

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC**

**Before the Honorable Bryan F. Moore
Administrative Law Judge**

In the Matter of

**CERTAIN *BOTULINUM TOXIN*
PRODUCTS AND PROCESSES FOR
MANUFACTURING OR RELATING TO
SAME**

Investigation No. 337-TA-1313

**RESPONDENTS' RESPONSE COMPLAINANT'S MOTION *IN LIMINE* NO. 2
TO EXCLUDE TESTIMONY AND EXHIBITS FROM THE INITIAL WITNESS
STATEMENT OF JULIAN PARKHILL, PH.D. (RX-0005C) (Mot. No. 1313-029)**

I. INTRODUCTION

Pursuant to 19 C.F.R. §§ 210.37, and Ground Rule 6.4.3, 9, 13.6.6, Respondents Hugel Inc., Hugel America, Inc. (collectively, "Hugel"), and Croma Pharma GmbH ("Croma") (together "Respondents") respectfully submit this response to Complainant's Motion in *Limine* No. 2 to preclude Respondents' expert Dr. Julian Parkhill from relying on certain exhibits and to exclude the portions of Dr. Parkhill's questions and answers and demonstratives that reference those exhibits ("Compl. MIL 2").

In order to streamline the issues, Respondents hereby withdraw the portions of Q/A 174 from Dr. Parkhill's witness statement and RDX-0005C.014 that reference RX-0662 and RX-0663 and the portions of Q/As 66 and 76 that reference RX-1060 and RX-1139 as shown in the highlighted version of RX-0005C attached as Appendix A. A revised version of RDX-0005C.014 is also attached as Appendix B. Medytox's motion with respect to these Q/As is therefore moot. However, these exhibits should remain available for Respondents to use on

cross-examination because they are proper cross exhibits. Nor has Medytox asked to strike the exhibits themselves.

As Respondents have alerted Medytox and the Staff, the citation to RX-0823 in Q/A 41 of Dr. Parkhill's witness statement is a typographical error; the reference should have been to RX-0029C (Kyu Hwan Yang deposition designations).¹ Respondents will correct this in Dr. Parkhill's amended witness statement along with updated citations to joint exhibits pursuant to the attorney advisor's request.

Finally, the ALJ should deny Complainant's motion as it pertains to Q/As 167-168 referencing RX-1142 and Q/A 154 referencing RX-1173 and RX-1174 for the reasons set forth below.

II. ARGUMENT

The subject matter of Q/As 167-168—the likelihood of leaks or escapes of *C. botulinum* and other laboratory strains into the environment—was disclosed in Dr. Parkhill's expert report and discussed extensively at his deposition. *See, e.g.*, CX-0160C.0023, .0026-28 (Parkhill Expert Report) at ¶¶ 89, 93-104; *see, e.g.*, Appendix C (Parkhill Dep. Tr.) at 35:5-12, 36:9-37:9, 107:20-109:7, 109:22-112:1, 116:18-22, 130:12-131:4, 160:22-161:13, 163:16-165:13, 230:13-24. RX-1142 is a review article discussing laboratory leaks published December 22, 2023. Compl. MIL 2, at Ex. G. RX-1142 is powerful, independent evidence consistent with Dr. Parkhill's opinion that laboratory leaks are “not only possible, but ha[ve] demonstrably occurred on many occasions.” CX-0160C.0025 (Parkhill Expert Report) ¶ 93. Because this review article was published after Dr. Parkhill submitted his expert report and testified at deposition, Dr.

¹ Dr. Parkhill cited the Yang deposition transcript in his expert report at paragraph 99, notes 82-83. *See* CX-0160C.0026 (Parkhill Report).

[REDACTED]

Parkhill could not have cited it on those occasions. Therefore, Dr. Parkhill’s discussion of RX-1142 is neither untimely nor improper and should not be foreclosed by Ground Rule 13.6.6. *See Certain Kinesiotherapy Devices and Components Thereof*, Inv. No. 337-TA-823, Order No. 38 (Aug. 20, 2012) at 5-6 (“the purpose of [a rule similar to Ground Rule 13.6.6] is to give the opposing party notification in advance of the hearing of the issues to be contested and the substance of any expert opinions on those issues. In so doing, the rule confines the issues for hearing and avoids prejudicial surprises.”).

Medytox’s objection appears limited to Dr. Parkhill’s citation of RX-1173 and RX-1174 in the fourth paragraph of Q/A 154, as highlighted in Appendix A. The remaining portions of Q/A 154 are not challenged—a tacit admission by Medytox that the general subject matter is found in Dr. Parkhill’s expert report or deposition testimony. *See* Compl. MIL 2, at 5. The challenged portion of Q/A 154 cites RX-1173 and RX-1174 as support for Dr. Parkhill’s statement that “the odds of *C. botulinum* ending up in canned goods... is unfortunately common.” RX-001C.0046. This opinion itself is *not* new—it is found in Dr. Parkhill’s expert report. CX-0160C.0028 at ¶ 104 (“it is quite possible for laboratory stains of *C. botulinum* to be released into the environment”); CX-1053C.0010 (Parkhill Decl.) at ¶ 30 (it “cannot be excluded that CBFC26... was isolated from a contaminated food source”). Thus, Medytox was on notice of and questioned Dr. Parkhill at deposition on this opinion. *See, e.g.*, Appendix C at 163:16-165:13.

Moreover, RX-1173 and RX-1174 are an excerpt of the U.S. Centers for Disease Control’s website and a publicly available journal article concerning *C. botulinum* in canned foods, respectively. Compl. MIL 2, at Exs. H, I. Medytox’s motion does not articulate how Dr. Parkhill’s citation of publicly available documents to support previously disclosed opinions

[REDACTED]

creates any prejudice to Medytox. Accordingly, because Dr. Parkhill’s opinion was disclosed and Medytox has not been prejudiced, Medytox’s request to exclude the challenged portion of Q/A 154 should be denied. *See Certain Movable Barrier Operator Systems and Components Thereof*, Inv. No. 337-TA-1209, Order No. 22 at 4 (March 28, 2023) (denying motion to exclude because the challenged Q/As were “not substantially different” than the expert’s previous opinions and there was no prejudice to movant); *see also Certain Liquid Crystal Display Devices, Including Monitors, Televisions, and Modules, and Components Thereof*, Inv. No. 337-TA-749, Order No. 26 at 1-2 (August 30, 2011) (“[a]n expert may provide more detail in his witness testimony, as long as the opinion at issue is fairly disclosed.”).

Finally, Dr. Parkhill’s Q/As 154 and 167-168 are directly responsive to the new opinions regarding laboratory leaks that Dr. Keim expressed for the first time in his witness statement. *See* EDIS Doc. ID 812636 (Resp. Mot. in *Limine* No. 3) at 5-6 (seeking to exclude CX-0002C.58-59 (Keim WS) at Q/A 176-179, 181-182). They are also responsive to Dr. Lenski’s new opinion *expressed for the first time at his deposition in response to questions from Medytox’s counsel* that Hugel’s lab leak theory is “implausible to the point that it’s... impossible.” Appendix D (Lenski Dep.) at 236:2-9; *see also* CX-0003C.19 (Lenski WS) at Q/A 92-93.²

Thus, Medytox chose not to address Hugel’s laboratory leak arguments in expert reports but rather raised new arguments in deposition and trial testimony and is now moving to preclude

² Ground Rule 13.6.6 allows an expert’s trial testimony to include deposition testimony. Accordingly, Hugel did not move to exclude Q/As 92-93 from Dr. Lenski’s witness statement. However, to the extent the ALJ agrees with Medytox’s argument that it is improper to use redirect questioning at a deposition to introduce entirely new opinions (*see* Compl. Mot. in *Limine* No. 4, EDIS Doc. ID 812657, at 3-4, citing *Certain Wireless Mesh Networking Prod. & Related Components Thereof*, Inv. No. 337-TA-1131, Order No. 33 (Aug. 30, 2019)), these Q/As should be excluded.

Respondents' experts from responding to those new arguments. Fairness demands that Respondents have the opportunity to present evidence rebutting Medytox's belatedly disclosed arguments. *See Certain Reduced Ignition Proclivity Cigarette Paper Wrappers and Products Containing Same*, Inv. No. 337-TA-756, Order No. 29 (Oct. 31, 2011) at 7-8 (denying complainant's motion to exclude documents because "fairness requires" that respondents be allowed to respond to complainants' "belatedly espoused" contentions and "it would be an injustice to limit the evidence to the assertions [of] one party's experts when there are... legitimate opposing contentions."). The opinions and evidence supporting those opinions that Medytox seeks to exclude from Dr. Parkhill's witness statement will be helpful to Your Honor's weighing of the competing expert opinions.

III. CONCLUSION

For the foregoing reasons, Respondents respectfully request that the Administrative Law Judge deny Complainant's Motion *in Limine* No. 2 to exclude Dr. Parkhill's testimony in Q/As 167-168 that references RX-1142 and Q/A 154 that references RX-1173 and RX-1174. Regardless of the ALJ's decision on Complainant's motion, exhibits RX-0662, RX-0663, RX-0823, RX-1060, RX-1142, RX-1173 and RX-1174 should remain on Respondents' exhibit list for potential use on cross-examination.

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