

No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

*ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT*

**JOINT APPENDIX
(VOLUME 1)**

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PETITION FOR A WRIT OF CERTIORARI FILED: OCT. 4, 2012
CERTIORARI GRANTED: DEC. 7, 2012

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UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 10-12729

FEDERAL TRADE COMMISSION, PLAINTIFF-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., PAR PHARMACCU-
TICAL COMPANIES, INC., PADDOCK
LABORATORIES, INC., SOLVAY PHARMACEUTICALS, INC.

PAR PHARMACCU-TICAL COMPANIES, INC., PADDOCK
LABORATORIES, INC., DEFENDANTS-COUNTER
CLAIMANTS-APPELLEES

FEDERAL TRADE COMMISSION, PLAINTIFF-COUNTER
DEFENDANT-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., SOLVAY PHARMA-
CEUTICALS, INC., DEFENDANTS-APPELLEES

Filed: June 15, 2010

DOCKET ENTRIES

(1)

DATE	PROCEEDINGS
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* * * * *

6/30/10 CIVIL APPEAL DOCKETED. Notice of appeal filed by Appellant Federal Trade Commission on 06/10/2010. Fee Status: Fee Not Required.

* * * * *

7/22/10 JURISDICTIONAL QUESTION issued as to Federal Trade Commission and Paddock Laboratories, Inc., Par Pharmaceutical Companies, Inc., Solvay Pharmaceuticals, Inc. and WPI.

* * * * *

7/27/10 Appellant's Brief filed by Appellant Federal Trade Commission. Service date: 07/26/2010 by US—mail Attorney for Appellee(s): Eakes, Grannon, Rabin, Raptis, Roberti, Ryan, Singla, Sunshine, Trigg, Valentine, Weinberger, York.

7/27/10 Record Excerpts filed by Appellant Federal Trade Commission. Service date: 07/26/2010 US mail—Attorney for Appellee(s): Bonder, Eakes, Gidley, Grannon, Kent, Rabin, Raptis, Roberti, Ryan, Singla, Sunshine, Trigg, Weinberger, York; email—Attorney for Appellee: Valentine.

7/27/10 E-Brief Tendered: Appellant brief for Appellant Federal Trade Commission.

DATE	PROCEEDINGS
8/5/10	Response to Jurisdictional Question filed by Paul James Larkin, Jr. for Appellant Federal Trade Commission, Eric Grannon for Appellees Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc., Steven Craig Sunshine for Appellee WPI and Jeffrey I. Weinberger for Appellee Solvay Pharmaceuticals, Inc.
	* * * * *
11/10/10	E-Brief Tendered: Appellee brief for Appellees Paddock Laboratories, Inc. and Par Pharmaceutical Companies, Inc.
11/10/10	Appellee's Brief filed by Appellees Paddock Laboratories, Inc. and Par Pharmaceutical Companies, Inc.. Service date: 11/10/2010 US mail—Attorney for Appellant(s): Albert, DeMille-Wagman, Liebes, Meier, Robertson, Unt, Woodward.
11/12/10	E-Brief Tendered: Appellee brief for Appellee WPI.
11/12/10	Appellee's Brief filed by Appellees Solvay Pharmaceuticals, Inc. and WPI. Deficiencies: Attorney signature. (corrections revd 11/19/10) Service date: 11/10/2010 US mail—Attorney for Appellant(s): Albert, DeMille-Wagman, Liebes, Meier, Woodward.—[Edited 11/22/2010 by TLR]

* * * * *

DATE	PROCEEDINGS
12/3/10	Certificate of Readiness filed as to Appellant Federal Trade Commission.
12/3/10	Record on Appeal filed. Record Part: Pleadings, 11 Vol ROA; Record Part: Exhibits, 1 sealed Envelope
12/15/10	E-Brief Tendered: Reply brief for Appellant Federal Trade Commission.
12/16/10	Reply Brief filed by Appellant Federal Trade Commission. Service 12/15/2010 US mail—Attorney for Appellee(s): Gidley, Grannon, Raptis, Roberti, Ryan, Sunshine, Trigg, Weinberger, York; email—Attorney for Appellee: Valentine.
1/19/11	ORDER: Motion to file appendix filed by Attorney Mark G. Trigg for Appellees Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc. is GRANTED. SM
1/19/11	Appendix filed by Attorney Mark G. Trigg for Appellees Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.. Service date: 11/10/2010 US mail—Attorney for Appellant(s): Albert, DeMille-Wagman, Liebes, Meier, Woodward; Attorney for Appellee(s): Bonder, Eakes, Gidley, Grannon, Kent, Rabin, Raptis, Roberti, Ryan, Singla, Sunshine, Trigg, Weinberger, York; email—Attorney for Appellee: Valentine.

* * * * *

DATE	PROCEEDINGS
5/13/11	Oral argument held. Oral Argument participants were Lawrence DeMille-Wagman for Appellant Federal Trade Commission, Eric Grannon for Appellees Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc. and Jeffrey I. Weinberger for Appellee Solvay Pharmaceuticals, Inc. * * * * *
4/25/12	Opinion issued by court as to Appellant Federal Trade Commission. Decision: Affirmed. Opinion type: Published. Opinion method: Signed.
4/25/12	Judgment entered as to Appellant Federal Trade Commission. * * * * *
6/11/12	Petition for rehearing en banc filed by Appellant Federal Trade Commission. (ECF: Mark Hegedus)
7/17/12	Supplemental Authority filed by Appellant Federal Trade Commission. Service date: 07/17/2012 US mail—Attorney for Appellees: Bonder, Gidley, Grannon, Kent, Rabin, Raptis, Roberti, Sunshine, Weinberger; email—Attorney for the Appellees: Eakes, Singla, Trigg, Valentine, York. (ECF: Mark Hegedus)

DATE	PROCEEDINGS
7/18/12	ORDER: The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled, the Petition(s) for Rehearing En Banc filed by Appellant Federal Trade Commission are DENIED.. [6619216-1]
7/27/12	Mandate issued as to Appellant Federal Trade Commission.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA (AT-
LANTA)

No. 1:09-cv-00955-TWT

FEDERAL TRADE COMMISSION, STATE OF CALIFORNIA,
PLAINTIFF

v.

WATSON PHARMACEUTICALS, INC., PAR PHARMACEU-
TICAL COMPANIES, INC., PADDOCK LABORATORIES,
INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS

PAR PHARMACEUTICAL COMPANIES, INC., PADDOCK
LABORATORIES, COUNTER CLAIMANT

v.

FEDERAL TRADE COMMISSION, STATE OF CALIFORNIA,
COUNTER DEFENDANTS

Filed: Apr. 10, 2009

DOCKET ENTRIES

DOCKET		
DATE	NUMBER	PROCEEDINGS
1/27/09		SEALED LODGED COMPLAINT sought to be filed by Plaintiffs Federal Trade Commission, The State of California. (ghap) [Transferred from California Central on 4/10/2009.] (Entered: 02/05/2009) * * * * *
1/29/09	4	**REDACTED—PUBLIC VERSION**SEALED COMPLAINT against Defendants Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., Solvay Pharmaceuticals, Inc. (Filing fee \$ 350: NO FEE REQUIRED), filed by plaintiffs Federal Trade Commission, The State of California. (ghap) Modified on 2/6/2009 (ds). (ds). [Transferred from California Central on 4/10/2009.] (Entered: 02/05/2009) * * * * *
2/12/09	8	First Amended Complaint (mat) Modified on 2/23/2009 (mat). [Transferred from California Central on 4/10/2009.] (Entered: 02/17/2009)

DOCKET
DATE NUMBER PROCEEDINGS

2/12/09 9 Stipulation to place on the public record plaintiffs' Amended Complaint and permanently seal plaintiffs' initial complaint filed on January 29, 2009. (mat) Modified on 2/23/2009 (mat). [Transferred from California Central on 4/10/2009.] (Entered: 02/17/2009)

* * * * *

2/27/09 44 NOTICE OF MOTION AND Joint MOTION to Transfer Case to Northern District of Georgia filed by Defendant Solvay Pharmaceuticals, Inc.. Motion set for hearing on 3/30/2009 at 10:00 AM before Judge Mariana R. Pfaelzer. (Attachments: # 1 Motion, # 2 Declaration of Julia York, # 3 Declaration of Eric Granon, # 4 Declaration of Clare Carmichael, # 5 Declaration of John Roberti, # 6 Exhibit Roberti Exhibit A, # 7 Exhibit Roberti Exhibit B, # 8 Exhibit Roberti Exhibit C, # 9 Exhibit Roberti Exhibit D, # 10 Exhibit Roberti Exhibit E, # 11 Exhibit Roberti Exhibit F, # 12 Exhibit Roberti Exh G, # 13 Exhibit Rob-

DOCKET
DATE NUMBER PROCEEDINGS

erti Exh H, # 14 Exhibit Robert
Exh I, # 15 Exhibit Roberti Exh J,
16 Exhibit Roberti Exh K, # 17
Exhibit Roberti Exh L, # 18 Exhib-
it Roberti Exh M, # 19 Exhibit
Roberti Exh N, # 20 Exhibit Rob-
erti Exh O, # 21 Exhibit Roberti
Exh P, # 22 Exhibit Roberti Exh Q,
23 Exhibit Roberti Exh R, # 24
Exhibit Roberti Exh S, # 25 Exhibit
Roberti Exh T, # 26 Exhibit Rob-
erti Exh U, # 27 Exhibit Roberti
Exh V, # 28 Exhibit Roberti Exh
W, # 29 Exhibit Roberti Exh X,
30 Exhibit Roberti Exh Y, # 31
Exhibit Roberti Exh Z, # 32 Exhib-
it Roberti Exh AA, # 33 Exhibit
Roberti Exh BB, # 34 Exhibit Rob-
erti Exh CC, # 35 Exhibit Roberti
Exh DD) (Richardson, Teri) [Tran-
sferred from California Central on
4/10/2009.] (Entered: 02/27/2009)

* * * * *

3/16/09 53 OPPOSITION to Joint MOTION to
Transfer Case to Northern District
of Georgia 44, Joint MOTION to
Transfer Case to Northern District

DOCKET		
DATE	NUMBER	PROCEEDINGS
		of Georgia 45 filed by Plaintiff Federal Trade Commission. (Robertson, J) [Transferred from California Central on 4/10/2009.] (Entered: 03/16/2009)
3/16/09	54	OPPOSITION re: Joint MOTION to Transfer Case to Northern District of Georgia 44 <i>Opposition of the State of California to Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia Based Upon a Lack of Personal Jurisdiction</i> filed by Plaintiff The State of California. (Attachments: # 1 Declaration of Cheryl Johnson in Support of Opposition to Motion to Transfer Venue, # 2 Declaration of Kathleen Foote in Support of Opposition to Motion to Transfer Venue) (Johnson, Cheryl) [Transferred from California Central on 4/10/2009.] (Entered: 03/16/2009) * * * * *
3/23/09	59	REPLY In Support Of Joint MOTION to Transfer Case to Northern District of Georgia 44 filed by De-

DOCKET		
DATE	NUMBER	PROCEEDINGS
		defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	60	DECLARATION re Reply (Motion related) 59 <i>Of Joseph Todisco In Further Support of Joint Motion to Transfer Venue to the Northern District of Georgia</i> filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	61	DECLARATION of Scott Tarriff re Reply (Motion related) 59 <i>in Further Support of Joint Motion to Transfer Venue to the Northern District of Georgia</i> filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	62	DECLARATION of Julia K. York re Reply (Motion related) 59 <i>In Support of Defendants' Joint Motion to Transfer Venue</i> filed by Defendant Solvay Pharmaceuticals,

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	63	DECLARATION of David A. Buchen re Reply (Motion related) 59 <i>In Support of Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia</i> filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	64	DECLARATION of Vera Nackovic re Reply (Motion related) 59 <i>In Support of Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia</i> filed by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
3/23/09	65	DECLARATION of Vera Nackovic (part 2 of 2) re Reply (Motion related) 59, Declaration (non-motion) 64 <i>In Support of Defendants' Joint Motion to Transfer Venue to the Northern District of Georgia</i> filed

DOCKET		
DATE	NUMBER	PROCEEDINGS
		by Defendant Solvay Pharmaceuticals, Inc.. (Richardson, Teri) [Transferred from California Central on 4/10/2009.] (Entered: 03/23/2009)
		* * * * *
4/6/09	69	NOTICE OF MOTION AND MOTION to Dismiss Case filed by Defendant Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc.. Motion set for hearing on 5/11/2009 at 10:00 AM before Judge Mariana R. Pfaelzer. (Attachments: # 1 Notice of Motion, # 2 Declaration of Eric Grannon, # 3 Exhibits to Declaration of Eric Grannon, # 4 Proposed Order) (Grannon, Eric) [Transferred from California Central on 4/10/2009.] (Entered: 04/06/2009)
4/6/09	70	NOTICE OF MOTION AND Joint MOTION to Dismiss Case filed by Defendant Watson Pharmaceuticals, Inc.. Motion set for hearing on 5/11/2009 at 10:00 AM before Judge Mariana R. Pfaelzer. (Attachments: # 1 Joint Notice of Motion, # 2 Declaration of Julia K. York In Support

DOCKET		
DATE	NUMBER	PROCEEDINGS
		of Defendants' Joint Motion to Dismiss Plaintiffs' First Amended Complaint, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C, # 6 Exhibit D, # 7 Exhibit E, # 8 Exhibit F, # 9 Exhibit G, # 10 Exhibit H, # 11 Exhibit I, # 12 Exhibit J, # 13 Proposed Order [Proposed] Order, # 14 Proof of Service) (Adler, Douglas) [Transferred from California Central on 4/10/2009.] (Entered: 04/06/2009)
4/8/09	71	ORDER TRANSFERRING CASE by Judge Mariana R. Pfaelzer transferring case to Northern District of Georgia. (MD JS-6. Case Terminated.) (es) [Transferred from California Central on 4/10/2009.] (Entered: 04/06/2009)
		* * * * *
4/21/09	87	ANSWER to COMPLAINT (Discovery ends on 1/19/2010), COUNTERCLAIM to Plaintiff's First Amended Complaint against all plaintiffs by Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc.. (Trigg, Mark) Please

DOCKET
DATE NUMBER PROCEEDINGS

visit our website at <http://www.gand.uscourts.gov> to obtain Pretrial Instructions. Modified caps/duplicative text on 4/22/2009 (dr). (Entered: 04/21/2009)

* * * * *

4/21/09 94 Notice of Dismissal Without Prejudice by The State of California of claims against Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc. and Solvay Pharmaceuticals, Inc. pursuant to FRCP 41.a.1.A (dr) (Entered: 04/22/2009)

* * * * *

5/28/09 114 Second AMENDED COMPLAINT against all defendants, filed by Federal Trade Commission. (Attachments: # 1 Exhibit) (Liebes, Cindy) Please visit our website at <http://www.gand.uscourts.gov> to obtain Pretrial Instructions. (Entered: 05/28/2009)

5/28/09 115 Unopposed MOTION to Seal *Temporarily Exhibit A to FTC'S Second Amended Complaint and to Set Briefing Schedule for Motion for*

DOCKET		
DATE	NUMBER	PROCEEDINGS
		<i>Protective Order</i> by Federal Trade Commission. (Attachments: #1 Text of Proposed Order, #2 Exhibit) (Liebes, Cindy) (Additional attachment(s) added on 05/28/2009: #3 Exhibit A Filed Under Seal) (dr). Modified/verified by ryc Exhibit A on 05/28/2009 (dr). (Entered: 05/28/2009)
6/2/09	116	ORDER granting 115 Motion to Seal Temporarily Exhibit A to FTC's Second Amended Complaint. Signed by Judge Thomas W. Thrash, Jr on 6/1/09. (dr) (Entered: 06/02/2009)
6/5/09	117	MOTION for Protective Order with Brief In Support by Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Text of Proposed Order) (Bonder, Teresa) (Entered: 06/05/2009)
		* * * * *
6/15/09	121	MOTION to Stay <i>Proceedings</i> by Federal Trade Commission. (Attachments: # 1 Text of Proposed Order, # 2 Exhibit Declaration of

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Erin C. Burns) (Liebes, Cindy) (Entered: 06/15/2009)
6/17/09	122	RESPONSE in Opposition re 121 MOTION to Stay <i>Proceedings</i> filed by Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., Solvay Pharmaceuticals, Inc. (Attachments: # 1 Declaration, # 2 Exhibit Index, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C, # 6 Exhibit D, # 7 Exhibit E, # 8 Exhibit F, # 9 Exhibit G, # 10 Exhibit H, # 11 Exhibit I, # 12 Exhibit J, # 13 Exhibit K, # 14 Exhibit L, # 15 Exhibit M, # 16 Exhibit N, # 17 Text of Proposed Order) (Bonder, Teresa) (Entered: 06/17/2009)
6/17/09	123	RESPONSE re 117 MOTION for Protective Order filed by Federal Trade Commission. (Attachments: # 1 Affidavit Bradley S. Albert, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E, # 7 Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K) (Robertson,

DOCKET		
DATE	NUMBER	PROCEEDINGS
		John) (Entered: 06/17/2009)
6/22/09	124	ANSWER to 87 Counterclaim of <i>Par and Paddock</i> by Federal Trade Commission (Robertson, John) Please visit our website at http://www.gand.uscourts.gov to obtain Pretrial Instructions. (Entered: 06/22/2009)
6/26/09	125	REPLY BRIEF re 117 MOTION for Protective Order filed by Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B) (Bonder, Teresa) (Entered: 06/26/2009)
		* * * * *
7/6/09	128	REPLY BRIEF re 121 MOTION to Stay <i>Proceedings</i> filed by Federal Trade Commission. (Attachments: # 1 Affidavit Llewellyn O. Davis, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E) (Robertson, John) Modified on 7/8/2009 to correct text to accurately reflect efiled pleading (tcc). (Entered: 07/06/2009)
7/8/09		Submission of 117 MOTION for Protective Order, 121 MOTION to

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Stay <i>Proceedings</i> , submitted to District Judge Thomas W. Thrash. (dr) (Entered: 07/08/2009) 07/17/2009 * * * * *
7/20/09	130	MOTION to Dismiss with Brief In Support by Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Brief) (Bonder, Teresa) (Entered: 07/20/2009)
7/20/09	131	MOTION to Dismiss <i>The Second Amended Complaint</i> with Brief In Support by Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc.. (Attachments: # 1 Brief in Support of Defendants Par Pharmaceutical Companies, Inc. and Paddock Laboratories, Inc.'s Motion to Dismiss the Second Amended Complaint, # 2 Exhibit, # 3 Text of Proposed Order) (Trigg, Mark) (Entered: 07/20/2009) * * * * *
8/21/09	137	RESPONSE in Opposition re 131 MOTION to <i>Dismiss The Second</i>

DOCKET		
DATE	NUMBER	PROCEEDINGS
		<i>Amended Complaint</i> , 130 MOTION to Dismiss filed by Federal Trade Commission. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5) (Robertson, John) (Entered: 08/21/2009)
		* * * * *
9/11/09	139	REPLY BRIEF re 130 MOTION to Dismiss filed by Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit Index, # 2 Exhibit A, # 3 Exhibit B) (Bonder, Teresa) (Entered: 09/11/2009)
9/11/09	140	RESPONSE in Support re 131 MOTION to Dismiss <i>The Second Amended Complaint</i> filed by Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc.. (Attachments: # 1 Exhibit C, # 2 Exhibit D) (Trigg, Mark) (Entered: 09/11/2009)
9/22/09		Submission of 130 MOTION to Dismiss, 131 MOTION to Dismiss <i>The</i>

DOCKET
DATE NUMBER PROCEEDINGS

Second Amended Complaint, submitted to District Judge Thomas W. Thrash. (dr) (Entered: 09/22/2009)

* * * * *

1/7/10	152	Minute Entry for proceedings held before Judge Thomas W. Thrash, Jr: Motion Hearing held on 1/7/2010. The Court heard argument from counsel on pending motions to dismiss and took the matter under advisement and will issue a written order as soon as possible. Associated Cases: 1:09-md-02084-TWT et al. (Court Reporter Susan Baker) (fap) (Entered: 01/08/2010)
2/22/10	153	ORDER granting (8), (9), (22), (23) Motion to Dismiss as to the claims of the FTC and the Indirect Purchasers, granting in part and denying in part (24), (25), (26), (27), (28), (29) Motion to Dismiss as to the claims of the Direct Purchasers in case 1:09-md-02084-TWT; granting (130) Motion to Dismiss; granting (131) Motion to Dismiss in case 1:09-cv-00955-TWT; granting in part and denying in part (124) Motion to

DOCKET
DATE NUMBER PROCEEDINGS

Dismiss; granting in part and denying in part (125) Motion to Dismiss in case 1:09-cv-00956-TWT; granting in part and denying in part (134) Motion to Dismiss; granting in part and denying in part (135) Motion to Dismiss in case 1:09-cv-00957-TWT; granting in part and denying in part (127) Motion to Dismiss; granting in part and denying in part (128) Motion to Dismiss in case 1:09-cv-00958-TWT; granting in part and denying in part (62) Motion to Dismiss; granting in part and denying in part (63) Motion to Dismiss in case 1:09-cv-02776-TWT; granting (62) Motion to Dismiss; granting (63) Motion to Dismiss in case 1:09-cv-02848-TWT; granting in part and denying in part (79) Motion to Dismiss; granting in part and denying in part (80) Motion to Dismiss in case 1:09-cv-02913-TWT; granting (59) Motion to Dismiss; granting (60) Motion to Dismiss in case 1:09-cv-02914-TWT; granting (59) Motion to Dismiss; granting (60) Motion to Dismiss in case 1:09-cv-02915-TWT;

DOCKET		
DATE	NUMBER	PROCEEDINGS
		granting in part and denying in part (61) Motion to Dismiss; granting in part and denying in part (62) Motion to Dismiss in case 1:09-cv-03019-TWT. Signed by Judge Thomas W. Thrash, Jr on 2/22/10. Associated Cases: 1:09-md-02084-TWT et al. (dr) (Entered: 02/23/2010)
2/23/10	154	ORDER granting 117 Motion for Protective Order. Signed by Judge Thomas W. Thrash, Jr on 2/23/10. (dr) (Entered: 02/24/2010)
4/16/10	155	MOTION for Judgment by Federal Trade Commission. (Attachments: # 1 Text of Proposed Order) (Albert, Bradley) (Entered: 04/16/2010)
4/20/10	156	ORDER granting 155 Motion for Entry of Judgment pursuant to Fed. R. Civ. P. 58(D). Signed by Judge Thomas W. Thrash, Jr on 4/19/10. (dr) (Entered: 04/21/2010)
4/21/10	157	CLERK'S JUDGMENT that pursuant to Fed.R.Civ.P.58 the Federal Trade Commission's claims are dismissed with prejudice. (dr)—Please refer to http://www.ca11.uscourts.gov to obtain an appeals

DOCKET		
DATE	NUMBER	PROCEEDINGS
		jurisdiction checklist—(Entered: 04/21/2010)
5/26/10		Civil Case Terminated. (dr) (Entered: 05/26/2010)
6/10/10	158	NOTICE OF APPEAL as to 156, order 157 Clerk's Judgment by Federal Trade Commission. Transcript Order Form due on 6/24/2010 (Albert, Bradley) Modified on 6/11/2010 to link order appealed. (fem). (Entered: 06/10/2010)
		* * * * *
8/3/10	162	STIPULATION of Dismissal With Prejudice of the Counterclaim of Defendants Paddock Laboratories, Inc., Par Pharmaceutical Companies, Inc.. (Grelecki, Ryan) Modified on 8/4/2010 to correct duplicate text. (cem) (Entered: 08/03/2010)
8/4/10		Clerk's Entry of Dismissal APPROVING 162 Stipulation of Dismissal with prejudice of the counterclaim pursuant to Fed. R. Civ. P. 41(a)(1)(ii). (cem) (Entered: 08/04/2010)
		* * * * *

DOCKET		
DATE	NUMBER	PROCEEDINGS
4/25/12	173	USCA Opinion received re: 158 Notice of Appeal filed by Federal Trade Commission. In accordance with FRAP 41(b), the USCA mandate will issue at a later date. Case Appealed to USCA Case Number 10-12729. (fem) (Entered: 04/25/2012)
		* * * * *
7/27/12	174	Certified copy of JUDGMENT of USCA AFFIRMING the decision of the District Court re 173 USCA Opinion re: 158 Notice of Appeal filed by Federal Trade Commission Case Appealed to USCA Case Number 10-12729. (fem) (Entered: 07/27/2012)

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA AT-
LANTA DIVISION

Civil Action
File No. 1:09-CV-00955-TWT

FEDERAL TRADE COMMISSION, ET AL., PLAINTIFF

v.

WATSON PHARMACEUTICALS, INC., ET AL., A CORPORA-
TION; PAR PHARMACEUTICAL COMPANIES, INC., A
CORPORATION; PADDOCK LABORATORIES, INC.,
A CORPORATION; AND SOLVAY PHARMACEUTICALS,
INC., A CORPORATION, DEFENDANTS

Filed: May 28, 2009

**SECOND AMENDED COMPLAINT FOR
INJUNCTIVE AND OTHER EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission (FTC), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) (2005), for a permanent injunction against defendants Watson Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., Paddock Laboratories, Inc., and Solvay Pharmaceuticals, Inc., to undo and prevent their unfair methods of competition in or affecting

commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

I. Nature of the Case

1. This case challenges agreements by Watson, Par, and Paddock to delay until 2015 the sale of low-cost generic versions of AndroGel, a widely prescribed branded testosterone replacement drug, in exchange for substantial payments from Solvay.

2. By 2006, AndroGel had grown to be Solvay's top-selling pharmaceutical product, with U.S. sales of over \$300 million. The prospect of generic competition, however, threatened Solvay's AndroGel profits. Several years earlier, Watson and Paddock (which then partnered with Par) had filed applications with the U.S. Food and Drug Administration to market generic versions of AndroGel, and by early 2006 Watson had received final approval to market its generic product. Defendants knew that if generic entry were to occur, Solvay's sales would plummet, as generic AndroGel would be priced dramatically lower than branded AndroGel. Solvay's loss, however, would be consumers' gain, as they would save hundreds of millions of dollars by purchasing lower-cost generic alternatives.

3. After Watson and Paddock had announced their plans to sell generic AndroGel, Solvay sued the generic companies for infringing the only patent Solvay had relating to AndroGel. In the ensuing litigation, each of the generic companies vigorously asserted that its product was outside the scope of Solvay's patent, that the patent was invalid, and that Solvay withheld important infor-

mation from the Patent and Trademark Office in obtaining the patent. Had the patent suit proceeded, Solvay's patent was unlikely to prevent generic entry.

4. Eventually, Defendants recognized that they would each be better off by cooperating and sharing in Solvay's monopoly profits than by competing. Solvay's own financial analysis highlighted this dynamic. From this analysis, Solvay knew that it would need to pay the generic firms to agree to stay off the market until 2015, Solvay's desired generic entry date. At the same time, Solvay knew that—because eliminating price competition would preserve its monopoly profits—it could easily afford to pay the generic firms to delay their entry until 2015.

5. In the end, Watson, Par, and Paddock agreed to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years. Together with Solvay, they also identified ways to transfer the money to the generic firms: via co-promotion arrangements and a back-up supply deal executed on the same day as the companies' patent settlements.

6. As a result of Defendants' agreements, Watson and Par, rather than competing against Solvay, are partnering with Solvay to promote AndroGel and share in monopoly profits—with expected payments of hundreds of millions of dollars collectively. Solvay's substantial payments to Watson, Par, and Paddock—not the strength of Solvay's patent—have prevented generic competition to AndroGel until 2015. These agreements

deny consumers the opportunity to purchase lower-cost, generic versions of AndroGel, at a cost of hundreds of millions of dollars a year.

II. Jurisdiction and Venue

7. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345

8. This Court has personal jurisdiction over each Defendant pursuant to 15 U.S.C. § 53(b), and because each Defendant has the requisite constitutional contacts with the United States of America.

9. Venue in this district is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). Each Defendant resides, transacts business, committed an illegal or tortious act, or is found in this District.

10. Defendants' general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

11. Each Defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. The Parties

12. Plaintiff Federal Trade Commission is an administrative agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Wash-

ington, D.C. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces.

13. Defendant Watson Pharmaceuticals, Inc. (together with its affiliates, “Watson”) is a publicly traded, for-profit company, incorporated in Nevada and with its principal place of business located in Corona, California. Watson is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2007, Watson had net revenues of approximately \$2.5 billion.

14. Defendant Par Pharmaceutical Companies, Inc. (together with its affiliates, “Par”) is a publicly traded, for-profit company, incorporated in Delaware and with its principal place of business located in Woodcliff Lake, New Jersey. Par is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products. In the twelve months ending December 31, 2007, Par had total revenues of approximately \$770 million.

15. Defendant Paddock Laboratories, Inc. (together with its affiliates, “Paddock”) is a privately held, for-profit company, incorporated in Minnesota and with its principal place of business located in Minneapolis, Minnesota. Paddock is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing generic drug products.

16. Defendant Solvay Pharmaceuticals, Inc. (together with its affiliates, “Solvay”) is incorporated in Georgia and has its principal place of business in Marietta, Georgia. Solvay Pharmaceuticals is a subsidiary of Solvay, S.A., a Belgian company whose shares are listed on the Euronext Brussels stock exchange and traded over-the-counter in the United States via American Depositary Receipts. Solvay includes Unimed Pharmaceuticals, Inc., Solvay’s wholly owned subsidiary. Solvay is engaged in the distribution and sale of branded pharmaceutical products, including AndroGel. In the twelve months ending December 31, 2007, Solvay’s U.S. net pharmaceutical revenues totaled about \$1.2 billion, over \$400 million of which were U.S. sales of AndroGel.

IV. Background

A. The regulatory system governing pharmaceuticals in the United States

17. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

18. A company seeking approval from the U.S. Food and Drug Administration (“FDA”) to market a new drug (*i.e.*, a branded drug) must file a New Drug Application

(“NDA”) demonstrating the safety and efficacy of its product.

19. An “AB-rated” generic drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug and there is no significant difference in the quality, safety, and efficacy of the two drugs.

20. A company seeking to market an “AB-rated” generic version of a branded drug must also file an application with the FDA, but may file an Abbreviated New Drug Application (“ANDA”).

21. When a branded drug is covered by one or more patents, a generic drug company that intends to market its generic drug prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA that either (1) the generic version does not infringe the patents on the brand-name drug, or (2) the patents are invalid. This is referred to as a “paragraph IV certification.”

22. If a generic drug company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the generic drug company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA for the generic drug until the earliest of (1) patent expiry, (2) district court resolution of the patent litigation in favor of the generic

company, or (3) the expiration of an automatic 30-month waiting period.

23. The Hatch-Waxman Act gives the first generic company filing an ANDA containing a paragraph IV certification a period of protection from competition with other generic versions of the drug. As to drugs for which the first paragraph IV filing was made before December 2003, as is the case here, the FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first company begins commercial marketing of its generic version of the drug, or (2) an appeals court finds the patent(s) claiming the branded drug invalid or not infringed. This is referred to as “180-day exclusivity.”

B. The consumer benefits of generic drugs

24. Although therapeutically the same as its branded counterpart, the first AB-rated generic equivalent to a branded drug is typically priced significantly lower than the brand. Upon the entry of additional AB-rated generic drugs, generic drug prices generally fall even more.

25. Because of these price advantages, states encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless a physician or the patient directs otherwise. These state laws facilitate substitution of lower-priced AB-rated generic drugs for higher-priced branded drugs.

26. Many third party payers of prescription drugs (*e.g.*, health insurance plans, Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts.

27. As a result of lower prices and the ease of substitution, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a significant reduction of the branded drugs' unit and dollar sales.

28. Competition from generic drugs generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved \$8 to \$10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent branded drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50 percent by purchasing generic drugs when available. According to the National Association of Chain Drug Stores, the average retail price for a brand-name prescription was about \$119 in 2007, while the average retail price for a generic prescription was about \$34.

29. Significant consumer savings can result when generic companies successfully challenge patents and enter prior to patent expiration. For example, a generic company's successful challenge invalidating a patent covering the antidepressant drug Prozac resulted in generic entry 2½ years before patent expiry and about \$2.5 billion in estimated consumer savings. A successful

challenge invalidating patents covering the cancer drug Taxol resulted in generic entry over 11 years before patent expiry and estimated consumer savings of more than \$3.5 billion.

30. There are many other examples of successful patent challenges by generic drug companies. Indeed, empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the alleged infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the alleged infringers had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.

C. Solvay's AndroGel prescription drug

31. Solvay markets a branded prescription drug called AndroGel. AndroGel is a pharmaceutical gel containing synthetic testosterone. Testosterone was first artificially synthesized in 1935 and has been available in various drug products since the 1950s. Pharmaceutical gel products have also been available for decades.

32. In August 1995, Solvay licensed the U.S. rights to the testosterone gel formulation used for AndroGel from the Belgian pharmaceutical company Besins Healthcare,

S.A. (together with its affiliates, “Besins”), which had developed the formulation. At the same time, Besins agreed to provide commercial supply of AndroGel to Solvay after the FDA approved the product for sale.

33. Solvay filed a U.S. New Drug Application for AndroGel in April 1999, which the FDA approved in February 2000. AndroGel is approved for testosterone replacement therapy in men with low testosterone. Low testosterone is often associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions, and can result in fatigue, muscle loss, and erectile dysfunction.

34. Solvay’s sales of AndroGel have grown substantially over time. In 2000, U.S. AndroGel sales were approximately \$26 million. By 2003, U.S. sales had grown to about \$277 million. By 2007, U.S. AndroGel sales were over \$400 million.

35. From 2000 through 2007, cumulative U.S. sales of AndroGel were over \$1.8 billion. These sales substantially exceeded Solvay’s costs of developing AndroGel.

36. AndroGel has consistently been Solvay’s highest-selling product. In 2007, sales of AndroGel accounted for about one third of Solvay’s U.S. pharmaceutical revenues.

37. Solvay sells AndroGel at prices far above Solvay’s cost of obtaining the product from Besins, making AndroGel highly profitable for Solvay. Even accounting for other direct expenses Solvay allocates to selling and marketing AndroGel, Solvay’s profit margin on AndroGel net sales is substantial.

D. Solvay's formulation patent

38. Testosterone, the hormone contained in AndroGel, is unpatented. Patents covering the synthesis of artificial testosterone expired decades ago.

39. In August 2000, five years after Solvay licensed AndroGel from Besins, Solvay and Besins employees applied for a U.S. patent relating to AndroGel. The patent did not claim testosterone itself or methods of using testosterone generally, but rather covered the use of a particular pharmaceutical gel formulation containing testosterone and other specified ingredients in certain amounts.

40. As described in a report by the United States Government Accountability Office, patent examiners are generally expected to process an average of 87 patent applications per year and have time quotas of a total of 19 hours to process each application from its filing through its final acceptance or rejection. These time quotas are reinforced by examiners' bonus compensation, which is largely tied to the number of applications processed to completion. The patent application process is an ex parte process in which patent examiners rely upon the information and candor of applicants. The vast majority of all patent applications are ultimately granted.

41. In prosecuting the patent application relating to AndroGel, Solvay submitted to the patent examiner multiple disclosure statements identifying more than 400 articles and patents discussing previous testosterone and hormone therapies, together with copies of each of

these hundreds of articles and patents in multiple notebooks, comprising more than three feet of materials for the examiner to attempt to review. In addition, Solvay filed more than 240 additional pages of papers, responses, amendments, and declarations.

42. The patent Solvay prosecuted issued on January 7, 2003 as Patent No. 6,503,894 (the “formulation patent”). Five months later, Solvay requested that the Patent and Trademark Office “correct” many claims of the formulation patent—claims originally requested and advocated by Solvay—by inserting a scientific term that would substantially reduce the amount of one of the components of the formulation and change the coverage of the claims. Nonetheless, Solvay represented that this “correction” would not “alter the substance of the patent in any way that would necessitate reevaluation by an Examiner.” The certificate of correction issued some six months later.

43. The formulation patent expires in August 2020. In 2007, Solvay received six months of additional exclusivity from the FDA, until February 2021, based on Solvay’s submission of studies relating to the use of the product in a pediatric population.

V. Potential Generic Competition to AndroGel

A. Generic companies challenge Solvay’s formulation patent

44. In May 2003, Watson and Paddock each filed an application with the FDA for approval to market a generic version of AndroGel. As part of their applications, Watson and Paddock certified that their generic prod-

ucts did not infringe Solvay's formulation patent and that the patent was invalid.

45. Watson filed its ANDA before Paddock and was therefore eligible for 180-day exclusivity under the Hatch-Waxman Act.

46. Paddock sought a partner to share the costs and risks associated with litigation, together with the rewards from a successful outcome. Paddock eventually reached a deal with Par, which was a top-ten generic drug company and a veteran of pharmaceutical patent litigation. Under the deal, Par agreed to share litigation costs with Paddock, market Paddock's generic product following launch, and share in the resulting profits. Par agreed to partner with Paddock on generic AndroGel only after conducting diligence on Paddock's ANDA in light of Solvay's formulation patent.

47. In August 2003, Solvay and Besins filed separate patent infringement lawsuits against Watson and Paddock, alleging that each infringed the formulation patent. Under the Hatch-Waxman Act, Solvay's lawsuits triggered automatic 30-month stays of final FDA approval of Watson's and Paddock's generic versions of AndroGel. Under FDA rules, the stays expired in January 2006.

B. Solvay prepares for the threat of generic competition

48. In early 2006, under the direction of a new CEO, Solvay analyzed the financial risk from potential generic competition to AndroGel. Solvay concluded that this risk was substantial. As the company's CEO noted at

the time, if generics were to enter, “the economics are obviously not good.”

49. Solvay estimated that if generic products were to launch in mid-2006, Solvay would lose about 90 percent of its AndroGel sales within a year. Even factoring in the cost savings to Solvay from not purchasing and promoting AndroGel, Solvay estimated that generic competition would cut its profits by about \$125 million a year.

50. Watson projected a similar dramatic impact from generic AndroGel entry. A February 2006 Watson forecast projected that generic AndroGel would sell for about 25 percent of the price of branded AndroGel within a year of generic entry, and that generic products would capture nearly 80 percent of all prescriptions.

51. Par’s forecasts projected even steeper price reductions from generic entry. A Par forecast, also prepared in February 2006, projected that the price of generic AndroGel would fall to 15 percent of the branded price within a year and that 90 percent of all prescriptions would go to generic products.

52. In late January 2006, Watson received final FDA approval for its generic product, meaning the FDA had determined that Watson’s generic AndroGel was as safe and effective as branded AndroGel. With final FDA approval, Watson could launch its generic version of AndroGel unless Solvay was able to satisfy the relevant burdens to obtain a preliminary injunction in the patent case to prevent Watson’s launch.

53. Solvay realized that Watson’s receipt of final FDA approval represented a near-term threat to its AndroGel

franchise. Shortly after Watson received FDA approval, Solvay's CEO advised his superiors in Europe that Watson might launch sometime in 2006 even if the patent litigation had not concluded: "The next event will be a court hearing probably in June [2006]. They could then launch if things go well for them."

54. This concern was well-founded. As of February 2006, Watson's forecast for generic AndroGel reflected a generic entry date of January 2007. A February 2006 Par forecast assumed that Watson would launch in March 2006, and Par would follow in September 2006. Par's CEO reported to investment analysts in February 2006 that if generic AndroGel didn't launch in 2006, it "should certainly hit in 2007."

55. Both Watson and Par/Paddock took concrete steps to prepare for a generic launch. Paddock, which had an average annual company-wide equipment budget of about \$1 million, spent about \$750,000 on commercial manufacturing equipment for generic AndroGel. Watson also ordered commercial manufacturing equipment for generic AndroGel and planned for manufacturing validation in mid-2006 and commercial manufacturing in late 2006.

56. In spite of the threat of generic entry, Solvay did not try to obtain from the court a preliminary injunction to prevent Watson's or Par/Paddock's launch. Rather, Solvay searched for ways to settle its patent disputes and eliminate the near-term threat of generic competition without risking an adverse court decision.

VI. Solvay Pays Watson and Par/Paddock for their Agreement Not to Compete

A. Solvay enters negotiations knowing it will have to compensate Watson and Par/Paddock in exchange for deferred generic competition

57. In preparation for settlement negotiations with Watson and Par, Solvay put together a financial model to analyze its settlement options (hereinafter the “Project Tulip Financial Analysis”) (attached as Ex. A). Solvay had already decided that it wanted to defer generic entry until 2015. The 2015 entry date was not based on Solvay’s view of the likelihood of prevailing in the patent litigations against its potential generic rivals, but instead was selected for internal business purposes. The purpose of the Project Tulip Financial Analysis was to assess—by evaluating the generics’ expected return from continuing to litigate—whether, and under what circumstances, the generic companies would accept this delayed entry date. From the Project Tulip Financial Analysis, Solvay concluded that Watson and Par might agree to a settlement that somewhat deferred generic entry. But if Solvay wanted a settlement that delayed generic entry until 2015, it had to pay Watson and Par.

58. The Project Tulip Financial Analysis also confirmed that Solvay could easily afford to buy Watson’s and Par’s agreement not to compete. By deferring competition, the parties would preserve monopoly profits that could be shared amongst them—at the expense of the consumer savings that would result from price competition. Thus, even after paying Watson and Par a share of its profits, Solvay still expected to make more

in AndroGel profits by maintaining its monopoly until 2015 than by continuing to litigate.

59. Solvay's Project Tulip Financial Analysis was discussed among the company's CEO and other key executives and formed the basis for Solvay's negotiating strategy. When it negotiated with Watson and Par, Solvay expected that it would need to compensate the generic companies to obtain their agreement not to launch generic AndroGel until 2015.

B. Solvay and Watson agree not to compete but rather to cooperate and share monopoly profits

60. At the beginning of settlement negotiations, Watson proposed that Solvay share AndroGel revenues with Watson through an arrangement under which Watson would co-promote AndroGel to doctors. Just months before, a consulting firm had helped Solvay conduct a comprehensive analysis of Solvay's AndroGel promotion options. That analysis concluded that AndroGel co-promotion was unlikely to make sense for Solvay, and that Watson did not meet the criteria set forth for potential co-promotion partners. Nonetheless, Solvay quickly agreed to consider allocating a portion of AndroGel sales to Watson through a co-promotion arrangement as a means to buy years of protection from competition.

61. Watson was willing to accept Solvay's 2015 generic entry date only if the price was right on the co-promotion arrangement. Watson insisted that it receive a high share of profits from all AndroGel sales to urologists, the group of doctors to which Watson would promote AndroGel. Watson demanded not only a share of

incremental AndroGel sales that Watson might help build, but also a majority share of Solvay's established sales and business. Solvay relented. On April 27, 2006, Solvay's CEO reported to his superiors in Europe that Solvay and Watson had "agreed terms on the Urology 'carve-out' . . . as a basis for settlement of the current litigation."

62. Watson agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. Branded pharmaceutical companies frequently introduce a "line extension," or a new branded product that is related to but different from an existing product, to preserve sales of a branded franchise. This is an effective commercial strategy because generic versions of the existing product are not automatically substitutable for the new "line extension" product.

63. In the case of AndroGel, Solvay plans to market a testosterone gel containing 1.62% testosterone—more than the 1% testosterone contained in AndroGel—that would allow patients to achieve similar therapeutic benefits with less volume of gel. Solvay plans to shift sales from AndroGel to its new low volume product before 2015. Solvay told Watson of its plans for a line extension product during settlement negotiations. Watson accepted Solvay's 2015 generic entry date even though a line extension product could have a severe negative impact on its potential sales of generic AndroGel by 2015. Watson would not have accepted the 2015 generic entry date

in light of these risks, absent Solvay's sharing of AndroGel monopoly profits through the co-promotion deal.

64. Only after Solvay and Watson had agreed to a generic entry date and a "urology carve-out," including the percentage of urology-based profits that Watson would receive, did the parties negotiate other key terms of the co-promotion arrangement, including the number of sales calls Watson would be required to make to doctors.

65. On September 13, 2006, Solvay, Besins, and Watson entered written agreements to settle their patent litigation. Under the parties' settlement, Watson agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.

66. Solvay and Watson simultaneously entered into the co-promotion deal that provided substantial compensation to Watson. Under the deal, Watson agreed to promote AndroGel to urologists and Solvay agreed to share AndroGel profits with Watson through September 2015. At the time it negotiated the deal, Solvay projected that it would pay Watson about \$19 million during the first year of its agreement, rising to over \$30 million annually by the end of the deal. Under the parties' arrangement, Watson also obtained the right to co-promote any line extension product, and thus share in any profits of that product.

67. The compensation Solvay agreed to provide Watson was designed to, and did, induce Watson to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than

compete, Solvay and Watson agreed to cooperate on AndroGel and share in monopoly profits.

68. Solvay and Watson filed a voluntary stipulation of dismissal terminating their patent litigation in the district court. The parties did not file their settlement and co-promotion agreements with the court, nor were the agreements contingent on court approval.

C. Solvay, Par, and Paddock agree not to compete but rather to cooperate and share monopoly profits

69. Under its partnership with Paddock, Par was responsible for conducting the patent litigation with Solvay and negotiating any settlement.

70. Par, like Watson, was willing to settle the AndroGel patent litigation and stay out of the market for the right price. In the words of a senior Par executive, Par was looking to “extract payments” from Solvay in settlement negotiations.

71. During negotiations, Par quickly accepted Solvay’s proposed 2015 generic entry date, contingent on the parties’ ability to reach agreement on the value that Par would receive in a settlement.

72. To agree on a value, Solvay and Par exchanged forecasts analyzing the profits Par would make from sales of generic AndroGel beginning in 2007. These forecasts discounted Par’s generic AndroGel revenues to reflect Par’s probability of prevailing in the patent litigation. According to a senior Solvay executive, Solvay developed these forecasts to “demonstrate to [Par] what [its] options are, either litigate or enter into these—this

business arrangement. . . . And if we entered into the business arrangement, we wouldn't be litigating. They go hand in hand.”

73. Based on the discounted value of Par's forecasted profits from selling generic AndroGel from 2007 through 2015—which Par would forgo in a settlement—Solvay and Par were able to “agree on a value” Par would receive in exchange for settling the litigation. Solvay and Par agreed on the payments Par would receive for deferring entry before agreeing on the other terms of the deal. On May 13, 2006, the parties confirmed by e-mail their “agreed-upon settlement of \$12 million per year for 6 years coupled with manufacturing/development and/or a co-promotion between Par and Solvay.”

74. About two weeks after Solvay agreed to pay Par \$12 million per year for six years, the parties met to discuss what type of business arrangement would accompany the settlement. The parties considered a number of options, including co-promoting various Solvay drugs; manufacturing AndroGel or serving as a back-up manufacturer; and assisting in development of new AndroGel formulations. Ultimately, the parties decided that Par would co-promote AndroGel to doctors and receive \$10 million annually, and Paddock would serve as a back-up manufacturer for AndroGel and receive \$2 million annually. As a Besins executive stated in an e-mail, a “back-up manufacturer strategy [was] a partial way to compensate Parr [sic] for not entering the market.”

75. After Solvay and Par had agreed to the 2015 generic entry date and \$12 million per year in payments, and settled on the concept of AndroGel co-promotion,

the parties negotiated other key terms of the co-promotion arrangement. In an initial term sheet, Solvay proposed that Par perform at least 90,000 sales calls a year and promote AndroGel first in each call. Under this proposal, Solvay would have paid Par about \$110 per sales call, about the same amount Solvay had received in another co-promotion arrangement it had entered. Solvay ultimately agreed, however, to accept substantially fewer sales calls—only 30,800—and Par did not even commit to promoting AndroGel in the first position. Under the final agreement, Solvay agreed to pay Par over \$300 per sales call.

76. On September 13, 2006, the same day the Solvay/Watson agreements were signed, Solvay, Besins, Par, and Paddock entered written agreements to settle their patent litigation. Under the parties' settlement, Par and Paddock agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.

77. Solvay and Par simultaneously entered into co-promotion and back-up manufacturing deals which provided substantial compensation to Par and Paddock. Under the co-promotion deal, Solvay agreed to pay Par \$10 million per year for six years and Par agreed to promote AndroGel to primary care doctors. Under the back-up manufacturing deal, which Par signed but assigned to Paddock, Solvay agreed to pay Paddock \$2 million per year for six years and Paddock agreed to serve as a back-up manufacturer for AndroGel. Solvay also agreed to reimburse Paddock for any capital expendi-

tures associated with meeting FDA requirements to manufacture AndroGel.

78. At the same time Par signed its agreements with Solvay, it agreed to pay \$6 million up front to Paddock, which was accomplished by transferring title of Paddock's ANDA to Par. This payment was necessary to obtain Paddock's assent to the patent settlement.

79. The compensation Solvay agreed to provide Par and Paddock was designed to, and did, induce Par and Paddock to settle the AndroGel patent litigation by agreeing to refrain from marketing generic AndroGel until 2015. Rather than compete, Solvay, Par and Paddock agreed to cooperate on AndroGel and share in monopoly profits.

80. The district court hearing the patent litigation dismissed Solvay's patent lawsuit against Paddock under a consent judgment filed by the parties. The parties did not file their settlement, co-promotion, and back-up manufacturing agreements with the court, nor were the agreements contingent on court approval.

D. Solvay's business deals with Watson and Par/Paddock make economic sense only as payments to defer generic entry

81. The co-promotion and back-up manufacturing deals induced Watson, Par, and Paddock to agree to refrain from marketing generic AndroGel until 2015 and provided Solvay the means to share preserved AndroGel monopoly profits with its potential competitors.

82. Solvay's co-promotion deals with Watson and Par are not independent business transactions, for at least the following reasons:

- Prior to settlement discussions with Watson and Par, Solvay had not been looking for a co-promotion partner. Its 2006 business plan for AndroGel assumed “no co-promotion during plan period”; two prior AndroGel co-promotion efforts had been canceled because they had “no significant impact” on sales trends; and a late 2005 analysis from a consulting firm had concluded that future AndroGel co-promotion offered “little revenue upside.”
- Solvay's payments to Watson and Par far exceed the value of the services provided. Solvay projected that it would pay Watson more than \$19 million annually, or over \$300 per sales call. Solvay agreed to pay Par \$10 million per year, also over \$300 per sales call. By contrast, Solvay had previously entered an AndroGel co-promotion deal involving projected payments of around \$30-\$45 per sales call. A senior Watson executive has stated that even \$150 per call would be a “ridiculous” rate—and yet Watson and Par are receiving more than twice that rate from Solvay.
- Other terms of the co-promotion deals also depart from industry standards. Among other things, unlike Solvay's previous AndroGel co-promotion agreements, Solvay cannot terminate either deal early if co-promotion does not improve AndroGel sales.

- Before agreeing to the co-promotion deals, Solvay did not analyze how the Watson or Par co-promotion efforts would affect AndroGel sales—as it did before entering into earlier AndroGel co-promotion agreements.
- When it entered the co-promotion deals, Solvay examined the “Estimated Impact of Settlement” on Solvay’s budget and accounted for co-promotion as a cost of settlement rather than a profitable business deal.

83. Solvay was willing to enter into the co-promotion deals only because Watson and Par agreed to refrain from competing with generic AndroGel until 2015.

84. Solvay’s back-up manufacturing deal with Paddock is not an independent business transaction, for at least the following reasons:

- The back-up manufacturing deal guarantees Paddock \$2 million per year for six years, regardless of whether Paddock ever manufactures AndroGel or ever becomes FDA-qualified to manufacture AndroGel.
- Before settlement discussions with Par, Solvay had considered and rejected several options for AndroGel back-up manufacturing. Solvay had concluded that the \$10-12 million in capital expenditures required to qualify a back-up manufacturer could not be justified in light of the reliable source of supply from Besins.

- Before entering the back-up manufacturing deal, Solvay conducted no diligence on Paddock's manufacturing facilities. A later site visit showed that Paddock was not able to manufacture AndroGel using Besins' already-FDA-approved process, requiring substantial and lengthy efforts to conform Paddock's facilities and processes to meet FDA-approved standards. Solvay has paid Paddock \$2 million per year since September 2006 despite the fact that Solvay did not even apply for the required FDA approval for Paddock to serve as a back-up manufacturer until November 2008. Under the parties' deal, Solvay must also reimburse Paddock for any capital expenditures in connection with its qualification efforts.

85. Solvay was willing to enter into the back-up manufacturing deal only because Par and Paddock agreed to refrain from competing with generic AndroGel until 2015.

VII. Solvay's Patent Was Unlikely to Prevent Generic Competition to AndroGel

86. Over the course of their patent litigation with Solvay and Besins, Watson and Par/Paddock developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the formulation patent and that the patent was invalid and/or unenforceable. As a result, Solvay was not likely to prevail in each of its patent lawsuits to prevent competition to AndroGel.

87. Watson and Par/Paddock argued that the scope of the formulation patent was limited, and that their products were outside the scope of the patent claims. They assembled evidence that their generic products did not infringe the patent because their products contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent.

88. Watson and Par/Paddock also argued that the formulation patent was invalid. Among other things, these firms developed evidence that:

- The patent was invalid under 35 U.S.C. § 102(b) for prior commercial sale or public use of the patented invention, in that Besins offered the invention for sale to Solvay in 1995—a fact that Solvay and Besins withheld from the Patent and Trademark Office.
- The patent was invalid as obvious under 35 U.S.C. § 103 because the gel formulations and related methods covered by the patent were obvious variations of existing products and methods. As a Paddock executive noted in a 2006 e-mail characterizing the views of Paddock’s CEO, Paddock was “providing [testosterone] gel formulations to customers over 10 years ago, so the patent simply cannot be valid.”
- Many of the patent claims were invalid under 35 U.S.C. § 112 for failure to meet the “written description” requirement.

89. The generic firms also argued that the certificate of correction, which changed the scope of some of the patent claims, was invalid and, because the certificate of correction issued after Solvay filed its patent suits, the certificate did not apply to the pending litigations. Watson further argued that the patent was unenforceable based on evidence that Solvay and Besins did not disclose their 1995 commercial supply agreement to the patent examiner when they applied for the formulation patent.

90. By late 2005, Watson and Par/Paddock had filed motions for summary judgment on two of these issues, and addressed others in claim construction briefing and expert reports.

91. Solvay and Besins bore the burden of proving that Watson and Par/Paddock each infringed the formulation patent—in other words, that the generic products were within the scope of the patent claims. Solvay and Besins had not met their burden when the litigation ended in settlements.

92. Solvay and Besins were unlikely to prevent generic entry through their patent lawsuits. To do so, Solvay and Besins had to prove infringement by both Watson and Par/Paddock, and also had to defeat each of the generics' invalidity and unenforceability arguments. If either Watson or Par/Paddock had prevailed on any one of these issues, Solvay's formulation patent could not have blocked generic entry, and consumers would have saved millions of dollars a year.

VIII. The AndroGel Settlements Harm Competition and Consumer Welfare

93. Prior to their settlement, Solvay and Watson were potential competitors. By entering into their agreement, Solvay and Watson eliminated the potential that (1) Watson would have entered “at risk” and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Watson would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Watson would have agreed to settle their patent litigation on terms that did not compensate Watson, but provided for generic entry earlier than 2015.

94. Prior to their settlement, Solvay and Par/Paddock were potential competitors. By entering into their agreement, Solvay and Par/Paddock eliminated the potential that (1) Par/Paddock would have entered “at risk” and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Par/Paddock would have agreed to settle their patent litigation on terms that did not compensate Par/Paddock, but provided for generic entry earlier than 2015.

95. If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay’s patent. During settlement negotiations with Solvay, Par prepared forecasts that showed the risk to Solvay if it settled with Watson and not with Par—that risk being that Par would continue to litigate and prevail.

Par's forecasts also showed that, even as a generic applicant entering six months after Watson, Par expected to earn significantly more in generic AndroGel profits than its expected costs of litigation.

96. Defendants eliminated this potential competition and harmed consumers by entering agreements that compensated Watson and Par/Paddock for agreeing to refrain from marketing generic AndroGel until 2015. Defendants' agreements to eliminate potential competition until 2015 were based not on the strength of Solvay's patent, but on the compensation Solvay provided to Watson, Par, and Paddock in exchange for a 2015 generic entry date. Absent compensation, Watson and Par/Paddock would not have agreed to refrain from competing until 2015.

97. Moreover, absent the compensation Solvay agreed to provide, generic competition to AndroGel would have occurred before 2015 because (1) Watson and/or Par/Paddock would have marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Solvay would not have prevailed against each of Watson and Par/Paddock in the patent litigation; or (3) Solvay would have agreed to settle the patent litigation on terms that did not compensate Watson and Par/Paddock, but provided for generic entry earlier than 2015.

98. Entry of generic AndroGel would give consumers the choice between branded AndroGel and lower-priced generic versions of AndroGel. Many consumers would choose to purchase lower-priced, generic drugs instead of higher-priced, branded AndroGel. Entry of generic

versions of AndroGel would quickly and significantly reduce Solvay's sales of AndroGel, promote economic efficiency, and lead to a significant reduction in the average price purchasers pay for AndroGel and its generic equivalents. Consumers would save hundreds of millions of dollars a year by purchasing generic versions of AndroGel. Through their anticompetitive agreements, Defendants have retained those potential consumer savings for themselves.

99. The ability to launch generic versions of AndroGel in 2015 will likely provide little benefit to consumers because Solvay plans to switch sales from AndroGel to its new branded product, a low volume version of AndroGel, well before 2015. Generic AndroGel would not be automatically substitutable for Solvay's new branded product. Moreover, Solvay has even considered pulling AndroGel from the market before generics enter in 2015, which would likely eliminate altogether the market for generic AndroGel.

100. The Hatch-Waxman Act was designed to promote generic competition while preserving incentives for branded innovation. Exclusion payment settlements, including Defendants', distort the careful balance achieved by the Hatch-Waxman Act by eliminating generic companies' incentives to compete.

101. Exclusion payments are not a natural by-product of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies. For instance, in fiscal year 2004, following FTC enforcement actions chal-

lenging exclusion payments, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved an exclusion payment.

102. Through its exclusion payment settlements, Solvay bought protection from competition not contemplated by the Hatch-Waxman Act—with consumers paying the price for its anticompetitive conduct.

IX. Solvay's Market and Monopoly Power

103. Solvay has exercised and continues to exercise market and monopoly power in the United States with respect to AndroGel. Direct evidence of this power includes Solvay's ongoing ability to price AndroGel substantially higher than the projected price of competing generic versions of AndroGel and to exclude potential competitors by providing significant compensation to forestall entry.

104. In addition, Solvay's market and monopoly power can be shown through circumstantial evidence, including a high share of a relevant market with substantial barriers to entry. Empirical and documentary evidence demonstrate that the relevant market for antitrust purposes in this case is no broader than testosterone drugs delivered transdermally (through the skin) and approved by the FDA for sale in the United States. Other testosterone drugs, such as those delivered by injection, are not close enough substitutes to prevent Solvay and other market participants from profitably raising prices. AndroGel has consistently accounted for more than 70 percent of transdermal testosterone drug sales. Sub-

stantial barriers to entry exist in the transdermal testosterone drug market, including the need to conduct expensive clinical trials and obtain FDA approval.

105. Narrower relevant product markets may also exist for purposes of assessing Defendants' conduct and Solvay's market and monopoly power, including one consisting of AndroGel and its generic equivalents. A unique competitive relationship exists between branded drugs and their generic equivalents, including AndroGel and generic AndroGel. Although other testosterone drugs may be used to treat low testosterone, the availability of these drugs is not sufficient to prevent the anti-competitive effects from Defendants' conduct. Solvay has consistently held a 100 percent share of sales of AndroGel and its generic equivalents. Possible sellers of generic AndroGel face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities, and Solvay's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit. Moreover, Defendants' agreements have diminished the economic incentives to potential generic entrants of challenging the AndroGel formulation patent, since the terms of the agreements allow for immediate entry of generic AndroGel by Watson and Par/Paddock upon the launch of generic AndroGel by any other generic manufacturer.

Count I

Restraint of Trade—Against Watson and Solvay

106. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above. The

agreement between Watson and Solvay that Watson will not compete by marketing a generic version of AndroGel until 2015, in exchange for compensation, is an unfair method of competition that violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count II

Restraint of Trade—Against Par, Paddock, and Solvay

107. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above.

108. The agreement among Par, Paddock, and Solvay that Par/Paddock will not compete by marketing a generic version of AndroGel until 2015, in exchange for compensation, is an unfair method of competition that violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count III

Monopolization—Against Solvay

109. Plaintiffs reallege and incorporate by reference the allegations in all of the paragraphs above.

110. At all times relevant to this complaint, Solvay has had monopoly power in the United States with respect to AndroGel.

111. Solvay has willfully maintained its monopoly power through its agreements with Watson, Par, and Paddock that those companies will not compete by marketing generic versions of AndroGel until 2015, in exchange for compensation. Entry of a generic version of AndroGel would eliminate Solvay's monopoly with respect to AndroGel. At the time of the agreements, Wat-

son and Par/Paddock were threats to enter with generic versions of AndroGel before 2015. Eliminating this threat of generic entry is conduct that is reasonably capable of contributing significantly to Solvay's continued monopoly power. Solvay has willfully maintained its monopoly and excluded competition through its anti-competitive conduct. Solvay has unlawfully extended its monopoly not on the strength of its patent, but rather by compensating its potential competitors.

112. Solvay's acts are anticompetitive and constitute an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26 and its own equitable powers, enter final judgment against Defendants on Counts I-III, declaring, ordering, and adjudging:

1. That the agreement between Watson and Solvay violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
2. That the agreement among Par, Paddock, and Solvay violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

3. That Solvay's course of conduct, including its agreements with Watson, Par, and Paddock, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
4. That Defendants are permanently enjoined from engaging in similar and related conduct in the future; and
5. That the Court grant such other equitable relief as the Court finds necessary to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: May 28, 2009

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Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
(Atlanta)

Civil Docket For Case No. 1:03-cv-02501-TWT

UNIMED PHARMACEUT, ET. AL.

v.

WATSON PHARMACEUTICALS, INC.

DOCKET ENTRIES

DOCKET		
DATE	NUMBER	PROCEEDINGS
8/21/03	1	COMPLAINT filed and summons(es) issued. Consent form to proceed before U.S. magistrate and pretrial instructions given to attorney; jury demand FILING FEE \$ 150.00 RECEIPT # 509983 (jdb) (Entered: 08/25/2003)
		* * * * *
8/21/03	3	AMENDED COMPLAINT by plaintiff Unimed Pharmaceut adding Laboratories Besins; jury demand (jdb) (Entered: 08/25/2003)

* * * * *

DOCKET
DATE NUMBER PROCEEDINGS

10/27/03 8 ANSWER by Watson Pharma to first amended complaint [3-1] and COUNTERCLAIM against Unimed Pharmaceut, Laboratories Bessins Discovery ends 7/23/04 (dr) (Entered: 10/29/2003)

* * * * *

11/17/03 10 ANSWER by Unimed Pharmaceut to counterclaim [8-2]; jury demand. (dr) (Entered: 11/21/2003)

* * * * *

2/26/04 22 HEARING HELD before Judge Thomas W. Thrash to resolve scheduling issues; Court is allowing plus 15 depositions to be taken for both cases and each dft 12 depositions extending time limits from 7 hours to 10 hours each; Mr. Ladow to prepare order (dr) (Entered: 03/03/2004)

* * * * *

7/12/04 40 Minute Entry for Telephone Conference regarding electronic discov-

DOCKET
DATE NUMBER PROCEEDINGS

ery dispute held on 7/12/2004 before Judge Thomas W. Thrash Jr.; Court directed filing of letters from counsel regarding disputes; Court set forth limitations as to electronic discovery as detailed on the record as accepted in Exhibit A & B. (Exhibits attached to minute entry in case 03-cv-2503-TWT) (Court Reporter Darla Coulter.) (dr) (Entered: 07/21/2004)

* * * * *

10/5/04 46 NOTICE of Hearing: In Chambers telephone Conference set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr. on discovery dispute. (ss) (Entered: 10/05/2004)

* * * * *

10/15/04 49 NOTICE of Hearing: In Chambers Conference by telephone set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr., amended to include further discovery disputes. (ss) (Entered: 10/15/2004)

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* * * * *

10/21/04 52 Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: In Chambers Conference held on 10/21/2004; Court heard from counsel re discovery; counsel advised issues in latter by Mr. Rabin have been resolved; Court DENIES the motion to compel; Mr. Taylor to prepare order summarizing Court's rulings. (Court Reporter Darla Coulter.) (dr) (Entered: 10/28/2004)

* * * * *

7/25/05 89 First Claim Construction Brief of *Watson Pharmaceuticals, Inc.* (Rabin, David) (Entered: 07/25/2005)

* * * * *

7/25/05 91 FILED UNDER SEAL First Markman Brief of *Unimed Pharmaceuticals, Inc. and Laboratories Besins Iscovesco.* (Attachments: # 1 Exhibit Exhibit A (Part 1)# 2 Exhibit Exhibit A (Part 2)# 3 Ex-

DOCKET
DATE NUMBER PROCEEDINGS

hibit Exhibit B# 4 Exhibit Exhibit
C# 5 Exhibit Exhibit D# 6 Exhibit
Exhibit E# 7 Exhibit Exhibit F# 8
Exhibit Exhibit G# 9 Exhibit Ex-
hibit H# 10 Exhibit Exhibit I (Part
1) # 11 Exhibit Exhibit I (Part 2)
12 Exhibit Exhibit I (Part 3)# 13
Exhibit Exhibit I (Part 4)# 14 Ex-
hibit Exhibit J# 15 Exhibit Exhibit
K# 16 Exhibit Exhibit L# 17 Ex-
hibit Exhibit M# 18 Exhibit Exhib-
it N# 19 Exhibit Exhibit O)
(Ferguson, James) Modified on
7/28/2005 to restrict access as plea-
ding inadvertently contained sealed
material—attorney advised to file
motion to seal pleading w/in 24
hours—chambers contacted (fmm).
Modified on 8/3/2005 (dr). (En-
tered: 07/25/2005)

* * * * *

8/12/05 106 RESPONSE re 91 Markman
Brief,, filed by Watson Pharmaceu-
ticals, Inc.. (Attachments: # 1
Appendix Appendix Exhibits
38-42) (Rabin, David) (Entered:
08/12/2005)

DOCKET
DATE NUMBER PROCEEDINGS

8/12/05 107 Second Claim Construction Brief filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco.. (Attachments: # 1 Exhibit Cover and Index# 2 Exhibit P-S# 3 Exhibit T (Pages 1-11) # 4 Exhibit T (Pages 12-22)# 5 Exhibit U-V# 6 Exhibit W# 7 Exhibit X-DD# 8 Exhibit EE) (Ferguson, James) (Entered: 08/12/2005)

* * * * *

9/9/05 117 MOTION for Partial Summary Judgment with Brief In Support by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Brief # 2 Statement of Material Facts) (Rabin, David)—Please refer to <http://www.gand.uscourts.gov> to obtain the Notice to Respond to Summary Judgment Motion form contained on the Court's website.—(Entered: 09/09/2005)

* * * * *

10/17/05 122 Consolidated Memorandum in Opposition re 117 MOTION for Partial

DOCKET
DATE NUMBER PROCEEDINGS

Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Attachments: # 1 Exhibit A.1# 2 Exhibit A (part 2)# 3 Exhibit A (part 3)# 4 Exhibit B# 5 Exhibit C# 6 Exhibit D# 7 Exhibit E# 8 Exhibit F# 9 Exhibit G# 10 Exhibit H# 11 Exhibit I (part 1)# 12 Exhibit I (part 2)# 13 Exhibit I (part 3)# 14 Exhibit I (part 4)# 15 Exhibit J# 16 Exhibit K# 17 Exhibit L (part 1)# 18 Exhibit L (part 2)# 19 Exhibit M# 20 Exhibit N# 21 Exhibit O# 22 Exhibit P# 23 Exhibit Q# 24 Exhibit R# 25 Exhibit S# 26 Exhibit T# 27 Exhibit U# 28 Exhibit V (part 1)# 29 Exhibit V (part 2)# 30 Exhibit W# 31 Exhibit X (part 1)# 32 Exhibit X (part 2)# 33 Exhibit Y# 34 Exhibit Z# 35 Exhibit AA# 36 Exhibit BB) (Ferguson, James) Modified text on 10/18/2005 (dr). (Entered: 10/17/2005)

10/17/05 123 STATEMENT re 122 Response in Opposition to Motion,, filed by Unimed Pharmaceuticals, Inc.,

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
10/17/05	124	Response to Statement of Material Facts re 117 MOTION for Partial Summary Judgment filed by Uni- med Pharmaceuticals, Inc., Labora- tories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
* * * * *		
11/11/05	139	RESPONSE to 123 Statement of <i>additional facts which are material and present a genuine issue for trial by plaintiffs</i> filed by Watson Pharmaceuticals, Inc.. (Rabin, Da- vid) Modified text on 11/14/2005 (dr). (Entered: 11/11/2005)
11/11/05	140	REPLY to plaintiff's consolidated opposition to 117 MOTION for Partial Summary Judgment filed by Watson Pharmaceuticals, Inc. (Rabin, David) Modified text on 11/14/2005 (dr). (Entered: 11/11/2005)

DOCKET
DATE NUMBER PROCEEDINGS

* * * * *

11/23/05 144 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 for Failure to Comply with the Written-Description Requirement* with Brief In Support by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Memorandum of Law in Support# 2 Statement of Material Facts as to Which There are No Genuine Issues to be Tried) (Rabin, David)—Please refer to <http://www.gand.uscourts.gov> to obtain the Notice to Respond to Summary Judgment Motion form contained on the Court's website.—(Entered: 11/23/2005)

* * * * *

12/19/05 151 RESPONSE in Opposition re 144 MOTION for Partial Summary Judgment *of Invalidity of Claims 1-30 for Failure to Comply with the Written-Description Requirement* filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Isco-

DOCKET
DATE NUMBER PROCEEDINGS

vesco. (Attachments: # 1 Exhibit
CC# 2 Exhibit DD# 3 Exhibit
EE# 4 Exhibit FF# 5 Exhibit
GG# 6 Exhibit HH# 7 Exhibit
II# 8 Exhibit JJ# 9 Exhibit KK)
(Ferguson, James) (Entered:
12/19/2005)

12/19/05 152 STATEMENT re 151 Response in
Opposition to Motion, filed by Uni-
med Pharmaceuticals, Inc., Labora-
tories Besins Iscovesco. (Ferguson,
James) (Entered: 12/19/2005)

12/19/05 153 Response to Statement of Material
Facts re 144 MOTION for Partial
Summary Judgment of *Invalidity
of Claims 1-30 for Failure to Com-
ply with the Written-Description
Requirement* filed by Unimed
Pharmaceuticals, Inc., Laboratories
Besins Iscovesco. (Ferguson,
James) (Entered: 12/19/2005)

* * * * *

1/19/06 164 REPLY Memorandum of Law
in Support its 144 MOTION for
Partial Summary Judgment of *In-*

DOCKET
DATE NUMBER PROCEEDINGS

validity of Claims 1-30 for Failure to Comply with the Written-Description Requirement filed by Watson Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit 48# 2 Exhibit 49# 3 Exhibit 50# 4 Exhibit 51# 5 Exhibit 52# 6 Exhibit 53) (Rabin, David) (Entered: 01/19/2006)

1/19/06 165 RESPONSE re 123 *Statement of Additional Facts Which Are Material and Present a Genuine Issue for Trial* filed by Watson Pharmaceuticals, Inc.. (Rabin, David) (Entered: 01/19/2006)

* * * * *

5/17/06 Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: In Chambers Telephone Conference held on 5/17/2006. (At direction of Court this is only entry) (Court Reporter Darla Coulter.) (ss) (Entered: 05/17/2006)

6/1/06 Minute Entry for proceedings held before Judge Thomas W. Thrash

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Jr.: Telephone Conference held on 6/1/2006. (No PDF attached) (Court Reporter Darla Coulter.) (ss) (Entered: 06/05/2006)
7/5/06		Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Status Conference held on 7/5/2006. No PDF attached. (Court Reporter Andy Ashley.) (ss) (Entered: 07/05/2006)
7/31/06		Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Status Conference held on 7/31/2006. Proceedings ORDERED UNDER SEAL. No PDF attached. (Court Reporter Elise Evans.) (ss) (Entered: 07/31/2006)
8/1/06	170	NOTICE of TELECONFERENCE Hearing: Status Conference set for 9/6/2006 02:15 PM before Judge Thomas W. Thrash Jr., plaintiff counsel to originate call. (ss) (Entered: 08/01/2006)
9/6/06	171	NOTICE of TELECONFERENCE Hearing: Status Confer-

DOCKET		
DATE	NUMBER	PROCEEDINGS
		ence set for 9/13/2006 02:15 PM before Judge Thomas W. Thrash Jr. (ss) (Entered: 09/06/2006)
9/6/06	172	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/6/2006. (Court Reporter Pat Tanner.) (dr) Additional attachment(s) added/verified by cdg on 9/7/2006 (dr). (Entered: 09/07/2006)
9/13/06	173	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/13/2006. (Court Reporter Andy Ashley.) (dr) Additional attachment(s) added/verified by cdg on 9/13/2006 (dr). (Entered: 09/13/2006)
9/14/06	174	STIPULATION of Dismissal by Unimed Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Grout, Bradley) (Entered: 09/14/2006)

DOCKET
DATE NUMBER PROCEEDINGS

9/15/06 Clerk's Entry of Dismissal re: 174
Stipulation of Dismissal (dr) (En-
tered: 09/15/2006)

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
(Atlanta)

Civil Docket for Case # 1:03-cv-02503-TWT

UNIMED PHARMACEUT, ET. AL.

v.

PADDOCK LABORATORIES

DOCKET ENTRIES

DOCKET		
DATE	NUMBER	PROCEEDINGS
8/21/03	1	COMPLAINT filed and summons(es) issued. Consent form to proceed before U.S. magistrate and pretrial instructions given to attorney; jury demand FILING FEE \$ 150.00 RECEIPT # 509983 (jdb) (Entered: 08/25/2003)
		* * * * *
8/22/03	4	AMENDED COMPLAINT by plaintiff adding Laboratories Besins; jury demand (jdb) (Entered: 08/25/2003)
		* * * * *

DOCKET		
DATE	NUMBER	PROCEEDINGS
10/2/03	11	ORDER by Judge Richard W. Story, that the Clerk is DIRECTED to reassign case to Judge Thomas W. Thrash. (cc) (lme) (Entered: 10/03/2003)
		* * * * *
10/22/03	14	ANSWER by Paddock Laboratories to complaint [4-1] and COUNTERCLAIM against Unimed Pharmaceut, Laboratories Besins Discovery ends 7/18/04, 11/11/03 for Unimed Pharmaceut (dr) (Entered: 10/24/2003)
11/12/03	15	ANSWER by Unimed Pharmaceut to counterclaim [14-2]; jury demand. (dr) (Entered: 11/19/2003)
		* * * * *

DOCKET

DATE NUMBER PROCEEDINGS

2/24/04 26 HEARING HELD before Judge Thomas W. Thrash to resolve scheduling issues; Court is allowing plus 15 depositions to be taken for both cases and each dft 12 depositions extending time limits from 7 hours to 10 hours each; Mr. Ladow to prepare order (dr) (Entered: 03/03/2004)

* * * * *

7/12/04 32 Minute Entry for Telephone Conference regarding electronic discovery dispute held on 7/12/2004 before Judge Thomas W. Thrash Jr.; Court directed filing of letters from counsel regarding disputes; Court set forth limitations as to electronic discovery as detailed on the record as accepted in Exhibit A & B; (Attachments: # 1 Attachment 1# 2 Attachment 1 Exhibit A# 3 Attachment 1 Exhibit B# 4 Attachment 2# 5 Attachment 2 Exhibit 1# 6 Attachment 2 Exh 2# 7 Attachment 2 Exh 3# 8 Attachment 2 Exh 4# 9 Attachment 2 Exh 5# 10 Attachment 2 Exh 6# 11 Attach-

DOCKET		
DATE	NUMBER	PROCEEDINGS
		ment 2 Exh 7# 12 Attachment 2 Exh 8# 13 Attachment 2 Exh 9# 14 Attachment 2 Exh 10# 15 Attach- ment 2 Exh 11# 16 Attachment 2 Exh 12# 17 Attachment 2 Exh 13# 18 Attachment 2 Exh 14# 19 Attachment 2 Exh 15# 20 Attach- ment 2 Exh 16# 21 Attachment 2 Exh 17# 22 Attachment 2 Exh 18) (Court Reporter Darla Coulter.) (dr) (Entered: 07/21/2004)
		* * * * *
10/5/04	37	NOTICE of Hearing: In Chambers telephone Conference set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr. on discovery dispute. (ss) (Entered: 10/05/2004)
10/15/04	38	NOTICE of Hearing: In Chambers Conference by telephone set for 10/21/2004 10:00 AM before Judge Thomas W. Thrash Jr., amended to include further discovery disputes. (ss) (Entered: 10/15/2004)
10/21/04	39	Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: In Chambers Conference held

DOCKET

DATE NUMBER PROCEEDINGS

on 10/21/2004; Court heard from counsel re discovery; counsel advised issues in latter by Mr. Rabin have been resolved; Court DENIES the motion to compel; Mr. Taylor to prepare order summarizing Court's rulings. (Court Reporter Darla Coulter.) (dr) (Entered: 10/28/2004)

* * * * *

7/25/05 59 FILED UNDER SEAL First Claim Construction Brief by Paddock Laboratories. (Attachments: # 1 # 2 # 3 # 4 # 5 # 6 # 7 # 8 # 9 # 10 # 11) (Trigg, Mark) Modified on 7/27/2005 to restrict access as pleading inadvertently contained sealed material—attorney advised to file motion to seal pleading w/in 24 hours—chambers contacted. (fmm). Modified on 8/3/2005 (dr). (Entered: 07/25/2005)

7/25/05 60 FILED UNDER SEAL First Markman Brief *Unimed Pharmaceuticals, Inc. and Laboratories Besins Iscovesco*. (Attachments: # 1 Exhibit A (Part 1)# 2 Exhibit A (Part

DOCKET		
DATE	NUMBER	PROCEEDINGS
		2)# 3 Exhibit B# 4 Exhibit C# 5 Exhibit D# 6 Exhibit E# 7 Exhibit F# 8 Exhibit G# 9 Exhibit H# 10 Exhibit I (Part 1)# 11 Exhibit I (Part 2)# 12 Exhibit I (Part 3)# 13 Exhibit Part I (Part 4)# 14 Exhibit J# 15 Exhibit K# 16 Exhibit L# 17 Exhibit M# 18 Exhibit N# 19 Exhibit O) (Ferguson, James) Modified on 7/28/2005 to restrict access as pleading inadvertently contained sealed material—attorney advised to file motion to seal pleading w/in 24 hours—chambers contacted. (fmm). Modified on 8/3/2005 (dr). (Entered: 07/25/2005)
		* * * * *
8/12/05	70	Second Claim Construction Brief filed by Paddock Laboratories, Inc... (Attachments: # 1 # 2) (Trigg, Mark) (Entered: 08/12/2005)
8/12/05	71	Second Claim Construction Brief filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco.. (Attachments: # 1 Exhibit Cover and Index# 2 Exhibit P-S# 3

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Exhibit T (Pages 1-11)# 4 Exhibit T (Pages 12-22)# 5 Exhibit U-V# 6 Exhibit W# 7 Exhibit X-DD# 8 Exhibit EE) (Ferguson, James) (Entered: 08/12/2005)
		* * * * *
8/26/05	78	NOTICE by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco re 71 Claim Construction Brief, <i>Supplemental Pleading Regarding Claim Construction</i> (Attachments: # 1 Exhibit A) (Ferguson, James) (Entered: 08/26/2005)
		* * * * *
9/27/05	80	MOTION for Partial Summary Judgment with Brief In Support by Paddock Laboratories, Inc.. (Attachments: # 1 Brief Memorandum of Law in Support of its Motion for Partial Summary Judgment as to the Inapplicability and Invalidity of the Certificate of Correction # 2 Statement of Material Facts) (Trigg, Mark)—Please refer to http://www.gand.uscourts.gov to obtain the Notice to Respond to

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Summary Judgment Motion form contained on the Court's website.— (Entered: 09/27/2005)
10/17/05	81	Consolidated Memorandum in Opposition re 80 MOTION for Partial Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) Modified text on 10/18/2005 (dr). (Entered: 10/17/2005)
10/17/05	82	STATEMENT re 81 Response in Opposition to Motion filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
10/17/05	83	Response to Statement of Material Facts re 80 MOTION for Partial Summary Judgment filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (Entered: 10/17/2005)
		* * * * *
10/18/05	90	MOTION for Partial Summary Judgment <i>of Invalidity of Claims 1-30 of the '894 Patent for Lack of a</i>

DOCKET		
DATE	NUMBER	PROCEEDINGS

Written Description as Required by 35 U.S.C. 112 with Brief In Support by Paddock Laboratories, Inc.. (Attachments: # 1 Brief Memorandum in Support of Paddock's Motion for Partial Summary Judgment of Invalidity of Claims 1-30 of the '894 Patent as Lacking a Written Description as Required by 35 U.S.C. 112, First Paragraph with Respect to the Claimed Ranges of Sodium Hydroxide# 2 Statement of Material Facts Paddock's Statement of Material Facts as to Which There is No Genuine Issue to be Tried in Support of its Motion for Partial Summary Judgment of Invalidity of Claims 1-30 of the '894 Patent Lacking a Written Description Under 35 U.S.C. 112) (Trigg, Mark)—Please refer to <http://www.gand.uscourts.gov> to obtain the Notice to Respond to Summary Judgment Motion form contained on the Court's website.—(Entered: 10/18/2005)

* * * * *

DOCKET		
DATE	NUMBER	PROCEEDINGS
11/11/05	97	REPLY to Response to Motion re 80 MOTION for Partial Summary Judgment <i>in Further Support of its Motion for Partial Summary Judgment as to the Inapplicability and Invalidity of the Certificate of Correction</i> filed by Paddock Laboratories, Inc.. (Trigg, Mark) (Entered: 11/11/2005)
11/11/05	98	RESPONSE to 82 Statement of <i>Additional Facts Which are Material and Present a Genuine Issue for Trial</i> filed by Paddock Laboratories, Inc.. (Trigg, Mark) Modified on 11/14/2005 (dr). (Entered: 11/11/2005)
* * * * *		
12/19/05	106	RESPONSE re 90 MOTION for Partial Summary Judgment of <i>Invalidity of Claims 1-30 of the '894 Patent for Lack of a Written Description as Required by 35 U.S.C. 112</i> filed by Unimed Pharmaceuticals, Inc., Laboratories Besins Iscovesco. (Attachments: # 1 Exhibit CC# 2 Exhibit DD# 3 Exhibit

DOCKET		
DATE	NUMBER	PROCEEDINGS
		EE# 4 Exhibit FF# 5 Exhibit GG# 6 Exhibit HH# 7 Exhibit II # 8 Exhibit JJ# 9 Exhibit KK) (Ferguson, James) (Entered: 12/19/2005)
12/19/05	107	STATEMENT re 106 Response to Motion, filed by Unimed Pharma- ceuticals, Inc., Laboratories Besins Iscovesco. (Ferguson, James) (En- tered: 12/19/2005)
12/19/05	108	Response to Statement of Material Facts re 90 MOTION for Partial Summary Judgment of <i>Invalidity of Claims 1-30 of the '894 Patent for Lack of a Written Description as Required by 35 U.S.C. 112</i> filed by Unimed Pharmaceuticals, Inc., La- boratories Besins Iscovesco. (Ferg- uson, James) (Entered: 12/19/2005)
		* * * * *
1/19/06	120	REPLY BRIEF re 90 MOTION for Partial Summary Judgment of <i>In- validity of Claims 1-30 of the '894 Patent for Lack of a Written De- scription as Required by 35 U.S.C. 112</i> filed by Paddock Laboratories,

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Inc.. (Trigg, Mark) (Entered: 01/19/2006)
1/19/06	121	RESPONSE re 107 Statement of <i>Additional Facts Which are Mat- erial and Present a Genuine Issue for Trial with Respect to Paddock's Motion for Summary Judgment that Claims 1-30 of the '894 Patent are Invalid under 35 ?112</i> filed by Paddock Laboratories, Inc.. (Trigg, Mark) (Entered: 01/19/2006)
		* * * * *
7/24/06	123	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Sta- tus Conference held on 7/24/2006. (Court Reporter David Ritchie.) (ss) Modified access and verified by edg on 7/27/2006 (dr). (Entered: 07/24/2006)

DOCKET		
DATE	NUMBER	PROCEEDINGS
7/24/06	124	NOTICE of Telephone Status Conference scheduled for 9/6/06, 2:00 p.m. EST. Plaintiff's counsel to originate call. (ss) (Entered: 07/24/2006)
		* * * * *
9/6/06	127	NOTICE of TELECONFERENCE Hearing: Status Conference set for 9/13/2006 02:00 PM before Judge Thomas W. Thrash Jr.. (ss) (Entered: 09/06/2006)
9/6/06	128	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/6/2006. (Court Reporter Pat Tanner.) (dr) Additional attachment(s) added/verified by cdg on 9/7/2006 (dr). (Entered: 09/07/2006)

DOCKET		
DATE	NUMBER	PROCEEDINGS
9/13/06	129	FILED UNDER SEAL—Minute Entry for proceedings held before Judge Thomas W. Thrash Jr.: Telephone Conference held on 9/13/2006. (Court Reporter Andy Ashley.) (dr) Additional attachment(s) added/verified by cdg on 9/13/2006 (dr). (Entered: 09/13/2006)
9/14/06	130	PROPOSED CONSENT ORDER Consent Judgment and Order of Permanent Injunction. (Grout, Bradley) (Entered: 09/14/2006)
9/15/06	131	CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION (see order for details) Signed by Judge Thomas W. Thrash Jr. on 9/15/06. (dr) (Entered: 09/15/2006)
9/15/06		Civil Case Terminated. (dr) (Entered: 09/15/2006)
7/9/08	132	FILED UNDER SEAL—TRANSCRIPT of Telephone Conference held on 9/13/06, before Judge Thomas W. Thrash, Jr. Court Reporter/Transcriber Andy Ashley,

DOCKET		
DATE	NUMBER	PROCEEDINGS
		Telephone number 404-215-1478. (dr) (dr). (Entered: 07/09/2008)
7/16/08	133	FILED UNDER SEAL—TRANSCRIPT of Proceedings held on 9/6/06, before Judge Thomas W. Thrash, Jr. Court Reporter/Transcriber Pat Tanner, Telephone number 404-215-1468. (dr) Modified on 10/7/2008 (dr). Modified on 10/14/2008 to correct docket text (fmm). (Entered: 07/17/2008)

* * * * *

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Docket No. 01:03-cv-2501-TWT
UNIMED PHARMACEUTICALS, INC., ET AL., PLAINTIFF
v.
WATSON PHARMACEUTICALS, INC., DEFENDANT

No. 01:03-cv-2503-TWT
UNIMED PHARMACEUTICALS, INC., ET. AL., PLAINTIFF
v.
PADDOCK LABORATORIES, INC., DEFENDANT

Filed: Feb. 26, 2004

**TRANSCRIPT OF PROCEEDINGS BEFORE THE
HONORABLE THOMAS W. THRASH, JR.
UNITED STATES DISTRICT JUDGE**

[13]

THE COURT: All Right. Anything else we need to do today?

MR. BLACKSTOCK: Not for the Plaintiff, your Honor.

THE COURT: This has all the appearances of a long, complicated, expensive, difficult case.

Is there anything that I can do to prevent any of [14] that from happening?

I guess not.

All right.

MR. BLACKSTOCK: Your Honor, we will not hesitate to let you know if we believe the court can be of assistance.

MR. WHITE: Your Honor, likewise. I think one thing we can do is as soon as we see a problem coming, if we are able to bring it to your attention before it becomes multiple problems, that would be helpful.

THE COURT: Well, Mr. Blackstock is familiar with how we handle cases, and I am—And I know my Courtroom Deputy cringes every time she hears me say this, but I am available. And if a disagreement can be resolved by telephone conference call rather than having written motions filed and briefs and back and forth and ongoing festering disagreement that drags on for weeks and months at a time, I'd rather resolve it in a telephone call.

Sometimes you need to precede the telephone call with an exchange of letters to me setting forth the nature of the disagreement just so I have some idea of what it is that you're having a problem with, but I'll do anything to avoid having you all file motions. Anything to avoid that.

All right. Thank you very much.

Court's in recess until further order.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Case No.: 1:03-CV-2503

UNIMED PHARMACEUTICALS, INC., A
DELAWARE CORPORATION, AND LABORATORIES
BESINS ISCOVESCO, A DELAWARE CORPORATION,
PLAINTIFFS

v.

PADDOCK LABORATORIES, INC. A MINNESOTA
CORPORATION, DEFENDANT

Filed: Sept. 15, 2006

**CONSENT JUDGMENT AND ORDER OF
PERMANENT INJUNCTION**

This action for patent infringement (the “Litigation”) has been brought by Plaintiff Unimed Pharmaceuticals, Inc. (“Unimed”) (a wholly-owned subsidiary of Solvay Pharmaceuticals, Inc. (“Solvay”)), and Laboratories Besins Iscovesco (“Besins”), against Defendant Paddock Laboratories, Inc. (“Paddock”) for infringement of United States Patent No. 6,503,894 (the “894 Patent”), covering a pharmaceutical transdermal gel sold under the trademark Androgel® (the “Unimed Product”). Each of Unimed, Solvay, and Besins (the “Plaintiffs”) and Paddock, together with its assignee Par Pharmaceutical Companies, Inc. (“Par”), acknowledge there is signifi-

cant risk to each of them associated with the continued prosecution of this Litigation and have consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules, and as reflected in the consent judgment set forth herein.

Plaintiffs and Paddock, together with Par, have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would result in a number of public interest benefits. Pursuant to a settlement agreement and ancillary patent license agreement (the "Agreements") entered into for the final resolution of this Litigation, Par will be able to market the Paddock Product, as defined herein, by no later than 2016, allowing entry of a generic version of the Unimed Product in advance of the 2020 expiration of the '894 Patent, which competition otherwise might not have occurred or been allowed to continue had Plaintiff prevailed on any one of the numerous claims brought against Paddock in the Litigation.

The proposed settlement also would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Paddock during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This will afford Plaintiffs and Paddock the opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the Parties and consumers alike, such as by investing more money in marketing,

research and development and education of physicians and patients regarding use and benefits of the Unimed Product, that will facilitate competition and the benefits therefrom approximately five years earlier than could be achieved if the Paddock Product were permanently enjoined during the life of the '894 patent.

In order to effectuate this settlement, Par consents to the jurisdiction of this Court.

Plaintiffs and Paddock now consent to this Judgment and Order of Permanent Injunction (the "Judgment") and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.

2. The '894 Patent is owned by Plaintiffs (or its affiliates) and is valid and enforceable, as asserted in their Complaint against Paddock, in all respects.

3. Paddock and Par acknowledge that the claims of the '894 Patent are valid and enforceable in all respects.

4. Paddock and Par acknowledge that the sale of the product described in its Abbreviated New Drug Application No. 76-744 (the "Paddock Product") would infringe the claims of the '894 Patent, as asserted in the Complaint against Paddock.

5. Paddock assigned its rights in the Paddock Product to Par and Par has assumed certain obligations to defend Paddock in the Litigation.

6. As a result, Paddock and Par are barred from practicing the '894 Patent until

the earliest of (a) August 31, 2015, provided there is no commercialization sufficient to trigger Hatch-Waxman 180 day exclusivity; (b) the date any Generic Testosterone Gel Product (as defined in the relevant Agreements) is offered for sale in the Territory (as defined in the relevant Agreements); or (c) in any other event, February 28, 2016, by manufacturing, marketing or selling the Paddock Product, pursuant to the terms of the parties' Agreements that permit the practice of the '894 Patent.

7. The submission of Paddock's Abbreviated New Drug Application No. 76-744 under Section 505(j) of the Federal Food, Drug and Cosmetic Act is an act of infringement of the '894 Patent under 35 U.S.C. 271(e)(2)(A).

8. Paddock and Par would infringe the '894 Patent by selling, offering to sell, importing and/or using the Paddock Product.

9. All affirmative defenses, claims and counter-claims, which have been or could have been raised by Paddock in this action with respect to the validity or enforceability of the '894 Patent, are dismissed with prejudice.

10. Except as agreed to by the parties pursuant to the Agreements in settlement of this Litigation or otherwise, Paddock and Par are also hereby enjoined and estopped during the term of the '894 Patent, from making any challenge to the validity or enforceability of the '894 Patent with respect to the claims asserted against Paddock, or from marketing and selling the Paddock Product.

11. The foregoing injunction against Paddock and Par shall take effect immediately upon entry of this Judgment, and shall continue generally with respect to the '894 Patent coterminous with the license grant provided by the Agreements, unless earlier terminated or modified by further order of this Court.

12. The parties waive all right to appeal from this Judgment.

13. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment.

14. Each party is to bear its own costs and attorney's fees.

Dated: Sept. 14, 2006

By: /s/ BRADLEY W.
GROUT

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Paddock Laboratories,
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SO ORDERED, this 15th day of September, 2006

/s/ THOMAS W. THRASH
THOMAS W. THRASH JR.
United States District
Judge