Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION : CIVIL ACTION
:
PLAINTIFF :
:
VS. :
:
ABBVIE INC. ET AL. :
:
DEFENDANTS : NO. 14-CIV-5151

WEDNESDAY, FEBRUARY 7, 2018
COURTROOM 16A
PHILADELPHIA, PA

BEFORE THE HONORABLE HARVEY BARTLE, J.

NONJURY TRIAL
DAY 1

SUZANNE R. WHITE, CM
FEDERAL CERTIFIED REALTIME REPORTER
FIRST FLOOR U. S. COURTHOUSE
601 MARKET STREET
PHILADELPHIA, PA 19106
(215)627-1882

PROCEEDINGS RECORDED BY STENOTYPE-COMPUTER,
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APPEARANCES:

DANIEL S. BRADLEY, ESQUIRE
REBECCA L. EGELAND, ESQUIRE
GARTH HUSTON, ESQUIRE
HEATHER M. JOHNSON, ESQUIRE
HANNAH LAMB, ESQUIRE
THOMAS D. MAYS, ESQUIRE
PATRICIA M. MCDERMOTT, ESQUIRE
MARKUS H. MEIER, ESQUIRE
KARA L. MONAHAN, ESQUIRE
PETER J. TAYLOR, ESQUIRE
MATTHEW B. WEPRIN, ESQUIRE
JAMES WEINGARTEN, ESQUIRE
FEDERAL TRADE COMMISSION
600 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20580

FOR THE PLAINTIFF

STUART N. SENATOR, ESQUIRE
JEFFREY I. WEINBERGER, ESQUIRE
RANDALL G. SOMMER, ESQUIRE
ADAM R. LAWTON, ESQUIRE
MUNGER TOLLES & OLSON LLP
350 SOUTH GRAND AVENUE
LOS ANGELES, CA 90071
JEFFREY.WEINBERGER@MTO.COM
STUART.SENATOR@MTO.COM
RANDALL.SOMMER@MTO.COM
ADAM.LAWTON@MTO.COM

FOR THE DEFENDANTS ABBVIE, INC., ABBOTT LABORATORIES, AND UNIMED PHARMACEUTICALS

MELINDA F. LEVITT, ESQUIRE
GREGORY E. NEPPL, ESQUIRE
FOLEY & LARDNER LLP
SUITE 500
3000 K STREET, N.W.
WASHINGTON, DC 20007

FOR THE DEFENDANT BESINS HEALTHCARE, INC.

(THE CLERK OPENS COURT.)

THE COURT: GOOD MORNING. YOU MAY BE SEATED.

ALL COUNSEL: GOOD MORNING, YOUR HONOR.

THE COURT: THE COURT HAS BEFORE IT THIS MORNING THE CASE OF FEDERAL TRADE COMMISSION VERSUS ABBVIE, INC. ET AL., CIVIL ACTION 14-5151.

THE PARTIES WOULD LIKE TO MAKE OPENING STATEMENTS.

MS. MCDERMOTT, YOU ARE GOING TO DO SO FOR THE GOVERNMENT?

MS. MCDERMOTT: I AM, YOUR HONOR.

THE COURT: YOU MAY PROCEED.

MS. MCDERMOTT: GOOD MORNING, YOUR HONOR.

MAY IT PLEASE THE COURT, I'M PATTY MCDERMOTT ON BEHALF OF THE FEDERAL TRADE COMMISSION.

AND, YOUR HONOR, I HAVE A SET OF DEMONSTRATIVES THAT I WILL BE USING THIS MORNING. I HAVE HARD COPIES FOR YOUR HONOR, MS. MANCHISI, MS. WHITE AND THE DEFENDANT'S COUNSEL, IF I MAY APPROACH THE BENCH.

THE COURT: YOU MAY.

MS. MCDERMOTT: YOUR HONOR, THIS CASE IS ABOUT DEFENDANT'S SCHEME TO DELAY A LOW COST GENERIC COMPETITION TO ITS FLAGSHIP DRUG ANDROGEL. IT'S ABOUT

DEFENDANT'S FILING OF TWO SHAM PATENT INFRINGEMENT LAWSUITS TO PROTECT THEIR ANDROGEL MONOPOLY.

THE FIRST SUIT WAS FILED AGAINST TEVA IN APRIL OF 2011 IN THE DISTRICT OF DELAWARE. THE SECOND WAS FILED AGAINST PERRIGO IN OCTOBER 2011 IN THE DISTRICT OF NEW JERSEY. AS YOU KNOW, THIS COURT HAS ALREADY HELD THAT BOTH LAWSUITS WERE WITHOUT QUESTION OBJECTIVELY BASELESS. THAT MEANS NO REASONABLE LITIGANT COULD POSSIBLY HAVE BELIEVED THEY COULD PREVAIL ON THEIR CLAIM THAT TEVA'S OR PERRIGO'S PRODUCTS INFRINGED THE ANDROGEL PATENT. YET DEFENDANTS FILED THOSE SUITS ANYWAY. THE EVIDENCE WILL SHOW DEFENDANTS KNEW JUST BY FILING THOSE FRIVOLOUS ACTIONS THEY WOULD TRIGGER AN AUTOMATIC STATUTORY PROVISION THAT BLOCKED THE FDA'S ABILITY TO APPROVE THOSE GENERICS FOR UP TO 30 MONTHS. THAT IS COMMONLY REFERRED TO AS THE 30-MONTH STAY.

FACED WITH THE THREAT OF IMMINENT COMPETITION, DEFENDANTS USED GOVERNMENTAL PROCESSES, HERE TWO FEDERAL COURT -- TWO FEDERAL COURTS IN THE HATCH-WAXMAN ACT AS ANTICOMPETITIVE WEAPONS TO SECURE PROTECTION THAT ANY REASONABLE LITIGANT WOULD KNOW THE ANDROGEL PATENT COULD NOT PROVIDE. USING THESE SHAM LAWSUITS, DEFENDANTS WERE ABLE TO PREVENT TEVA AND PERRIGO FROM COMPETING WITH ANDROGEL UNTIL DECEMBER 2014. THESE TACTICS DEPRIVED CUSTOMERS OF

IS SHOWN ON THAT SCREEN WAS THE RELEVANT MARKET.

THE WITNESSES WILL ALSO EXPLAIN HOW ABBOTT PRICE COMPETED. FOR EXAMPLE, ABBOTT GAVE SIGNIFICANT REBATES TO INSURANCE COMPANIES. ABBOTT DID THIS TO TRY TO GET FORMULARY TIER PLACEMENT THAT REDUCED INSURANCE PAPERWORK AND KEPT THE PATIENT CO-PAY LOW. THE EVIDENCE WILL SHOW THAT SOMETIMES OTHER DRUG COMPANIES WON THE PRICE COMPETITION FOR FORMULARY PLACEMENT BY OFFERING HIGHER REBATES THAN ABBOTT DID. ABBOTT ALSO PRICE COMPETED IN ANOTHER WAY WITH ITS CO-PAY ASSISTANCE CARD. IT PAID OR HAD A PROGRAM TO PAY A PORTION OF THE PATIENT'S CO-PAY AND THAT THIS WORKED TO GET THE PATIENT'S CO-PAY DOWN TO $25 OR LESS, AND THAT WAS TO ENSURE THAT THE PRICE FOR THE PATIENT WAS PRICED COMPETITIVE WITH OTHER TOPICALS, AS WELL AS INJECTABLES. EVEN SO, THE EVIDENCE WILL SHOW THAT THE INJECTIONS KEPT GAINING A BIGGER AND BIGGER SHARE OF TESTOSTERONE PRESCRIPTIONS.

YOU WILL ALSO HEAR SOME EVIDENCE INDICATING THAT FOR A PERIOD OF TIME, AND YOU SAW THIS IN THE OPENING OF MS. MCDERMOTT, THERE WERE PEOPLE AT ABBOTT THAT HAD THE VIEW THAT INJECTABLES WERE NOT CLOSE COMPETITORS FOR THE TOPICALS. AND THE FTC OBVIOUSLY LIKES THIS EVIDENCE. BUT WHAT MR. HYND AND MR. JAEGER WILL THEMSELVES EXPLAIN AND WHAT THE DOCUMENTS SHOW IS

THAT THESE PEOPLE INITIALLY HAD A BIT OF A BLIND SPOT WHEN IT CAME TO INJECTABLES. THEY CAME TO RECOGNIZE OVER TIME THAT ANDROGEL WAS VERY MUCH IN COMPETITION WITH INJECTABLES AND ALL THESE OTHER PRODUCTS AND THAT THIS COMPETITION EXISTED DURING THE ENTIRE PERIOD THAT MIGHT MATTER IN THIS CASE, FROM APRIL 2011 THROUGH THE END OF 2014.

YOU WILL HEAR FROM EXPERT ECONOMISTS. DEFENDANT'S EXPERT IS DR. PIERRE CREMIEUX. FOR DECADES DR. CREMIEUX HAS STUDIED, WORKED IN AND WRITTEN ABOUT THE ECONOMICS OF HEALTH CARE AND DRUG PRICING. NOW DR. CREMIEUX WILL TESTIFY THAT HE ANALYZED ACTUAL DATA RELATING TO COMPETITION AMONG PHARMACEUTICALS THAT ARE USED TO TREAT HYPOGONADISM. HE WILL EXPLAIN THAT THERE IS ROBUST COMPETITION. ANDROGEL DID NOT HAVE A MONOPOLY OR ANYTHING CLOSE. HE REVIEWED ACTUAL PATIENT DATA FROM INSURANCE CLAIMS NATIONWIDE OF OVER 18 MILLION PATIENTS. AND THE DATA SHOWS THAT PATIENTS SWITCHED PRODUCTS. THEY USED GEL, THEN THEY SWITCHED TO AN INJECTION OR THE OTHER WAY AROUND, OR THEY GO FROM ONE GEL TO ANOTHER GEL OR TO A PATCH, AND SO FORTH. THIS SWITCHING OCCURS BOTH TO ANDROGEL AND FROM ANDROGEL, EVIDENCE OF COMPETITION NOT MONOPOLY.

AT THE SUMMARY JUDGMENT ARGUMENT LAST YEAR AND EARLIER TODAY YOUR HONOR ASKED ABOUT OTHER

SITUATIONS WHERE INJECTIONS COMPETE WITH DRUGS ADMINISTERED WITHOUT NEEDLES. AND I DON'T HAVE CASE LAW. I AGREE WITH MS. MCDERMOTT. THERE IS NOT CASE LAW ON THAT.

BUT WHAT THERE IS, IS EVIDENCE OF ANOTHER EXAMPLE, RIGHT AT ABBOTT, RIGHT IN A DOCUMENT WE HAVE ALREADY SEEN. LET'S LOOK BACK AT THAT EXECUTIVE SUMMARY PAGE OF THE 2012 ANNUAL PLAN. SO JUST UNDER THE ITEM WE WERE LOOKING AT A MOMENT AGO, YOU WILL SEE THIS ENTRY IN THE DOWN COLUMN, PFIZER'S ORAL JAK, J-A-K, ENTRY Q3 2012 IN THE HUMIRA RA MARKET. WELL, WHAT DOES THAT MEAN?

SO PFIZER HAD A PRODUCT CALLED ORAL JAK. IT ENDED UP BEING MARKETED UNDER THE NAME XELJANZ, AND THAT WAS GOING TO ENTER THE MARKET IN THE THIRD QUARTER OF 2012. AS THE NAME SUGGESTS, ORAL, IT IS TAKEN BY MOUTH.

NOW, AS THE STATEMENT ALSO SAYS, XELJANZ COMPETES WITH HUMIRA. ABBOTT WITNESSES WILL EXPLAIN THAT HUMIRA IS ABBOTT'S BIGGEST SELLING DRUG. IT TREATS RHEUMATOID ARTHRITIS, A CONDITION THAT LIKE HYPOGONADISM CAN BE TREATED WITH REGULAR MEDICATION. HUMIRA IS AN INJECTABLE TAKEN EVERY OTHER WEEK. SO INJECTABLES CAN COMPETE WITH OTHER DRUG PRESENTATIONS, AND THEY DO HERE WITH HUMIRA, AND THEY DO WITH TESTOSTERONE.

NOW, DR. CREMIEUX WILL ALSO EXPLAIN

ANOTHER PIECE OF EVIDENCE ABOUT HOW COMPETITIVE THE MARKETPLACE WAS FROM APRIL OF 2011 TO DECEMBER OF 2014 PERIOD WE EMPHASIZE BECAUSE THAT IS THE ENTIRETY OF THE POTENTIALLY RELEVANT PERIOD HERE.

NOW, HERE IS A GRAPH OF THESE DRUG SHARES OF TESTOSTERONE REPLACEMENT PRODUCTS. YOU SEE ANDROGEL IN GREEN AND INJECTABLES IN ORANGE. AND WE HAVE COMBINED ANDROGEL AND -- ANDROGEL 1.62% AND ANDROGEL 1%, BOTH PRODUCTS. SO ANDROGEL'S SHARE OF TOTAL TESTOSTERONE REPLACEMENT THERAPY PRESCRIPTIONS AT THE BEGINNING OF THE PERIOD, MAY 2011, IS 48.8 PERCENT. AND THEN IT DECLINES AND CONSISTENTLY DECLINES ACROSS THE ENTIRE RELEVANT PERIOD, SO ITS SHARE IS 32.2 PERCENT IN DECEMBER OF 2014.

NOW, BY CONTRAST, INJECTABLES STARTED AT 30.9 PERCENT IN MAY OF 2011 AND THEY INCREASED TO 47.7 PERCENT BY DECEMBER OF 2014. IN OTHER WORDS, IN LESS THAN JUST THREE YEARS, THE PERCENTAGE SHARE OF THE TWO PRODUCTS ESSENTIALLY FLIPPED. NOW, BY THE WAY, THIS TREND HAS CONTINUED. BY NOVEMBER OF 2016, ALTHOUGH IT IS NOT ON THAT CHART, IT WILL BE IN THE EVIDENCE, THE PERCENTAGE OF PATIENTS WHO USE INJECTABLES ARE 60 PERCENT OF ALL PATIENTS ON TESTOSTERONE REPLACEMENT THERAPY.

SO I WOULD LIKE TO JUST PAUSE ON THAT FOR

A MOMENT, BECAUSE AS FTC SAID, THEY ARE GOING TO BRING IN SOME NEEDLES TO TRY AND GET A REACTION AND TO SAY PATIENTS DON'T LIKE NEEDLES, THESE ARE DIFFERENT MARKETS. BUT THE IMPORTANT POINT IS THE ACTUAL DATA, AND THE ACTUAL DATA SHOWS THAT FOR AT LEAST 60 PERCENT OF PEOPLE, NEEDLES DON'T MATTER BECAUSE THEY ARE USING THEM, SO THEY CAN'T BE AFRAID OF THEM OR UNWILLING TO TRY THEM. MAYBE FOR ADDITIONAL PEOPLE IT'S ALSO AN OPTION, BUT AT LEAST 60 PERCENT, WE HAVE THIS DATA, THEY ARE USING INJECTABLES AND THEY LIKE INJECTABLES.

SO, AGAIN, POWERFUL EVIDENCE THAT THESE PRODUCTS COMPETED AND THAT THERE WAS NO MONOPOLY HERE. AND YOU CAN SEE ALSO IN THIS CHART HOW MR. JAEGER WAS TAKEN BY SURPRISE AS INJECTABLES CONTINUE TO RISE OVER THE PERIOD AND HIS VIEW CHANGES AND HE REALIZES THE BLIND SPOT THAT HE ONCE HAD.

AND THERE IS NOT GOING TO BE A DISPUTE AT TRIAL ABOUT THESE NUMBERS OF PRESCRIPTIONS. THERE IS ALSO NOT GOING TO BE A DISPUTE THAT ALL THE PRODUCTS THAT I PUT UP ON THAT SCREEN ARE FOOD AND DRUG ADMINISTRATION-APPROVED THERAPIES FOR HYPOGONADISM.

SO WHAT IS FTC'S EVIDENCE? IT IS THE OPINION OF DR. SHAPIRO. THE EVIDENCE WILL SHOW DR. SHAPIRO DID NOT ANALYZE WHETHER THERE WERE MANY OTHER TESTOSTERONE PRODUCTS AVAILABLE DURING THE

RELEVANT PERIOD, AS INDEED THERE ARE.

DR. SHAPIRO DID NOT LOOK AT WHETHER THOSE THERAPIES ARE EQUALLY EFFECTIVE AT TREATING THE SAME CONDITION, AS INDEED THEY ARE.

DR. SHAPIRO DID NOT ANALYZE WHETHER PATIENTS SWITCH FROM ONE PRODUCT TO ANOTHER, AS IN FACT THEY DO.

SO WHAT DID DR. SHAPIRO DO? HE USED SOMETHING CALLED A HYPOTHETICAL MONOPOLIST TEST. WHAT IS THAT? IT IS A TEST DESIGNED TO ANALYZE BUSINESS MERGERS LIKE WHEN T-MOBILE WANTED TO MERGE WITH SPRINT.

THE COURT: ARE THERE CASES WHERE THAT HAS BEEN USED IN CASES THAT DON'T INVOLVE MERGERS?

MR. SENATOR: IN THE THIRD CIRCUIT, IT HAS NEVER BEEN ACCEPTED IN A CASE THAT WAS NOT ABOUT A BUSINESS MERGER. THE THIRD CIRCUIT HAS NEVER ACCEPTED IT IN THAT CONTEXT.

THE COURT: RIGHT. HASN'T IT SAID THAT IT IS USABLE IF IT IS IN A NONMERGER CONTEXT?

MR. SENATOR: IT HAS NOT RULED THAT OUT, AND OTHER COURTS IN THE OTHER CIRCUITS IN SOME CIRCUMSTANCES HAVE USED IT. BUT IMPORTANT POINT HERE I WOULD SUBMIT, YOUR HONOR, IS THAT IT IS INCONSISTENT WITH THE THIRD CIRCUIT CONTROLLING MYLAN DECISION, WHICH DEALT SPECIFICALLY WITH COMPETITION INVOLVING BRAND AND

GENERIC DRUGS.

AND FURTHERMORE, DR. CREMIEUX WILL EXPLAIN WHY IT DOES NOT WORK HERE.

THE COURT: WELL, HE DID NOT RULE OUT THE USE OF HYPOTHETICAL MONOPOLIST, DID HE?

MR. SENATOR: I THINK WE WILL EXPLAIN A TRIAL WITH DR. CREMIEUX THAT THE ANALYSIS THERE IS FUNDAMENTALLY INCONSISTENT WITH THE USE OF THE HYPOTHETICAL MONOPOLIST TEST. AND YOU DON'T HAVE TO TAKE MY WORD FOR IT OR HIS, BECAUSE IF YOU LOOK AT THE FTC'S BRIEF -- AMICUS BRIEF I BELIEVE IT WAS -- SEEKING RECONSIDERATION OR EN BANC REHEARING IN MYLAN, IT WAS PRECISELY BECAUSE IT SAID MYLAN IS INCONSISTENT WITH THE HYPOTHETICAL MONOPOLIST TEST, IT UNDERMINES THE HYPOTHETICAL MONOPOLIST TEST. THE FTC WANTS THAT TEST. THE THIRD CIRCUIT CLEARLY SAID NO.

THE COURT: I WILL HAVE TO REREAD MYLAN.

MR. SENATOR: AND READ THE AMICUS BRIEF THAT THEY FILED, WHICH WE SUBMITTED I BELIEVE WITH OUR SUMMARY JUDGMENT MOTION.

THE COURT: THANK YOU.

MR. SENATOR: NOW, IN A PHARMACEUTICAL MONOPOLIZATION CASE, THE HYPOTHETICAL MONOPOLIST TEST WILL ALWAYS CONCLUDE THAT A BRAND DRUG IS MONOPOLY BEFORE AN AB-RATED GENERIC ENTERS THE MARKET. IN HIS

DEPOSITION, DR. SHAPIRO IS NOT ABLE TO COME UP WITH A SINGLE COUNTER-EXAMPLE.

WHY IS THAT? IT IS BECAUSE GENERIC AB-RATED DRUGS ARE ALWAYS ABLE TO PRICE CHEAPER THAN BRAND-NAME DRUGS BECAUSE THE GENERIC COMPANY ALWAYS HAS A LOWER COST STRUCTURE. IT DOES NOT HAVE THE RESEARCH AND DEVELOPMENT COST OF THE BRAND-NAME COMPANY. AND THE NORMAL RULES OF SUPPLY AND DEMAND ON WHICH THE HYPOTHETICAL MONOPOLIST TEST IS BASED DOES NOT APPLY TO GENERIC DRUGS. THE GENERIC COMPANY GAINS MOST OF ITS PRESCRIPTIONS NOT BECAUSE PATIENTS DELIBERATELY CHOOSE THE AB-RATED GENERIC, BUT BECAUSE BY LAW, AS YOUR HONOR RECOGNIZED, BY STATE LAW, THE PHARMACIST MUST SUBSTITUTE THE AB-RATED GENERIC WHEN THE DOCTOR PRESCRIBES THE BRAND DRUG.

SO IT'S NOT JUST THAT WE HAVE THIS TEST AND IT HAS NOT BEEN USED HERE, BUT DR. CREMIEUX WILL EXPLAIN THE RULES THAT UNDERGIRD THIS TEST, THE RULES THAT MAKE IT APPROPRIATE IN OTHER CIRCUMSTANCES, JUST DON'T APPLY HERE.

SO IN SUM, THE EVIDENCE WILL SHOW THAT ANDROGEL FACED VIGOROUS COMPETITION DURING THE ENTIRETY OF THE RELEVANT PERIOD, AND DR. SHAPIRO'S OPINION ON THE HYPOTHETICAL MONOPOLIST TEST DOES NOT SHOW OTHERWISE.

FINALLY, LET ME SPEND A COUPLE OF MINUTES

ON SUPPOSEDLY EXCESS PROFITS.

FTC'S REQUEST FOR DISGORGEMENT, AS FTC ADMITS IN ITS STATEMENT, LOOKS AT WHAT WOULD HAVE HAPPENED HAD NO PATENT LITIGATION BEEN FILED AND MAKES TWO FUNDAMENTAL ASSUMPTIONS: THAT TEVA WOULD HAVE ENTERED THE MARKET IN JUNE 2012 EVEN THOUGH IT HAD NO AB-RATING, NO AUTOMATIC SUBSTITUTABILITY, AND THAT PERRIGO WOULD HAVE ENTERED THE MARKET WITH AN AB-RATED PRODUCT IN THE SUMMER OF 2013 EVEN THOUGH TEVA -- I'M SORRY -- PERRIGO DID NOT GET AN AB-RATING IN SUMMER OF 2013. IT DID NOT GET AN AB-RATING UNTIL JULY 23RD OF 2014, A YEAR LATER. AND TO OBTAIN ITS REQUEST OF DISGORGEMENT, FTC NEEDS TO PROVE THAT THESE ASSUMPTIONS ARE SUPPORTED BY THE EVIDENCE. BUT THEY ARE NOT.

LET ME TALK ABOUT TEVA FIRST. WOULD TEVA ACTUALLY HAVE ENTERED THE MARKET WITH A PRODUCT THAT A PHARMACY WOULD NOT AUTOMATICALLY SUBSTITUTE? NO. WHY NOT? TEVA'S MAUREEN CAVANAUGH WILL TESTIFY ON FRIDAY. SHE WILL TESTIFY THAT TEVA COULD NOT SELL THAT SORT OF PRODUCT WITHOUT USING A MARKETING AND SALES FORCE, AND TEVA WAS NOT SET UP FOR THAT HERE.

AND BECAUSE TEVA'S TESTOSTERONE GEL WAS NOT DIFFERENTIATED FROM ANDROGEL 1%, THERE WAS NO MARKETING ANGLE THAT ANY SALES FORCE COULD HAVE USED FOR SALESPEOPLE TO CONVINCE DOCTORS TO PRESCRIBE IT AND

PATIENTS TO TAKE IT. TEVA WAS DEPENDING ON GETTING AUTO-SUBSTITUTION AND IT NEVER GOT THAT.

MS. CAVANAUGH WILL EXPLAIN THAT DESPITE BEING A BIG DRUG COMPANY, TEVA HAS NEVER BEEN ABLE TO COME TO MARKET WITH AN UNDIFFERENTIATED PRODUCT THAT THE FDA HAS FOUND NOT -- HAS NOT FOUND TO BE AUTOMATICALLY SUBSTITUTABLE. TEVA HAS NEVER LAUNCHED SUCH A PRODUCT. NOT BEFORE JUNE OF 2012, NOT SINCE JUNE OF 2012, NOT ONCE.

TEVA HAD OTHER PROBLEMS TOO. IT FOUND OUT IN THE FDA APPROVAL PROCESS THAT ITS PUMP DISPENSERS DID NOT WORK. IT HAD TO PULL ITS APPLICATION TO THE FDA FOR APPROVAL OF A PUMP DISPENSER AND ONLY SEEK APPROVAL OF SINGLE-USE FOIL PACKETS OF ITS PRODUCT.

TEVA --

THE COURT: PUMP DISPENSER FOR THE GEL?

MR. SENATOR: CORRECT.

SO IT COMES IN TWO FORMS. THERE'S THE PUMP, AND THEN THERE IS A SINGLE-USE -- IT'S CALLED A SACHET. IT'S LIKE ONE OF THOSE LITTLE MUSTARD OR KETCHUP THINGS, YOU OPEN IT UP AND YOU SMEAR IT ON.

SO THEY COULD NOT USE THE PUMP. IT FINDS OUT OH, WE HAVE ONLY HAVE THE SACHETS AND IT INTERNALLY ESTIMATES THAT THAT IS GOING TO CUT OUT 40 PERCENT OF ANY MARKET THAT WE COULD HAVE EXPECTED TO HAVE GOTTEN.

THERE IS MORE PROBLEMS TOO FOR TEVA. FIRST, MANUFACTURING COULD TAKE UP TO TWO YEARS BECAUSE THIS IS A GEL YOU ARE MANUFACTURING, NOT A PILL. IT'S A FLAMMABLE GEL. YOU NEED SPECIAL MANUFACTURING FACILITIES. AND THE THIRD PARTY THAT WOULD HAVE DONE THE MANUFACTURING FOR TEVA SAID THEY REQUIRED A $10 MILLION GUARANTEE FROM TEVA. THE PRODUCT SUCCEEDS, PRODUCT SALES, YOU ARE GOING TO BE ON THE HOOK FOR $10 MILLION. TEVA WAS NEVER GOING TO COMMIT $10 MILLION TO A PRODUCT THAT WOULD NOT BE AUTO-SUBSTITUTED.

LET ME TURN TO PERRIGO. THE FTC'S DISGORGEMENT ASSUMES THAT IN SUMMER OF 2013 PERRIGO WOULD HAVE ENTERED THE MARKET WITH AN AB-RATED PRODUCT. BUT THE FDA DID NOT AWARD PERRIGO THAT AB-RATING UNTIL JULY OF 2014. AND I WOULD LIKE TO SHOW YOU WHAT ACTUALLY HAPPENED.

SO PERRIGO GETS MARKETING APPROVAL FROM FDA FOR ITS PRODUCT ON JANUARY 31, 2013. FTC'S EXPERT MR. PHELPS HAS SAID THAT THE FDA WON'T EVEN BEGIN CONSIDERING WHETHER TO GRANT THE PRODUCT BY PERRIGO AN AB-RATING UNTIL IT GRANTS MARKETING APPROVAL. IN FACT, IT USUALLY WILL NOT BEGIN CONSIDERING THAT QUESTION UNTIL HE SAYS -- HE USES THE WORD "SOMETIME AFTER MARKETING APPROVAL" BECAUSE IT TAKES A WHILE TO GET ALL THE RELEVANT INFORMATION OVER TO THE WHOLLY DIFFERENT

FDA DEPARTMENT THAT DECIDES THE AB-RATING.

THE COURT: HOW DOES THE FDA SUSPEND CONSIDERATION OF THE RATING IF THERE IS HATCH-WAXMAN LITIGATION GOING ON?

MR. SENATOR: IT'S THE OTHER WAY AROUND. THE FDA DOES NOT GET TO CONSIDERING THE RATING ANYWAY UNTIL AFTER APPROVAL OF THE DRUG, SO THE ISSUE NEVER ARISES.

THE COURT: WILL IT APPROVE IT IF THERE IS A HATCH-WAXMAN LITIGATION GOING ON?

MR. SENATOR: IT WILL ISSUE WHAT'S CALLED TENTATIVE APPROVAL IF THERE IS A HATCH-WAXMAN LITIGATION GOING ON.

THE COURT: THEY WILL CONTINUE CONSIDERING THE MATTER, THEY WILL NOT JUST PUT IT ASIDE?

MR. SENATOR: ABSOLUTELY. IT CONTINUES TO CONSIDER THE MATTER DURING LITIGATION.

THE COURT: EVEN THOUGH THERE IS LITIGATION GOING ON.

MR. SENATOR: AND MR. PHELPS, AGAIN, THEIR FDA EXPERT, AGREES WITH US. IT CONTINUES AND THERE ARE CIRCUMSTANCES WHERE THEY ACTUALLY CONCLUDE THEIR REVIEW AND THEN THEY ISSUE WHAT IS CALLED TENTATIVE APPROVAL. THEY ESSENTIALLY COME OUT AND SAY YOU ARE APPROVED, SO THE MINUTE THE STAY GOES AWAY, YOU