UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

Civil No. 19-2875 (RBK/JS)

This Document Relates to:

All Actions

STIPULATED ORDER REGARDING ESI SEARCH TERMS PERTAINING TO THE TEVA DEFENDANTS

THIS MATTER HAVING COME before the Court on the Manufacturer Defendants' Motion to Modify the ESI Search Terms (Dkt. 445); and

THIS COURT HAVING CONSIDERED the parties' submissions in support of and in opposition to said Motion, as well as the argument and representations of counsel made during the telephonic status conference on June 17, 2020,

IT IS HEREBY ORDERED as follows:

1) Given that an agreement has been reached between Plaintiffs and the Teva Defendants to resolve these parties' current dispute concerning ESI search terms as set forth in the pending Motion and related briefing, the Manufacturer Defendants' Motion to Modify the ESI Search Terms is **DENIED AS MOOT** with respect to Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, Actavis Pharma, Inc., and Arrow Pharm (Malta) Ltd. (collectively, the "Teva Defendants");

2) For purposes of adopting and formalizing the agreement reached between Plaintiffs and the Teva Defendants, the Court **FURTHER ORDERS** as follows:

a. Exhibit H to the December 23, 2019 Order (Dkt. 328 at 29-57) is hereby revised, supplemented and superseded as to the Teva Defendants per the modifications set forth in Exhibit H-1 to this Stipulated Order;

b. Plaintiffs and the Teva Defendants will continue good faith discussions regarding potential additional reasonable and proportional adjustments to the search terms as such needs are identified during the search, processing, review and/or production of the custodial documents, and the parties are permitted to apply any additional agreed-to modifications to these search terms without further order of the Court;

c. The parties will proceed in accordance with the ESI Protocol (Dkt. 125), as well as their representations and the Court's instructions made during the June 17, 2020 status conference, to resolve any future issues regarding the search terms through the meet and confer process that might arise during the processing, review, and production of the Teva Defendants' ESI.

SO ORDERED, this the day of June 2020.

JOEL SCHNEIDER United States Magistrate Judge

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EXHIBIT H-1

Except as modified below or otherwise agreed to the by the parties, search terms to be run in accordance with the terms and protocol entered by the Court on December 23, 2019 (Doc. 328).

Standalone	
Original Term	Agreed Modification
(*11025* or *18253* or *202223* or	*200435* OR *091519* OR 77530 OR
203311 or *203820* or *20473* or	077530 OR (77530 W/2 ANDA) OR
205347 or *20939* or *23491* or *24544*	anda077530 OR anda77530 OR
or *24873* or *29392* or *77530* or	anda_077530_ndma OR sanda077530
78030 or *90483* or *90642* or *90866*	OR 90642 OR 090642 OR (90642 W/2
or *91235*)	ANDA) OR anda090642 OR anda90642 OR
	anda_090642_ndma OR sanda090642
	OR 91235 OR 091235 OR (91235 W/2
	ANDA) OR anda091235 OR anda91235 OR
	anda_091235_ndma OR sanda091235
EIR or "establishment inspection report"	Move to Regulatory
OAI or "official action indicated"	Move to Regulatory
"voluntary action indicated"	Move to Regulatory
*diethylamine or "*diethyl amine"	Move to QA Testing
*dimethylformamide or DMF	Move "DMF" to QA Testing
(Form483) or (Form /3 483) or (483 /3 letter)	Move to Regulatory
or (483 /3 warn*) or (704 pre/3 b)	
carcin*	Move to Medical Conditions
FDA /10 warning	Delete Term
genotoxic*	Move to Regulatory
Authors or Inspectors	
Original Term	Agreed Modification
Barreto	(Barreto NOT W/2 Dan*)
Regu	latory
Original Term	Agreed Modification
("adverse event*" or AER) and (<drug name=""></drug>	Move to Medical Conditions
or <solvents> or <facility names="">)</facility></solvents>	
alert*	alert* /5 safe*
CFR or eCFR or "code of federal regulations"	Run term as "W/500" rather than "AND"
or USC or "United States Code" or "Title 21"	
inadequat*	Delete Term
inspect*	Run term as "W/500" rather than "AND"
	Run term as inspection* OR inspector*
	instead of inspect*
investigat*	Run term as "W/500" rather than "AND"
	Run term as investigation* OR investigator*
	instead of investigat*
major /3 change	Delete Term
(master /3 file) and (<drug name=""> or</drug>	Delete Term
<solvents>)</solvents>	

minor /3 change	Delete Term	
moderate /3 change	Delete Term	
Monthly /3 update	Delete Term	
observation*	Run term as "W/500" rather than "AND"	
OOS or "out of spec*" or "out-of-spec*"	Run term as "W/500" rather than "AND"	
OOT or "out-of-trend" or "out of trend"	Run term as "W/500" rather than "AND"	
PADER* and (<drug name=""> or <solvents> or</solvents></drug>	Do not run against "OR <regulatory< td=""></regulatory<>	
<facility names="">)</facility>	modifiers>"	
violat*	Run term as "W/500" rather than "AND"	
warn*	Run term as "W/500" rather than "AND"	
	<u>MP</u>	
Original Term	Agreed Modification	
"cover up*" or coverup* or "cover-up*"	("cover* up" or coverup or "cover-up" or	
	"cover* ups" or coverups or "cover-ups")	
delet* or destroy* or remov* or trash* or	Run term as "W/500" rather than "AND"	
shred*	Modified to remove email footer language per	
	agreement of the parties	
<term> AND (<drug name=""> OR</drug></term>	<term> AND (<drug name=""> OR</drug></term>	
(<solvents> AND NOT <other drug="" names="">)</other></solvents>	(<solvents> AND NOT <other drug="" names="">)</other></solvents>	
OR <regulatory modifiers=""> OR <inspect> OR</inspect></regulatory>	OR <regulatory modifiers=""> OR <inspect> OR</inspect></regulatory>	
<manufacturing modifiers=""> OR <medical< td=""><td><manufacturing modifiers=""> OR <facility< td=""></facility<></manufacturing></td></medical<></manufacturing>	<manufacturing modifiers=""> OR <facility< td=""></facility<></manufacturing>	
modifiers> OR <facility names="">)</facility>	names>)	
<u>OA Testing</u>		
Original Term	Agreed Modification	
aberran*	Run term as "W/200" rather than "AND"	
contami*	Run term as "W/500" rather than "AND"	
detect*	Run term as "W/500" rather than "AND"	
fail*	Run term as "W/500" rather than "AND"	
problem*	Run term as "W/200" rather than "AND"	
puri*	Run term as "W/200" rather than "AND"	
recall*	Run term as "W/200" rather than "AND"	
risk*	Run term as "W/200" rather than "AND"	
toxic*	Run term as "W/200" rather than "AND"	
validat*	Run term as "W/200" rather than "AND"	
	acturing	
Original Term	Agreed Modification	
"PROCESS I" or "PROCESS II"	Do not run against the following Solvent	
	terms:	
	• acid*	
	 amlodipine* 	
	 aqueous* 	
	AqueousHCT	

	HCTZ
	Hydrochlor*
assessment*	Run term as "W/200" rather than "AND"
batch /5 records	batch /3 records
(certificate or COA)	Run term as "W/300" rather than "AND"
discrepanc*	Run term as "W/500" rather than "AND"
expir*	Run term as "W/500" rather than "AND"
quench*	Run term as "W/500" rather than "AND"
reagent*	Run term as "W/500" rather than "AND"
reclaim*	Run term as "W/500" rather than "AND"
recover*	Run term as "W/500" rather than "AND"
recylcl*	Run term as "W/500" rather than "AND"
resal*	Run term as "W/500" rather than "AND"
resell*	Run term as "W/500" rather than "AND"
reuse*	Run term as "W/500" rather than "AND"
suppress*	Run term as "W/500" rather than "AND"
yield*	Run term as "W/500" rather than "AND"
error*	Run term as "W/500" rather than "AND"
	Modified to remove email footer language per
	agreement of the parties
temperature	Delete Term
Medical	Conditions
Original Term	Agreed Modification
blood*	Delete Term
death* or dead or fatal	death or deaths or dead or deadly or fatal
death* or dead or fatal	death or deaths or dead or deadly or fatal tities
death* or dead or fatal <u>En</u> Original Term	death or deaths or dead or deadly or fatal tities Agreed Modification
death* or dead or fatal <u>En</u> <u>Original Term</u> Ivax	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term
death* or dead or fatal En Original Term Ivax distribut*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term
death* or dead or fatal <u>En</u> <u>Original Term</u> Ivax distribut* <u>Drug</u>	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names
death* or dead or fatal	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification
death* or dead or fatal Ivax distribut* Original Term Ivax amlodipine*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents
death* or dead or fatal Ivax distribut* Original Term Original Term Original Term Amountation HCT or HCTZ	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents
death* or dead or fatal En Original Term Ivax distribut* Original Term Original Term Mlodipine* HCT or HCTZ detect*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND"
death* or dead or fatal Ivax Ivax distribut* Drug Original Term amlodipine* HCT or HCTZ detect*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents
death* or dead or fatal Original Term Ivax distribut* Original Term Original Term amlodipine* HCT or HCTZ detect* Original Term	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification
death* or dead or fatal Ivax Ivax distribut* Drug Original Term amlodipine* HCT or HCTZ detect*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification Index results and run as "OR" term without
death* or dead or fatal <u>Original Term</u> Ivax distribut* <u>Drug</u> <u>Original Term</u> amlodipine* HCT or HCTZ detect* <u>Sol</u> <u>Original Term</u> *azide*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification Index results and run as "OR" term without open-ended wildcard
death* or dead or fatal Original Term Ivax distribut* Original Term Original Term amlodipine* HCT or HCTZ detect* Original Term	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification Index results and run as "OR" term without open-ended wildcard Index results and run as "OR" term without
death* or dead or fatal En Original Term Ivax distribut* Drug Original Term amlodipine* HCT or HCTZ detect* Sol Original Term *azide* *formaldehyde*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Move to Ferme Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification Index results and run as "OR" term without open-ended wildcard Index results and run as "OR" term without open-ended wildcard
death* or dead or fatal Original Term Ivax Ivax distribut* Original Term amlodipine* HCT or HCTZ detect* Sol Original Term aszide* acid*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Agreed Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification Index results and run as "OR" term without open-ended wildcard Index results and run as "OR" term without open-ended wildcard Delete Term
death* or dead or fatal Original Term Ivax Ivax distribut* Original Term amlodipine* HCT or HCTZ detect* Sol Original Term aszide* acid*	death or deaths or dead or deadly or fatal tities Agreed Modification Delete Term Delete Term Names Move to Ferme Modification Move to Solvents Move to Solvents Move to Solvents Run term as "W/500" rather than "AND" vents Agreed Modification Index results and run as "OR" term without open-ended wildcard Index results and run as "OR" term without open-ended wildcard

"Abbreviated New Drug Application" or ANDA	Do not run against cGMP
CDC or "Centers for Disease Control"	Do not run against cGMP
DEA or "Drug Enforcement Administration"	Do not run against cGMP
or "Drug Enforcement Agency"	
"Environmental Protection Agency" or EPA	Do not run against cGMP
or USEPA or "US-EPA" or "1200	
Pennsylvania Avenue"	
NIH or "National Institutes of Health"	Do not run against cGMP
	ing Modifiers
Original Term	Agreed Modification
test*	Run term as "W/50" rather than "AND" with
	the following other terms:
	• quality
	 quanty validat*
	 impurit*
	-
	• risk* Run term as "W/200" rather than "AND" with
	the following other terms:
	• remov*
	• fail*
	• detect*
	• residu*
	• suitab*
	• puri*
	 problem*
	• recall*
	• complain*
	• GMP*
	• unknown*
	• peak*
	 observation*
	• contami*
	Chromato*
Medical Condi	itions Modifiers
Original Term	Agreed Modification
blood*	Delete Term
	/ Names
Identified Facility Name	Agreed Modification
Actavis	Delete Term
[FEI NUMBERS FOR FACILITIES]	Index results and run as "OR" term without
	open-ended wildcard
Ha-Marpe	Ha-Marpe OR HaMarpe
Jerusalem	
JLM	
JLAN	

JLM OSD	
JE1 Kimat HaMada	
Kiryat HaMada Malta	
Malta Ual for	
Hal far	
Arrow	
Birzebbugia	Variations to be tested
	ring Modifications
Original String	Agreed Modification
quality AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as "W/200" rather than "AND"
validat* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as "W/200" rather than "AND"
risk* AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	Run string as "W/200" rather than "AND"
(degradant* OR impurit*) AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))	(degradant*) AND ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*)) (impurit*) W/250 ((backup W/3 data) OR (impurit* AND degradant*) OR recall* OR residu* OR solvent* OR spike* OR test* OR (unknown W/3 peak) OR (unknown W/3 spike) OR (unknown W/3 impurit*) OR (unknown W/3 contamin*))
(remov* OR trash* OR shred*) AND	(remov* OR trash* OR shred*) AND
(Agency OR inspect* OR regulat*)	(inspector* OR inspection* OR regulator*)
validat* AND ((backup W/3 data) OR	Run string as "W/250" rather than "AND"
(impurit* AND degradant*) OR recall* OR	
residu* OR solvent* OR spike* OR test* OR	
(unknown W/3 peak) OR (unknown W/3	

spike) OR (unknown W/3 impurit*) OR	
(unknown W/3 contamin*))	
complain* AND ((backup W/3 data) OR	Run string as "W/250" rather than "AND"
(impurit* AND degradant*) OR recall* OR	
residu* OR solvent* OR spike* OR test* OR	
(unknown W/3 peak) OR (unknown W/3	
spike) OR (unknown W/3 impurit*) OR	
(unknown W/3 contamin*))	
residu* AND ((backup W/3 data) OR	Run string as "W/250" rather than "AND"
(impurit* AND degradant*) OR recall* OR	
solvent* OR spike* OR test* OR (unknown	
W/3 peak) OR (unknown W/3 spike) OR	
(unknown W/3 impurit*) OR (unknown W/3	
contamin*))	
risk* AND ((backup W/3 data) OR (impurit*	Run string as "W/250" rather than "AND"
AND degradant*) OR recall* OR residu* OR	
solvent* OR spike* OR test* OR (unknown	
W/3 peak) OR (unknown W/3 spike) OR	
(unknown W/3 impurit*) OR (unknown W/3	
contamin*))	
fail* AND ((backup W/3 data) OR (impurit*	Run string as "W/250" rather than "AND"
AND degradant*) OR recall* OR residu* OR	
solvent* OR spike* OR test* OR (unknown	
W/3 peak) OR (unknown W/3 spike) OR	
(unknown W/3 impurit*) OR (unknown W/3	
contamin*))	
problem* AND ((backup W/3 data) OR	Run string as "W/250" rather than "AND"
(impurit* AND degradant*) OR recall* OR	
residu* OR solvent* OR spike* OR test* OR	
(unknown W/3 peak) OR (unknown W/3	
spike) OR (unknown W/3 impurit*) OR	
(unknown W/3 contamin*))	