that Roche seeks to take place in India are in service of this litigation before this Court. With a Letter of Request from this Court, the anticipated seizures in India will provide crucial discovery in support of Roche's claims under U.S. law that would otherwise be concealed or destroyed.

Roche knows for a fact that the JMD Defendants are selling large volumes of dangerous counterfeit Accu-Chek® medical devices into the United States. Although Roche knows that many of the counterfeits are being sold in the United States through Amazon, Roche does not know the full distribution chain of the counterfeits. If Roche is unable to obtain, directly from the JMD Defendants, the documents necessary to trace their counterfeit sales, the result will be further risk that these dangerous counterfeit medical devices end up in the hands of unwitting U.S. patients, and the JMD Defendants' records of the patients to whom they have sold these counterfeits will be destroyed.

C. Counsel Has Substantial Experience Utilizing Letters of Request to Obtain Seizures Against Overseas Counterfeiters

U.S. district courts routinely grant Letters of Request in aid of anti-counterfeiting actions. Roche notes that the undersigned counsel has substantial experience obtaining and successfully utilizing Letters of Request to seek and execute seizures against internationally based counterfeiters who sell their products in the United States. *See* Potter Declaration ¶ 2 and Exs. A-G.

In fact, the undersigned counsel successfully sought a Letter of Request in a prior anti-counterfeiting case before this Court, signed by the late Judge Townes. *Id.* That case also involved counterfeit blood glucose test strips, and the *ex parte* seizure orders issued by the South African courts in response to this Court's Letter of Request were highly successful, allowed the plaintiff to collect crucial documents and information in aid of the action before this Court, and resulted in the shutting down of a counterfeiting network selling tens of thousands of counterfeit test strips into the United States. *Id.*

Moreover, the undersigned counsel recently presented, with Indian counsel, a Letter of Request from the Southern District of Florida to the Honorable High Court of Delhi at New Delhi – the exact same court, in the exact same courthouse, to which Roche seeks to present a Letter of Request in this case. Like this action, that prior action involved the counterfeiting of a U.S. manufacturer's medical devices in India, which India-based sellers were selling into the United States. The Letter of Request in that action led to the Indian court issuing an *Anton Piller* Order within a few days, and the immediate execution of seizures in New Delhi. The information from those seizures in New Delhi was relied upon by U.S. district courts in issuing injunctions that halted the sale of thousands of fake, contaminated surgical devices, stopping them from being implanted into American patients.

In sum, while the issuance of an *ex parte* seizure order in India is an issue to be decided by the Indian courts applying Indian law, Plaintiffs believe that the issuance of a Letter of Request will be of substantial assistance to the Indian courts; will very likely expedite the process by which Plaintiffs' Indian counsel can seek and obtain an *Anton Piller* Order in New Delhi; and, importantly, will permit Roche to immediately use the documents and information obtained from seizures in India in support of its claims in this action.

II. ROCHE IS ENTITLED TO AN *EX PARTE* SEIZURE ORDER UNDER THE LANHAM ACT

As noted above, the question of whether an *ex parte* seizure order—known as an *Anton Piller* order in India and elsewhere—should issue in India is a question to be determined by the Indian courts. In determining whether to issue a letter of request to the Indian judicial authorities, this Court should determine whether the requested relief is appropriate under United States law. As set forth below, the facts of this case are precisely the situation Congress had in mind when it provided for *ex parte* seizures under the Lanham Act as amended by the Trademark Counterfeiting Act of 1984.

A. The Trademark Counterfeiting Act Authorizes *Ex Parte* Seizure Orders

Faced with "an 'epidemic' of commercial counterfeiting," Congress enacted the Trademark Counterfeiting Act of 1984 to provide a meaningful remedy to victims of counterfeit trafficking. *See* S. Rep. No. 98-526, 98th Cong., 2d Sess. 5 (1984), reprinted in 1984 U.S.C.C.A.N. 3627, 3631 (citing *Montres Rolex, S.A. v. Snyder*, 718 F.2d 524, 528 (2d Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984)). The Counterfeiting Act amended the Lanham Act to expressly permit a court to grant an *ex parte* order of seizure in "[c]ivil actions arising out of [the] use of counterfeit marks," including "records documenting the manufacture, sale or receipt" of the counterfeit goods. 15 U.S.C. § 1116(d); *see, e.g.*, *Reebok Int'l, Ltd. v. Marnatech Enters.*,

Inc., 970 F.2d 552, 558 (9th Cir. 1992) (noting that lower court properly granted *ex parte* seizure order under section 1116, which "explicitly authoriz[es] the prejudgment seizure" documentary evidence and counterfeit goods).

B. Roche Has Met All of the Statutory Requirements for a Seizure Under the Lanham Act

Plaintiffs must satisfy seven statutory criteria before the court can grant an *ex parte* order of seizure under Section 1116. *See* 15 U.S.C. § 1116(d)(4)(B). As demonstrated below and in the accompanying declarations, Roche has met each requirement.

1. "[A]n order other than an ex parte seizure order is not adequate to achieve the purposes of section 1114 of this title." § 1116(d)(4)(B)(i).

Through direct purchases from the Defendants and examination by Roche's product experts, Plaintiffs have confirmed that Defendants are selling and offering for sale in the United States counterfeit Accu-Chek® medical devices. As recognized by Congress in enacting the Counterfeiting Act, defendants distributing counterfeit products are more likely than not to dispose or conceal the counterfeit goods when they are confronted with a trademark action. 130 Cong. Rec. H 12076, 12080 ("[M]any of those who traffic in counterfeits have become skilled at destroying or concealing counterfeit merchandise when a day in court is on the horizon."). This is especially true here, where Defendants are selling fake and expired medical devices that pose a serious risk to patient health and safety.

Roche cannot effectively trace the sale or distribution of the counterfeit Accu-Chek® products without obtaining, through a seizure, computer files and other business records documenting the role of the JMD Defendants in the chain of distribution. The JMD Defendants are Indian counterfeiters that operate from back-alley New Delhi homes and storefronts, with a network of apartments and storefronts that required extensive on-the-ground surveillance to

untangle. (Coleman Decl. ¶¶ 26-28). The JMD Defendants could easily dismantle their operations at a moment's notice.

Indeed, the JMD Defendants have already shown attempts to conceal their identities. Shortly after the counterfeits were discovered, a Roche employee based in India visited one of the JMD Defendants' offices, identifying himself as a Roche employee. (Sharma Decl. ¶ 9). It could hardly be considered a coincidence that, the very next day, the JMD's Defendants' principal, Defendant Yadav, removed his name as the point of contact from one of the JMD Defendants' Amazon storefronts. (Coleman Decl. ¶ 12).

Moreover, these Defendants have no brand equity in their stores and develop no reputation with consumers. Instead, they are able tap into the global supply chain by setting up storefront profiles on Amazon.com, allowing Defendants to borrow Amazon's unquestioned brand recognition among American consumers, and to leverage Amazon's extensive warehousing, picking, packing, and shipping capabilities to distribute their product. With this ability to outsource operational logistics to Amazon, Defendants could easily shut down their Amazon storefronts and then open a new storefront, selling counterfeit product, the next day.

Indeed, Defendants were able to establish themselves as Amazon sellers to U.S. consumers with no track record as medical device distributors, no business presence in the United States, and a business model that makes no sense. Defendants claim to sell new, authentic U.S. Accu-Chek® medical devices that have been exported from the United States *to* India, that the Defendants then sell back *from* India into the United States – all at discount pricing, despite the fact that the Defendants pay for Amazon to handle storage, delivery, and other logistics. The idea that new, authentic U.S. products would get cheaper as they pass through an Indian middleman, travelling halfway around the globe twice before reaching the

American consumer, is economically absurd. That the Defendants were able to establish themselves as Amazon storefronts despite the obvious illegitimacy of their sales demonstrates the ease with which counterfeiters can open a new Amazon storefront, even when selling FDA-regulated medical devices. An *ex parte* seizure is necessary to address the Section 1114 concerns that Defendants will conceal their counterfeiting, destroy their records, and disappear before meaningful action can be taken against them – only to reappear under the guise of a new business identity shortly thereafter, continuing to sell dangerous counterfeit medical devices to U.S. consumers.

2. "[T]he applicant has not publicized the requested seizure." § 1116(d)(4)(B)(ii).

The Counterfeiting Act prohibits parties from publicizing a seizure request. 15 U.S.C. § 1116(d)(4)(B)(ii). Roche has not disclosed its present application to Defendants or to any third party, and their application to the Court has been made *ex parte* and under seal. Potter Decl. ¶¶ 4-6. The application that will be brought before the judicial authorities in the Honorable High Court of Delhi at New Delhi, India will likewise maintain the secrecy of the requested seizure. *Id.* If Roche's motion is granted, both this case and the application before the Indian courts will remain sealed until the seizures in India have occurred and the Defendants are served at those seizures.

3. "[T]he applicant is likely to succeed in showing that the person against whom seizure would be ordered used a counterfeit mark in connection with the sale, offering for sale, or distribution of goods or services." § 1116(d)(4)(B)(iii).

The party seeking a seizure order must demonstrate likelihood of success in showing "that the person against whom seizure would be ordered used a counterfeit mark in connection with the sale, offering for sale, or distribution of goods or services." 15 U.S.C. § 1116(d)(4)(B)(iii). Plaintiffs have met this burden. Plaintiffs have submitted conclusive

evidence that Defendants are distributing, selling and offering for sale counterfeit Accu-Chek® products, which is sufficient to establish a "sale . . . or distribution of goods in commerce." Indeed, Defendants have delivered the counterfeit products directly to Plaintiffs' investigators in the Eastern District of New York.

4. "[A]n immediate and irreparable injury will occur if such seizure is not ordered." § 1116(d)(4)(B)(iv).

Because the counterfeit Accu-Chek® products consist of fake and expired medical devices, the counterfeits pose an immediate and significant risk of irreparable injury to American patients. Moreover, where likelihood of confusion is shown, irreparable injury to the manufacturer "almost inevitably follows." *Omega Importing Corp. v. Petri-Kine Camera Co.*, 451 F.2d 1190, 1195 (2d Cir. 1971). Indeed, irreparable injury is such a natural consequence of consumer confusion that it is "presumed" to exist whenever confusion is demonstrated. *Federal Express Corp. v. Federal Espresso, Inc.*, 201 F.3d 168, 174 (2d Cir. 2000) (proof of likelihood of consumer confusion in a unfair competition action creates "a presumption of irreparable harm"). "It would be difficult to imagine a clearer case of consumer confusion than the instant case in which defendant[], acting in direct competition with the plaintiff, sold counterfeit products on which plaintiff's registered marks appear in their entirety.'" *Procter & Gamble Co. v. Quality King Distribs., Inc.*, 123 F. Supp. 2d 108, 115 (E.D.N.Y. 2000) (citation omitted); *see RJR Foods, Inc. v. White Rock Corp.*, 603 F.2d 1058, 1060 (2d Cir. 1979) ("defendant's conscious imitation . . . supports at least a presumption that the similarity will cause customer confusion"); *Omega Importing Corp.*, 451 F.2d at 1194 ("The probabilities of confusion from the sale of another [product] bearing the identical name are too obvious to require detailed proof"); *see also* 15 U.S.C. § 1116(d)(1)(B)(ii) (a counterfeit mark is a "spurious designation that is identical with, or substantially indistinguishable from" a registered mark).

5. "[T]he matter to be seized will be located at the place identified in the application." § 1116(d)(4)(B)(v).

Roche's investigators in both the United States and India have performed an extensive investigation, including public-records searches and nearly a month of on-the-ground surveillance, to identify and confirm the locations at which the JMD Defendants have based their counterfeiting operations in New Delhi. (Coleman Decl. ¶¶ 26-28). Roche seeks to execute seizures at three locations in New Delhi, all of which are properties owned by Defendant Dileep Kumar Yadav. (*Id.* ¶ 32). As described below, all three locations are announced, either in publicly filed records or in local signage, as offices of JMD Enterprises, and Yadav has been seen entering each location. (*Id.*) As noted above, public records show that Yadav is founder of JMD Enterprises and was listed as the only contact person on DKY's Amazon storefront – until Yadav removed his name after an India-based Roche employee visited one JMD Enterprises's offices in New Delhi. (*Id.* ¶ 12).

The R.K. Plaza Commercial Space. Through public-records searching and online surveillance, Roche's investigators were able to locate a Food and Safety Standards of India (FSSAI) license number for JMD Enterprises. (*Id.* ¶ 30). The public records associated with that FSSAI license list JMD Enterprises's place of business as an office space in a commercial park known as R.K. Plaza: 1st floor, Plot No. 5, Shop No. 117, CS/OCF, R.K. Plaza, Sector 21, Rohini, New Delhi, India. (Coleman Decl. ¶ 30.). Public records confirm that Shop No. 117 within R.K. Plaza is owned by Defendant Yadav. (*Id.* ¶ 32). There is signage for JMD Enterprises in R.K. Plaza, and Roche's investigators observed an office assistant opening the Shop No. 117 commercial space during business days, sweeping up, getting tea, and the like. (*Id.* ¶¶ 27-32). Within the past several days, Roche's investigators also noticed packages being

frequently delivered to and from the R.K. Plaza commercial space, and observed Yadav visiting the location with some frequency. (*Id.* ¶ 39).

The JMD Offices Run Out of a Back-Alley Residential Apartment. Public records also confirm that Defendant Yadav is the owner of two apartment units that occupy the entirety of a floor of a back-alley residential apartment building in New Delhi: House No. 35, First Floor, Road No. 35, Pocket 16, Rohini Sector 20, New Delhi, India. (*Id.* ¶ 37). Roche's investigators have confirmed that signage for JMD offices is visible from the street on the balconies for both apartments. (*Id.* ¶ 38).

Shortly after JMD's counterfeiting was confirmed, in April 2024, a Roche employee based in India visited this location, entered one of the apartments, and saw four individuals in main room of the apartment, most of whom were working on computers. (Sharma Decl. ¶ 7). The individuals confirmed that they worked for JMD and sold diabetic supplies. (*Id.* ¶ 9). The Roche employee was able to see a back room of the apartment that was used as a store room, and saw Accu-Chek® products stored inside. (*Id.* ¶ 8). The storage room did not have an air conditioning unit. (*Id.* ¶ 12).

Since that initial visit by a Roche employee, Roche's private investigators have maintained surveillance at this location. (Coleman Decl. ¶ 35). Within the past several days, Roche's private investigators have observed Defendant Yadav and three other individuals entering the apartments frequently, as well as packages being delivered to and from the apartments. (Coleman Decl. ¶ 39).

JMD Enterprise's "Registered Office" and Yadav's Apartment. Public records confirm that Defendant Yadav also owns a residential apartment at Plot No. 8, 2nd floor, pocket 9, Rohini Sector 21, New Delhi, 110086. (*Id.* ¶ 32). Roche's private investigators have

observed signage identifying this address as the "registered off." of JMD Enterprises, and listing as an "additional off." the back-alley apartment building described immediately above. (*Id.* ¶ 31). In the past several days, Roche's investigators maintained surveillance on this location and observed Yadav frequently entering and exiting the location, and concluded that the apartment likely also functions as Yadav's primary residence. (*Id.* ¶ 44). Because JMD Enterprises lists this as its primary office, and because Yadav himself is likely to have counterfeiting records on his phone and other electronic devices that he maintains at his residence, counterfeits and/or records about the counterfeiting are likely to be found at this location as well.

6. "[T]he harm to the applicant of denying the application outweighs the harm to the legitimate interests of the person against whom seizure would be ordered of granting the application." § 1116(d)(4)(B)(vi).

The Counterfeiting Act permits a seizure if the Court concludes that the harm to the party seeking the seizure would, if that application were denied, exceed the harm to the party against whom seizure would be ordered if the application were granted. 15 U.S.C. § 1116(d)(4)(B)(vi). Here, the balance is clearly in Roche's favor. Defendants have no legitimate interest in selling, offering for sale, distributing, or manufacturing counterfeit Accu-Chek® medical devices. Roche, on the other hand, have a very strong interest in protecting the health and safety of patients that use Roche's Accu-Chek® products, and in protecting its own marks and goodwill from the harm caused by the Defendants' counterfeiting.

7. "[T]he person against whom seizure would be ordered, or persons acting in concert with such person, would destroy, move, hide, or otherwise make such matter inaccessible to the court, if the applicant were to proceed on notice to such person." § 1116(d)(4)(B)(vii).

An *ex parte* seizure order is proper where there is concern that the subject party, or persons acting on that party's behalf, "would destroy, move, hide, or otherwise make . . . inaccessible" documents or other materials relating to the manufacture, sale or distribution of

counterfeit products. 15 U.S.C. § 1116(d)(4)(B)(vii). This is a concern that tends to exist in the counterfeiting context, because, as Congress noted, "many of those who traffic in counterfeits have become skilled at destroying or concealing counterfeit merchandise when a day in court is on the horizon." S. Rep. No. 98-526, 98th Cong., 2d Sess. 5 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3627, 3632-33.

This criterion largely overlaps with the first criterion under the statute: *i.e.*, that an *ex parte* seizure is necessary to achieve the goals of the Trademark Counterfeiting Act. As noted above, the Defendants are willful counterfeiters selling out of India into the United States from back-alley apartment buildings in New Delhi where they could easily shut down operations on a moment's notice; they have no brand equity and rely on Amazon to provide their sales platform and handle storage and delivery logistics in the United States; they have demonstrated their ability to open an Amazon storefront with no history and no credibility, and could easily do so again under the guise of a different name; and Yadav has already taken steps to conceal himself by removing his name from DKY's Amazon's storefront after his company was visited by a Roche employee. Moreover, the counterfeit products at issue are small and easily moved or concealed, and because their business is online, the JMD Defendants' records are electronic and can be deleted with the push of a button.

There can be little question that the Defendants are willful counterfeiters. They are selling what they claim to be U.S. medical devices that Roche only distributes in the United States, but are selling them at a discount from India to U.S. customers. And even a cursory glance at the JMD Defendants' stock would reveal that all of their purported Accu-Chek SmartView® test strips have the same exact same serial number, which is supposed to be a unique, per-box identifier. The available evidence suggests it is likely that the JMD Defendants

are manufacturing the counterfeit Accu-Chek® products, but at minimum the evidence is clear that they are knowingly and willfully flooding the United States market with dangerous counterfeit medical devices.

In short, the Defendants are precisely the type of counterfeiters Congress had in mind when it passed the Trademark Anticounterfeiting Act. They are criminal counterfeiters conducting business out of apartments in New Delhi back alleys, selling their dangerous products online to U.S. customers. The notion that these Defendants would appropriately respond to service of a summons issued from a U.S. District Court and fully comply with their discovery obligations is far-fetched at best. The evidence very strongly suggests that the Defendants and their counterfeits will disappear, only to shortly reappear being sold under a new name, if an *ex parte* seizure order is not granted.

III. ROCHE IS ENTITLED TO A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION

Roche respectfully seeks an *ex parte* Temporary Restraining Order, along with an Order to Show Cause why the Temporary Restraining Order should not be converted into a preliminary injunction, prohibiting the Defendants from selling Accu-Chek® products in the United States. If granted, Roche would serve this Court's Temporary Restraining Order upon Defendants simultaneously with the execution of the seizures that Roche will seek from the Indian courts. Based on the experience and judgment of Roche's counsel, including its Indian counsel, Roche fully expects that with a Letter of Request from this Court, Roche will be able obtain an *Anton Piller* Order from the Indian courts in a matter of days, and execute seizures and serve this Court's Temporary Restraining Order in India well before the Temporary Restraining Order would expire.

"Federal courts have long recognized the need for immediate injunctive relief in trademark infringement cases due to the amorphous nature of the damage to the trademark and the resulting difficulty in proving monetary damages." *Multi-Local Media Corp. v. 800 Yellow Book, Inc.*, 813 F. Supp. 199, 202 (E.D.N.Y. 1993). Here, Roche seeks a Temporary Restraining Order to stop Defendants' trafficking of counterfeit Accu-Chek® medical devices, as well as unlawfully diverted international Accu-Chek® medical devices that are materially different from U.S. Accu-Chek® products. To obtain such relief, Roche must demonstrate "that it is likely to succeed on the merits, that it is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in its favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Roche easily meets all of those elements and therefore is entitled to immediate injunctive relief.

A. Roche Has a Strong Likelihood of Success on the Merits

Among other claims, Roche has alleged various causes of action against Defendants for violating Roche's trademark rights under the Lanham Act. Roche can prevail on its trademark claims by showing "(1) that it owns a valid, protectable trademark; (2) that the defendants used the registrant's trademark in commerce and without consent; and (3) that there was a likelihood of consumer confusion." *Proctor & Gamble Co. v. Quality King Distribs., Inc.* 123 F. Supp. 2d 108, 113 (E.D.N.Y. 2000); *see also Tanning Research Labs., Inc. v. Worldwide Imp. & Exp. Corp.*, 803 F. Supp. 606, 608-09 (E.D.N.Y. 1992). Roche has already established above the first two elements: Roche owns multiple distinct, valid registered trademarks for the products at issue (Robinson Decl. ¶ 3), and Defendants are making unauthorized use of those marks in U.S. commerce by advertising and selling counterfeit and diverted international Accu-Chek® products to U.S. consumers (McAleavey Decl. ¶¶ 8, 11). As set forth below, the evidence

also clearly establishes consumer confusion resulting from both the counterfeit Accu-Chek® products and the unlawfully diverted international Accu-Chek® products.

1. The Defendants Are Liable for Selling Counterfeit Accu-Chek® Products.

Because Defendants sold counterfeits that intentionally duplicate (albeit imperfectly) authentic Roche U.S. packaging, likelihood of consumer confusion with regard to those counterfeits is established as a matter of law. *See El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392, 396 (2d Cir. 1986) (holding "it is plain" that the sale of products that are "not genuine" violates the Lanham Act); *Omega Importing Corp. v. Petri-Kine Camera Co.*, 451 F.2d 1190, 1194 (2d Cir. 1971) ("The probabilities of confusion from the sale of another [product] bearing the identical name are too obvious to require detailed proof."); *Koon Chun Hing Kee Soy & Sauce Factory*, 2007 U.S. Dist. LEXIS 1404, at *32-33; *Lorillard Tobacco Co. v. Jamelis Grocery, Inc.*, 378 F. Supp. 2d 448, 455 (S.D.N.Y. 2005); *Philip Morris USA, Inc. v. Felizardo*, No. 03-CV-5891(HB), 2004 U.S. Dist. LEXIS 11154, at *18 (S.D.N.Y. June 17, 2004) ("[C]ounterfeit marks are inherently confusing."); *Gucci Am., Inc. v. Duty Free Apparel, Ltd.*, 286 F. Supp. 2d 284, 287 (S.D.N.Y. 2003) ("[C]ounterfeits, by their very nature, cause confusion."); *Procter & Gamble Co.*, 123 F. Supp. 2d at 115 ("It would be difficult to imagine a clearer case of consumer confusion than the instant case in which defendants, acting in direct competition with the plaintiff, sold counterfeit products on which plaintiff's registered marks appear in their entirety.'" (citation omitted)).

2. The Defendants Are Liable for Selling Diverted International Accu-Chek® Test Strips

Separate and apart from the counterfeit Accu-Chek® products, the Defendants are also liable under the Lanham Act for diverting and selling into the United States international Accu-Chek® test strips. International products sold inside the United States are often referred as

"gray goods" or the "gray market."[2] These international Accu-Chek test strips were manufactured by Roche, and were authentic products at the time they were distributed and sold outside the United States. But upon their diversion back into U.S. commerce, these international products are as a matter of law non-authentic, infringing goods, and their sale violates Roche's trademark rights under the Lanham Act, 15 U.S.C. §§ 1114(1) and 1125(a).

Roche owns the registered U.S. trademarks that appear on the international test strips sold by Defendants, which the Defendants sell in U.S. commerce without Roche's permission. (Robinson Decl. ¶ 3). Under black-letter law, those international products sold in the United States are infringing under the Lanham Act if they (1) were not intended to be sold in the United States and (2) are materially different than the goods authorized for sale in the United States. *E.g.*, *Original Appalachian Artworks, Inc. v. Granada Electronics, Inc.*, 816 F.2d 68, 71-73 (2d Cir. 1987).

In determining whether international products are different from goods authorized for sale in the United States, the Second Circuit has emphasized that courts must "apply a low threshold of materiality," requiring "no more than a slight difference which consumers would likely deem relevant when considering a purchase of the product." *Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 246 (2d Cir. 2009). *Id.* This is because "it is by subtle differences that consumers are most easily confused," and so "[t]he probability of confusion is great . . . when the same mark is displayed on goods that are not identical but that nonetheless bear strong similarities in appearance or function." *Societe Des Produits Nestle v. Casa Helvetia*, 982 F.2d 633, 641 (1st Cir. 1992).

[2] "A gray-market good is a foreign-manufactured good, bearing a valid United States trademark, that is imported without the consent of the United States trademark holder." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 285 (1988).

Here, the international Accu-Chek® test strips sold by Defendants are not intended for sale in the United States (McAleavey Decl. ¶¶ 34, 35). And the international Accu-Chek® test strips differ from U.S. Accu-Chek® test strips in myriad ways, including significant differences in trade dress, regulatory markings, and patient instructions. (*Id.* ¶¶ 34-39; *see supra* p. 18). The international boxes are also missing warnings that appear on the FDA-approved U.S. packaging and inserts, and omit references to Roche's toll-free U.S. consumer hotline. (*Id.*). Any one of these differences would by itself be sufficient to find the international products materially different under Second Circuit's "low threshold of materiality" analysis. Considered together, there can be no question that that international Accu-Chek® products are materially different and therefore infringing under the Lanham Act. *See, e.g., Abbott Labs. v. Adelphia Supply USA*, 2015 WL 10906060 (E.D.N.Y. Nov. 6, 2015) (finding packaging of international blood glucose test strips to be materially different from U.S. test strips based on a number of differences similar to those at issue here). In fact, because the international Accu-Chek® test strips do not fully comply with FDA regulations, they are illegal to sell in the United States – a fact that would certainly be relevant to U.S. consumers. *See, e.g., id.* (citing caselaw finding "finding deviation from FDA regulations material").[3]

3. The Defendants Are Strictly Liable Under the Lanham Act

Notably, while the evidence shows the Defendants acted willfully, trademark infringement is a strict liability offense. *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 25 (2d

[3] In addition to the numerous material differences between international and U.S. Accu-Chek test strips, the Defendants' sale of international test strips in the United States is infringing because those sales undermine Roche's quality-control efforts, including the use of its toll-free consumer hotline and its ability to issue a targeted recall. (Barron Decl. ¶¶ 20-21; *supra* pp. 15-17, 19); *Warner-Lambert Co. v. Northside Dev. Corp.*, 86 F.3d 3, 6 (2d Cir. 1996); *Zino Davidoff*, 571 F.3d at 243–45 (interference with ability to issue targeted recalls renders gray goods infringing); *Abbott Labs.*, 2015 WL 10906060, at *7 (finding sale of international test strips infringing because those sales affect the manufacturer's ability to issue targeted recalls and to inform patients about its U.S. call center).

Cir. 2004) ("[I]t is well established that wrongful intent is not a prerequisite to an action for trademark infringement . . . and that good faith is no defense." (citations and internal quotations omitted)); *Hard Rock Café Licensing Corp. v. Concession Servs., Inc.*, 955 F.2d 1143, 1152 n.6 (7th Cir. 1992) ("Sellers bear strict liability for violations of the Lanham Act."); *Taubman Co. v. Webfeats*, 319 F.3d 770, 775 (6th Cir. 2003); *Philip Morris USA Inc. v. Shalabi*, 352 F. Supp. 2d 1067, 1073-74 (C.D. Cal. 2004). Therefore, defendants are liable under the Lanham Act regardless of whether they were aware of the counterfeit or infringing nature of the products they sold. *Id.*; *Abbott Labs. v. Adelphia Supply USA*, 2019 WL 5696148 (E.D.N.Y. Sept. 30, 2019) (granting summary judgment and finding defendants strictly liable for selling materially different international blood glucose test strips in the United States). Roche's Lanham Act claims are not merely likely, but virtually certain to succeed.

B. Roche Is Suffering Irreparable Harm as a Result of Defendants' Activities

Because Roche has demonstrated a likelihood of success on the merits on its Lanham Act claims, it is entitled to a rebuttable presumption of irreparable harm as a matter of law pursuant to the Trademark Modernization Act of 2020. 15 U.S.C. § 1116(a).

Even without that presumption, where, as here, a Lanham Act plaintiff has succeeded in showing a likelihood of confusion, irreparable injury "almost inevitably follows." *Omega Importing Corp.*, 451 F.2d at 1195. The reason is simple: "because the losses of reputation and goodwill and subsequent loss of customers that Plaintiff will suffer are not precisely quantifiable[,] remedies at law cannot adequately compensate Plaintiff for its injuries." *Pretty Girl, Inc. v. Pretty Girl Fashions, Inc.*, 778 F. Supp. 2d 261, 270 (E.D.N.Y. 2011); *see also Church of Scientology Int'l v. Elmira Mission*, 794 F.2d 38, 44 (2d Cir. 1986) ("[A]llowing defendants the opportunity to reduce the marks' reputational value and goodwill by its continued unauthorized use constitutes the irreparable harm that is requisite to the issuance of the

preliminary injunction."); *New York City Triathlon, LLC v. NYC Triathlon Club, Inc.*, 704 F. Supp. 2d 305, 325 (S.D.N.Y 2010) ("It is well-settled that a trademark owner's loss of goodwill and ability to control its reputation constitutes irreparable harm sufficient to satisfy the preliminary injunction standard."). Immediate injunctive relief is, therefore, necessary to prevent further damage to Roche's reputation and goodwill – and, of course, to patient health and safety, none of which can be undone.

C. The Balance of Equities Tips Decisively in Roche's Favor

Here, the equities emphatically support the issuance of a temporary restraining order. First and foremost, as set forth above, the counterfeit Accu-Chek® products pose a threat to patient health and safety, as do the improperly stored and shipped international products. Before even considering the harm to Roche's goodwill, this threat to public health justifies immediate injunctive relief. *See, e.g.*, *Burger King Corp. v. Stephens*, No. 89-CV-7691, 1989 U.S. Dist. LEXIS 14527 at *33 (E.D. Pa. Dec. 6, 1989).

Because the law recognizes no excuse for selling counterfeit or unlawfully diverted international goods, the harm to Roche should the requested injunction be denied far outweighs the harm to Defendants if their conduct is preliminarily enjoined. Each and every sale of counterfeit or unlawfully diverted Accu-Chek® products infringes Roche's trademarks and causes harm to Roche's reputation. *See Microsoft Corp. v. ATEK 3000 Computer, Inc.*, No. 06-CV-6403 (SLT)(SMG), 2008 U.S. Dist. LEXIS 56689, at *17 (E.D.N.Y. Jul. 23, 2008). The Defendants have no right to manufacture or sell counterfeit Accu-Chek® medical devices, and no right to divert materially different international Accu-Chek® test strips into the United States. Simply put, there is no valid hardship that the Defendants can claim from the proposed injunctive relief.

D. An Injunction Is in the Public Interest

Roche respectfully submits that the public interest in an injunction is self-evident. It is in the public interest to prevent the sale of dangerous counterfeit medical devices. It is also in the public interest to prevent the sale in the United States of international medical devices that are not FDA approved, are materially different, and may be damaged because they have been improperly stored and shipped. And it is also in the public interest to prevent confusion and protect informed choice, especially in the context of medical devices used to manage a serious, lifelong disease. *Cytosport, Inc. v. Vital Pharmas., Inc.*, 617 F. Supp. 2d 1051, 1081 ("When a trademark is said to have been infringed, what is actually infringed is the right of the public to be free of confusion and the synonymous right of the trademark owner to control his products' reputation.") (E.D. Cal. 2009) (internal citation omitted); *Int'l Kennel Club of Chicago, Inc. v. Mighty Star, Inc.*, 846 F.2d 1079, 1092 n.8 (7th Cir. 1988) ("[T]he relevant consideration in determining whether the public interest will be disserved by the grant of an injunction is the consumer's interest in not being deceived about the products they purchased.'" (alteration in original).

E. The Injunction Should Prohibit the Sale of Any Accu-Chek® Product in the United States

Roche respectfully submits that the Temporary Restraining Order and preliminary injunction should prohibit the Defendants from selling any Accu-Chek® products in the United States. As set forth above, Roche has evidence that the Defendants are selling counterfeit versions of both Accu-Chek® test strips and Accu-Chek® lancets, and that the Defendants are also selling numerous brands of diverted international Accu-Chek® test strips, including Accu-Chek Guide®, Accu-Chek Aviva®, Accu-Chek Active®, and Accu-Chek Instant® test strips. Given the breadth of the Defendants' infringing sales across the Accu-Chek® brand, the

injunction will be effective stopping the Defendants' infringement only if it applies to the entire Accu-Chek® family of products. And there is no reason to believe that such an injunction would hamper any lawful sales of Accu-Chek® products in U.S. commerce, because it makes no economic sense for third-party distributors in India to be selling authentic U.S. Accu-Chek® products from India back into the United States. The Defendants' business model is plainly illicit, and the evidence shows that they make their ill-gotten profits by selling counterfeit and infringing products.

IV. ROCHE IS ENTITLED TO EXPEDITED DISCOVERY

Roche also respectfully seeks a limited expedited discovery order so that it may quickly investigate the distribution of counterfeit and infringing Accu-Chek® products in an effort to identify consumers who have received the counterfeits so that they can be warned and to identify any other distribution streams for these dangerous fake medical devices.

Federal courts have broad discretion to expedite the normal pace of discovery in cases seeking temporary or preliminary injunctive relief. 28 U.S.C. § 1657 directs that "the court shall expedite the consideration of . . . any action for temporary or preliminary injunctive relief." The Federal Rules of Civil Procedure allows for expedited discovery and an Advisory Committee comment to that rule notes that expedited discovery "will be appropriate in some cases, such as those involving requests for a preliminary injunction." Fed. R. Civ. P. 26(d) and Advisory Comm. Note.

Rule 30(a)(2)(A)(iii) provides that the Court may grant leave to take depositions "before the time specified" in the discovery rules. Similarly, Rule 34(b)(2)(A) provides that "[a] shorter or longer time may be . . . ordered by the court" for the production of documents than the rules would otherwise allow. Congress recognized that there is a special need for expedited discovery in counterfeiting cases, specifying in the Trademark Counterfeiting Act that a court

may modify the time limits for discovery "to prevent the frustration of the purposes of [a seizure order] hearing." 15 U.S.C. § 1116(d)(10)(B).

The standard for obtaining expedited discovery closely resembles the standard for obtaining preliminary injunctive relief. Four factors must be considered: "(1) irreparable injury, (2) some probability of success on the merits, (3) some connection between the expedited discovery and the avoidance of the irreparable injury, and (4) some evidence that the injury [that] will result without expedited discovery looms greater than the injury that the defendant will suffer if the expedited relief is granted." *Gidatex, S.R.L. v. Campaniello Imports, Ltd.*, 13 F. Supp. 2d 417, 420 (S.D.N.Y. 1998); *Twentieth Century Fox Film Corp. v. Mow Trading Corp.*, 749 F. Supp. 473, 475 (S.D.N.Y. 1990).

Like injunctive relief, expedited discovery "is routinely granted in actions involving infringement and unfair competition." *Benham Jewelry Corp. v. Aron Basha Corp.*, No. 97-CV-3841, 1997 U.S. Dist. LEXIS 15957, at *58 (S.D.N.Y. Oct. 14, 1997). There are numerous examples from within this Circuit alone. *See, e.g.*, *Philip Morris USA, Inc. v. Jackson*, 826 F. Supp. 2d 448, 450 (E.D.N.Y. 2011); *GAKM Res. LLC v. Jaylyn Sales, Inc.*, No. 08-CV-6030 (GEL) (THK), 2009 U.S. Dist. LEXIS 128595, at *3 (S.D.N.Y. May 21, 2009); *Cartier Int'l B.V. v. Ben-Menachem*, No. 06-CV-3917 (RWS), 2007 U.S. Dist. LEXIS 95366, at *1 (S.D.N.Y. Jan. 3, 2008); *Johnson & Johnson v. Champion Sales, Inc.*, No. 06-CV-5451 (SLT), Dkt. No. 3 (E.D.N.Y. Oct. 7, 2006); *ALCOA, Inc. v. ATM, Inc.*, No. 04-CV-5225 (DRH), Dkt. No. 9 (E.D.N.Y. Dec. 2, 2004); *Procter & Gamble Co. v. Xetal, Inc.*, No. 04-CV-2820 (DRH) (E.D.N.Y. July 7, 2004); *Chere Amie, Inc. v. Windstar Apparel Corp.*, 191 F. Supp. 2d 343, 344-45 (S.D.N.Y. 2001); *Hoffmann-La Roche, Inc. v. Medisca, Inc.*, No. 99-CV-163, 1999 U.S. Dist. LEXIS 2380, at *2 (N.D.N.Y. Mar. 3, 1999); *Tommy Hilfiger Licensing, Inc. v. Tee's Ave., Inc.*,

924 F. Supp. 17, 18 (S.D.N.Y. 1996); *Francis S. Denney, Inc. v. I.S. Labs., Inc.*, 737 F. Supp. 247, 248 (S.D.N.Y. 1990); *Am. Cyanamid Co. v. Campagna Per Le Farmacie in Italia S.P.A.*, 678 F. Supp. 1049, 1055 (S.D.N.Y. 1987), *aff'd*, 847 F.2d 53 (2d Cir. 1988); *Playskool, Inc. v. Prod. Dev. Grp., Inc.*, 699 F. Supp. 1056 (E.D.N.Y. 1988).

Applying the four factors set forth in *Gidatex*, and based on the authority cited above, the Court should grant the limited expedited discovery that Roche seeks. Roche has already demonstrated that the first two factors are met: (1) Roche's business reputation and goodwill are being irreparably harmed, and (2) Roche has a strong likelihood success on the merits. As for the third factor, discovery is a critical first step in exposing, and then shutting down, Defendants' counterfeiting. Expedited discovery will allow Roche to prepare for, and the Court to conduct, a prompt preliminary injunction hearing. It will also enable Roche to identify other persons and entities involved in the manufacture and distribution of the counterfeits. *See e.g., Twentieth Century Fox Film Corp.*, 749 F. Supp. at 475 (allowing discovery to proceed "on an expedited basis may very well lead to evidence of continuing infringement by [these] defendant[s] or others; it may also lead to the discovery of future plans to infringe or the discovery of additional infringing merchandise."). And, importantly, expedited discovery will allow Roche to identify consumers who received these dangers counterfeit goods.

Finally, with respect to the fourth factor, the harm to Roche if discovery proceeds at the ordinary pace will far outweigh any conceivable harm to Defendants should this request for expedition be granted. The scope of discovery is narrow. *See Fed. Express Corp. v. Fed. Espresso, Inc.*, No. 97-CV-1219, 1997 U.S. Dist. LEXIS 19144, at *5 (N.D.N.Y. Nov. 24, 1997) ("[T]he scope of permissible expedited discovery is limited to requests that are more narrowly 'tailored to the time constraints under which both parties must proceed [and] to the specific

issues that will have to be determined at the preliminary injunction hearing.'"). The proposed timetable calls for document production within three days of service of the request and depositions on three days' notice. These documents should be at Defendants' disposal and Defendants will suffer little if any "injury" from having to produce them sooner rather than later. Conversely, without expedition, Roche and the public will continue to be harmed by the sale of counterfeit Accu-Chek® medical devices.

Roche seeks both expedited discovery from the defendants and expedited third-party discovery. Expedited third-party discovery will allow Roche to identify and trace the manufacture and distribution of the counterfeits, both by following the flow of the counterfeiting proceeds, and by seeking information from online platforms and other distribution channels that are not yet known to Roche. Roche's proposed expedited discovery order also has certain provisions specifically directed at Amazon, requiring Amazon upon being served by a Roche subpoena to quickly produce the information Amazon has about the Defendants, as well as the Amazon customers who received the Defendants' counterfeit and infringing Accu-Chek® products. Because the Defendants have used Amazon to reach U.S. consumers in large numbers, Roche believes it crucial that it learn what Amazon knows about the Defendants' illicit operation as soon as possible.

Finally, Roche respectfully requests that the Expedited Discovery Order contain provisions limiting the dissemination of confidential documents, pending entry of a full Protective Order. Roche believes having such provisions from the outset of the case will obviate confidentiality objections from third parties from whom Roche seeks discovery. Roche also requests that the Expedited Discovery Order contain standard HIPAA protections; because the counterfeit and infringing products at issue are diabetes care medical devices, HIPAA

provisions will provide assurance that no personal health information is being improperly disclosed when, for example, Amazon provides the names of consumers who purchased the dangerous counterfeits. A proposed order is submitted herewith.

V. ROCHE IS ENTITLED TO AN ASSET FREEZE ORDER, AND THIS COURT SHOULD REQUEST THAT THE INDIAN COURTS ENTER AN ASSET FREEZE ORDER

Roche also respectfully requests that this Court issue an Asset Freeze Order against the Defendants. Roche further respectfully requests that this Court include in the Letter of Request a request that the Indian courts similarly issue an order freezing Defendants' assets. Once again, whether such order should issue as a matter of Indian law is a question for the Indian courts, but it is correct and appropriate for this Court to issue such a Letter of Request because Plaintiffs are entitled to an asset freeze under U.S. law.

Where, as here, a plaintiff seeks lost profits or other equitable remedies under the Lanham Act, 15 U.S.C. § 1117, a federal court has the "inherent equitable powers to order preliminary relief, including an asset freeze, in order to assure the availability of permanent relief." *Levi Strauss & Co. v. Sunrise Int'l Trading, Inc.*, 51 F.3d 982, 987 (11th Cir. 1995). Nearly a decade ago, the Second Circuit joined its three "sister circuits to have considered the issue" in holding that in Lanham Act trademark infringement actions, "the district court ha[s] the inherent equitable authority to issue [an] Asset Freeze Injunction." *Gucci Am., Inc. v. Bank of China*, 768 F.3d 122, 130, 132 (2d Cir. 2014).

Because "the Lanham Act authorizes the district court to grant [plaintiff] an accounting of [defendants'] profits as a form of final equitable relief, the district court ha[s] the inherent power to freeze [defendants'] assets in order to ensure the availability of that final relief." *Reebok*, 970 F.2d at 559; *see also Balenciaga Am., Inc. v. Dollinger*, No. 10 Civ 2912 (LTS), 2010 U.S. Dist. LEXIS 107733, at *22-24 (S.D.N.Y. Oct. 8, 2010) (collecting cases)

(citation omitted); *see also Republic of the Philippines v. Marcos*, 862 F.2d 1355, 1364 (9th Cir. 1988) (en banc) (Courts have "the power to issue a preliminary injunction to prevent a defendant from dissipating assets in order to preserve the possibility of equitable remedies."); *Reebok Int'l, Ltd. v. Marnatech Enters., Inc.*, 970 F.2d 552, 559 (9th Cir. 1992) ("Because the Lanham Act authorizes the district court to grant [plaintiff] an accounting of [defendant's] profits as a form of final equitable relief, the district court had the inherent power to freeze [defendant's] assets in order to ensure the availability of that final relief."); *Motorola Inc. v. Abeckaser*, No. 07-cv-3963, 2009 U.S. Dist. LEXIS 40660, at *8 (E.D.N.Y. May 14, 2009); *North Face Apparel Corp. v. TC Fashions, Inc.*, No. 05 CIV 9083, 2006 U.S. Dist. LEXIS 14226, at *10 (S.D.N.Y. Mar. 30, 2006) (in Lanham Act cases, "[d]istrict courts have the 'authority to freeze those assets which could [be] used to satisfy an equitable award of profits.'"). The purpose of such an order is "to preserve the possibility of an effective accounting of [the infringer's] profits and the return of the profits fraudulently obtained." *Reebok*, 970 F.2d at 560. Courts recognize that counterfeiters make their living by secrets and subterfuge, and therefore are likely to "hide their allegedly ill-gotten funds" if their assets are not frozen. *Id*. at 563; *accord Chanel, Inc. v. Classic-Bag-Shop*, No. 19-60491, 2019 U.S. Dist. LEXIS 42688, at *10 (S.D. Fla. Mar. 14, 2019) ("In light of the inherently deceptive nature of the counterfeiting business . . . Plaintiff has good reason to believe Defendants will hide or transfer their ill-gotten assets . . . unless those assets are restrained.").

The evidence set forth above demonstrates that the Defendants are willful counterfeiters and willful sellers of infringing, materially different, non-FDA-approved international test strips in the United States. The same evidence that demonstrates the Defendants are likely, if given notice, to disappear with their counterfeits also demonstrates that

the Defendants are likely, if given notice, to conceal or dissipate their ill-gotten gains if their assets are not frozen. Accordingly, to ensure that the accounting and lost profits sought by Roche under the Lanham Act are available at the conclusion of this action, and to limit the risk to consumers, the Court should issue an Asset Freeze Order and request that the Indian judicial likewise issue an order freezing Defendants' assets.

Roche seeks asset freezes under both this Court's inherent authority and under Indian law in part because Defendants are likely to have assets both in the United States – at minimum, in their Amazon vendor accounts – and in India. However, it bears note that this Court's authority to freeze assets is not limited to assets within this District, nor even to assets within the United States. *See, e.g.*, *Gucci America*, 768 F.3d at 129 (holding that district court may enjoin defendants' assets in a Lanham Act case irrespective of whether the court has personal jurisdiction over foreign banks that may hold such assets); *Citronelle-Mobile Gathering, Inc. v. Watkins*, 943 F.2d 1297, 1301 (11th Cir. 1991) (upholding district court order directing "banks or financial institutions wherever located to freeze the judgment debtors' assets." (internal quotation marks omitted)).

Similarly, this Court is armed with further authority under the All Writs Act, 28 U.S.C. § 1651, to issue such orders requiring the cooperation of banks and other non-parties that may have physical custody of defendants' assets. *See Burr & Forman v. Blair*, 470 F.3d 1019, 1026-27 (11th Cir. 2006) ("The power to issue writs under the Act is not circumscribed by the identity of the parties immediately before the court; at the court's discretion, writs may be issued to third parties who are in a position to frustrate a court's administration of its jurisdiction." (citing *United States v. New York Tel. Co.*, 434 U.S. 159, 174 (1977))). For this reason, asset freeze orders often issue in anti-counterfeiting actions, and the undersigned counsel has

successfully sought and utilized both Asset Freeze Orders from U.S. District Courts and Letters of Request from U.S. District Courts to freeze the assets of overseas counterfeiters. *See* Potter Decl. Exs. A-H.

VI. THE COURT SHOULD ISSUE AN ORDER PERMITTING ALTERNATIVE SERVICE

The Defendants are all Indian residents, and the evidence shows that they conduct all of their counterfeit sales in U.S. commerce through online platforms. Federal Rule of Civil Procedure 4(f)(3) provides that this Court may order that individuals outside the United States be served by any "method that is reasonably calculated to give notice," including any "means not prohibited by international agreement, as the court orders." And with one exception not applicable here, Rule 4(h) permits service on an overseas business or corporation "in any manner prescribed by Rule 4(f) for serving an individual."

"Service pursuant to subsection (3) is 'neither a last resort nor extraordinary relief. It is merely one means among several which enables service of process on an international defendant.'" *In re Grana y Montero S.A.A. Sec. Litig.*, No. 17-CV-1105, 2019 WL 259778, at *3 (E.D.N.Y. Jan. 9, 2019) (quoting *Rio Props., Inc. v. Rio Int'l Interlink*, 284 F.3d 1007, 1015 (9th Cir. 2002)). Thus, there is no requirement that plaintiffs attempt other forms of service before the Court provides for alternative service under Rule 4(f)(3). *Group One Ltd. v. GTE GmbH*, 523 F. Supp. 3d 323, 340-341 (E.D.N.Y. 2021) (collecting cases and concluding "Plaintiff was not required to attempt service through the Hague Convention before granting an order for seeking alternative service via email."); *Restoration Hardware, Inc. v. Lighting Design Wholesalers, Inc.*, No. 17 Civ. 5553, 2020 WL 4497160 (S.D.N.Y. Aug. 5, 2020) (collecting cases). "[T]he decision as to whether to allow alternative service 'by other means' lies within

the discretion of the court." *Group One*, 523 F. Supp. at 341 (quoting *Convergen Energy LLC v. Brooks*, No. 20-CV-3746, 2020 WL 4038353, at *4 (S.D.N.Y. July 17, 2020)).

India is a signatory to the Hague Convention. Although not required under Rule 4(f)(3), Roche has submitted plentiful evidence that service through the Hague Convention cannot occur here. Roche is seeking immediate *ex parte* relief because, as set forth above, the evidence shows that the Defendants are willful counterfeiters and infringers who are putting American patients at risk and causing Roche irreparable harm, and the Defendants are very likely to flee, destroy evidence, and dissipate assets if given notice through traditional channels.

Email and electronic service against the Defendants here is "not prohibited by international agreement" because the Hague Convention does not prohibit email service. Like many other signatories to the Hague Convention, India has objected to Article 10 of the Hague Convention, which permits service via postal mail. But a nation's objection to Article 10 does *not* mean that that email or other electronic service is "prohibited by international agreement," because Article 10 does not involve service by email or other electronic means. *Group One*, 523 F. Supp. at 341 (collecting cases holding that various nations' objections to Article 10 does not prohibit email or electronic service under Rule 4(f)(3)). Thus, courts have approved e-mail service upon defendants in India under Rule 4(f)(3). *E.g.*, *Gurung v. Malhotra*, 297 F.R.D. 215, 219 (S.D.N.Y. 2011).

The facts here are similar to those in *Pearson Education Inc. v. Doe 1 d/b/a Anything You Can Imagine*, No. 18-CV-380, 2019 WL 6498305 (S.D.N.Y. Dec. 2, 2019). There, the plaintiff brought claims against Indian companies selling "counterfeit textbooks" in U.S. commerce through their Amazon storefronts. *Id* at *1. Without attempting service through the Hague Convention, plaintiffs moved for an order allowing email service against the

Defendants pursuant to Rule 4(f)(3). *Id.* The court granted the plaintiffs' application, holding that India's objection to Article 10 did not prohibit email service, and that e-mail service complied with due process because "service by email is reasonably calculated to reach [the defendants] and give notice," given that the defendants "have run, and continue to run, an online business" through Amazon, and so "their email addresses are likely their primary mode of communication." *Id.* at *2-3.

Roche respectfully requests that the Court issue an order pursuant to Rule 4(f)(3) – and the equivalent Rule 4(h)(2) for the corporate Defendants – permitting Roche to effect service upon all Defendants via e-mail. As in *Pearson Education*, Roche has set forth above the evidence that the India-based Defendants' sales of counterfeit and infringing products in the United States is done through their online Amazon storefronts, and that the individual Defendants are the operators of their respective corporate Defendants. Roche's investigators have identified email addresses for the Defendants. (Coleman Decl. ¶¶ 33, 34, 47, 48). E-mail service is appropriate under Rule 4(f)(3) because it is reasonably calculated to give effective notice to the Defendants and is not prohibited by the Hague Convention or any other international agreement to which India is a party. Especially in light of the fact that service cannot be effected through the normal processes of the Hague Convention given the emergency, *ex parte* relief that Roche seeks here, Roche respectfully submits that e-mail service pursuant to Rule 4(f)(3) is by far the most effective, expeditious, and sensible means by which to give notice to the Defendants and serve them with copies of Roche's papers in this action.[4]

[4] As noted above, and as contemplated by the Trademark Counterfeiting Act, Roche does not intend to effect service on Defendants until after it has received and executed the contemplated *Anton Piller* seizure orders from the Indian courts. If Roche's application for alternate service is granted, Roche will provide electronic service of its papers in this action as soon as the contemplated *Anton Piller* orders are executed. Roche will of course also provide courtesy copies of its papers in this action when it executes those seizures, but electronic service will provide simultaneous, formal, and effective service on all Defendants.

In a belt-and-suspenders approach, Roche further proposes that in addition to e-mail service, that Roche simultaneously serve the Defendants through their Amazon storefronts. Specifically, Amazon allows the general public to contact sellers who have Amazon storefronts through its Amazon Buyer-Seller Messaging Services, also known as the Amazon Message Center service. Amazon states that when a member of the public sends such a message, "[y]our message will be sent to the seller via the Buyer-Seller Messaging Service. They'll respond to you by email within two business days."[5] Here, Roche has submitted substantial evidence that the Defendants sell most of their counterfeit and infringing products through their Amazon storefronts, and so messages submitted by Amazon are more than reasonably calculated to reach Defendants and give them notice. Other courts have approved alternative service on defendants running Amazon storefronts under Rules 4(f)(3) and 4(h) through Amazon's messaging service alone. *See Canon Inc. v. HefeiERLANDIANZISHANGwuyouxiangongsi*, 2021 WL 8651747 at *2 (E.D.N.Y. July 29, 2021) (collecting cases). As in *Canon*, Roche's service through the Amazon messenger service would include notice of this action, Plaintiffs' counsel's contact information, and a "unique download link with a complete set of service papers." *Id.* at *2. Here, Roche seeks an alternative service order specifying that Roche will serve via *both* email and via the Amazon messaging service, so that service upon the Defendants is even further assured.

CONCLUSION

For the above-stated reasons, the Court should grant Plaintiffs' Emergency Motion for the issuance of a Letter of Request directed to the judicial authorities in the Honorable High Court of Delhi at New Delhi, India, for an *ex parte* seizure order and asset freeze order against Defendants; for a Temporary Restraining Order and Order to Show Cause

[5] Amazon.com, "Contact a Third-Party Seller," https://www.amazon.com/gp/help/customer/display.html?nodeId=GLC8ZMBWMBTR6QZZ.

why a Preliminary Injunction should not issue; for an Expedited Discovery Order; for an Asset Freeze Order against the Defendants; for an order permitting service by email and Amazon's messaging service upon the Defendants under Fed. R. Civ. P. 4(f)(3) and 4(h)(2); and any other and further relief that the Court may deem just and proper.

Respectfully submitted,

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