

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF CALIFORNIA

3 **IN RE: INCRETIN-BASED**  
4 **THERAPIES PRODUCTS**  
5 **LIABILITY LITIGATION**

6 **Relates to: ALL CASES**

MDL No. 13-md-2452-AJB-MDD  
MEMORANDUM OF POINTS AND  
AUTHORITIES IN SUPPORT OF  
MOTION TO COMPEL AGAINST ALL  
DEFENDANTS FOR THEIR  
COMMUNICATIONS WITH OR  
RELATED TO CERTAIN FOREIGN  
REGULATORY AGENCIES

11  
12 **Introduction**

13 Several foreign regulatory agencies, including those in Canada, Switzerland, Israel,  
14 and Japan, have investigated whether Defendants' incretin drugs can cause pancreatic  
15 cancer, and have requested from Defendants scientific information relating to that  
16 question. Plaintiffs seek those particular communications ("Foreign Regulatory Files"),  
17 as well as pertinent internal company communications related to the Foreign Regulatory  
18 Files. Despite the obvious relevance to general causation, Defendants have refused to  
19 even search, much less produce, the Foreign Regulatory Files; Plaintiffs learned of this  
20 highly probative evidence via sporadic references to the inquires in Defendants' custodial  
21 files.<sup>1</sup>

22 The documents are also relevant to impossibility preemption, because any  
23 scientific evidence provided to foreign regulatory officials but *not* to the FDA could show  
24 under-reporting or misreporting by Defendants to the FDA, evidence which this Court

25 \_\_\_\_\_  
26 <sup>1</sup> It is likely that regulatory agencies in other countries have also raised the general  
27 causation issue with Defendants, and Plaintiffs are scouring the custodial files for  
28 references, but Defendants are in a far better position to know which regulatory  
authorities have asked these questions, and to which regulatory authorities they have  
provided information.

1 recognized “Plaintiffs must have a full opportunity to discover...” (Doc. 572 at 5).  
2 Defendants cannot deny that the Foreign Regulatory Files contain information *not*  
3 provided to FDA; part of their objection to producing the Foreign Regulatory Files is that  
4 de-duplication of the Foreign Regulatory Files to cull out documents already submitted to  
5 FDA would impose an undue burden on them, and that it would be easier for them simply  
6 to produce the Foreign Regulatory Files *in toto*. Plaintiffs do not oppose this solution, but  
7 Defendants refuse either.

### 8 **A. A Brief Summary of Meet and Confer Efforts**

9 On August 20, 2014, counsel for the parties participated in a conference call  
10 regarding Defendants' objections to producing foreign regulatory information and  
11 documents related to the incretin drugs. Plaintiffs took the position that they take in this  
12 motion. Defendants agreed to consider production of the Foreign Regulatory Files  
13 regarding Canada and other foreign regulators, if any, that had inquired of them regarding  
14 the relationship between their incretin drugs and pancreatic cancer. However, Defendants  
15 ultimately refused to produce any of the requested information other than foreign  
16 regulatory documents incidentally produced with custodial files (and, for Merck, site  
17 files).<sup>2</sup>

18 To limit the burden on Defendants, Plaintiffs proposed that the foreign discovery  
19 exclude documents already submitted to the FDA. The Court suggested this possible  
20 compromise in its Order Setting Discovery Protocol Dispute. (Doc. 568.) Defendants  
21 rejected this proposal; they say it would be quicker and less expensive for them to  
22  
23

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24 <sup>2</sup> Curiously, Defendants have taken the position that Foreign Regulatory Files are not  
25 relevant to general causation and/or preemption, except for the EMA, which they relied  
26 upon during Science Days and in their preemption briefing to date. However, the only  
27 logical difference between the EMA and other Foreign Regulatory Files appears to be  
28 that Defendants believe that the EMA may support some of their arguments in this MDL  
and that other Foreign Regulatory Files may counter some of their arguments in this  
MDL.

1 produce the entire Foreign Regulatory Files rather than just those portions that have not  
2 already been produced elsewhere.

3 To limit the burden on Defendants, Plaintiffs proposed narrowing their request, as  
4 described in the next paragraph. Defendants rejected this proposal as well.

5 **B-C. A Description of the Discovery Sought to be Compelled**

6 Plaintiffs seek to compel the written communications relating to pancreatic  
7 cancer sent to or received from the foreign regulatory agencies of Canada, Switzerland,  
8 Israel, Japan, and France, any foreign regulatory agencies that have communicated with a  
9 Defendant about the relationship between incretins and pancreatic cancer, and internal  
10 company communications regarding those same communications. The specific  
11 interrogatories and requests to produce and objections are attached as Exhibit A.<sup>3</sup> As  
12 noted above, Defendants have refused to identify with which foreign regulatory agencies  
13 they have discussed pancreatic cancer. Plaintiffs provide a brief description of the  
14 probable cause for each agency, as discovered within custodial productions as follows:

15 **Canada:** Health Canada is the regulatory agency charged with the regulation of  
16 prescription drugs in Canada. [REDACTED]

17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]

21 **Switzerland:** SwissMedic is the regulatory agency charged with the regulation of  
22 prescription drugs in Switzerland. [REDACTED]

23 [REDACTED]  
24 [REDACTED]

25 \_\_\_\_\_  
26 <sup>3</sup> Plaintiffs served General Causation Requests to Produce Nos. 25 and 51 and  
27 Interrogatory No. 27 on all Defendants. Those interrogatories and requests encompass  
28 Foreign Regulatory Files and related internal company communications. The select  
interrogatories and requests to produce and Defendants' objections are attached as  
Exhibit A.

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[REDACTED]

[REDACTED]

[REDACTED]  
[REDACTED]  
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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Israel:** The Ministry of Health (“MOH”) is the regulatory agency charged with the regulation of prescription drugs in Israel. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Japan:** The Pharmaceuticals and Medical Devices Agency (“PMDA”) is the regulatory agency charged with the regulation of prescription drugs in Japan. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED] Additionally, when Merck provided FDA with a white paper concerning the relationship between Merck’s incretin drugs and pancreatic cancer, “[s]tudies conducted only in Japan were excluded from all analyses.” (Ex. F, MRKJAN 10000484683-703, at 690.) This is direct evidence that PMDA was concerned about whether incretin drugs can cause pancreatic cancer.

**France:** The French Healthcare Authority (“FHA”) is the regulatory agency charged with the regulation of prescription drugs in France. [REDACTED]

[REDACTED]

1           **D. Statement as to Why the Documents are Relevant and Necessary**

2           The Foreign Regulatory Files as defined herein, and related internal company  
3 communications, are relevant to general causation because they contain documents  
4 concerning whether the incretin drugs are capable of causing pancreatic cancer.  
5 Plaintiff’s requests are limited to foreign regulatory discovery regarding agencies that  
6 have communicated with a Defendant about whether incretin drugs can cause pancreatic  
7 cancer. Plaintiffs are not seeking to compel production of all files concerning foreign  
8 regulation of incretin drugs. Therefore, Defendants contention that discovery sought to be  
9 compelled does not contain evidence relevant to general causation does not make sense.

10           The Foreign Regulatory Files are also relevant to impossibility preemption. Indeed,  
11 the Defendants themselves made the files relevant to this issue by asserting as an  
12 affirmative defense that FDA would not have permitted Defendants to change the incretin  
13 drug labels in any way with respect to pancreatic cancer. To establish their affirmative  
14 defense of impossibility preemption, Defendants have the burden to show with clear  
15 evidence that FDA would not have permitted a change in incretin drug labeling. Plaintiffs  
16 are entitled to challenge that assertion with instances of under-reporting or misreporting  
17 to the FDA. As day follows night, Defendants will say *Buckman Co. v. Plaintiffs’ Legal*  
18 *Comm.*, 531 U.S. 341 (2001), bars Plaintiffs from challenging the affirmative defense of  
19 impossibility preemption with such evidence. However, *Buckman*-style “fraud on the  
20 FDA” preemption has no application here, where Plaintiffs assert “a state-law claim that  
21 is independent of the FDA’s pre-market approval process that was at issue in *Buckman*.”  
22 *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (*cert. denied*, -- U.S. --,  
23 134 S.Ct. 2839 (2014)). *Buckman* is not at all germane to the issue before the Court; it is  
24 a red herring.<sup>4</sup>

25  
26  
27 <sup>4</sup> The inapplicability of *Buckman* is explained at length in Plaintiffs’ reply memorandum  
28 in support of a separate motion to compel and will not be reiterated at length here. The  
discussion appears in Document 613 at pages 5-6.

1 Defendants' claim that the discovery is unduly burdensome is also without merit.  
2 To the extent providing the discovery will impose a burden (which is very different from  
3 an undue burden) on Defendants, that burden is a result of their assertion of impossibility  
4 preemption and of the reality that the Foreign Regulatory Files contain information  
5 relevant to general causation that Plaintiffs cannot obtain from any source other than  
6 Defendants.

### 7 **Conclusion**

8 For the foregoing reasons, Plaintiffs respectfully request the Court enter an Order  
9 compelling Defendants to produce the written communications sent to or received from  
10 the foreign regulatory agencies of Canada, Japan, Switzerland, Israel, and France;  
11 compelling Defendants to produce the written communications sent to or received from  
12 other foreign regulatory agencies, if any, that have communicated with a Defendant about  
13 the relationship between incretins and pancreatic cancer; compelling Defendants to  
14 produced internal company communications regarding same; and granting such further or  
15 other relief as is proper.

16  
17 DATED: September 12, 2014

### **PLAINTIFFS' COUNSEL**

18  
19 s/Michael K. Johnson

20 Michael K. Johnson

21 Kenneth W. Pearson

22 **JOHNSON BECKER, PLLC**

23 33 South Sixth Street, Suite 4530

24 Minneapolis, Minnesota 55402

25 Telephone: (612) 436-1800

26 Facsimile: (612) 436-1801

27 **Email: [mjohnson@johnsonbecker.com](mailto:mjohnson@johnsonbecker.com)**

28 Tor A. Hoerman

Kenneth Brennan

**TORHOERMAN LAW LLC**

101 W. Vandalia Street, Suite 350

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Edwardsville, Illinois 62025  
Phone: (618) 656-4400  
Facsimile: (618) 656-4401  
[thoerman@torhoermanlaw.com](mailto:thoerman@torhoermanlaw.com)

Ryan L. Thompson  
**WATTS GUERRA LLP**  
5250 Prue Road, Suite 525  
San Antonio, Texas 78240  
Telephone: (210) 448-0500  
Facsimile: (210) 448-0501  
Email: [rthompson@wattsguerra.com](mailto:rthompson@wattsguerra.com)

Hunter J. Shkolnik  
**NAPOLI, BERN,  
RIPKA & SHKOLNIK LLP**  
350 Fifth Avenue  
New York, New York 10018  
Telephone: (212)267-3700  
Facsimile: (212)587-0031  
[hunter@napolibern.com](mailto:hunter@napolibern.com)

1 **CERTIFICATE OF SERVICE**

2 I hereby certify that on September 12, 2014, I caused the above document to be  
3 filed via the CM/ECF system for the Southern District of California, and the CM/ECF  
4 system served the same upon all registered users at their registered email addresses.

5 s/\_\_\_\_\_  
6 s/Michael K. Johnson

7 Michael K. Johnson  
8 Attorney for Plaintiffs  
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