UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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UNITED THERAPEUTICS CORPORATION,

Vs.

SANDOZ, INC.,

DEFENDANT

_____

CIVIL NO.
12-1617 (PGS)
13-316

MAY 1, 2014
CLARKSON S. FISHER COURTHOUSE
402 EAST STATE STREET
TRENTON, NEW JERSEY 08608

B E F O R E: THE HONORABLE PETER G. SHERIDAN
U.S. DISTRICT COURT JUDGE
DISTRICT OF NEW JERSEY

TRIAL DAY 1 - TUTORIAL

Certified as true and correct as required
by Title 28, U.S.C. Section 753
/S/ Francis J. Gable
FRANCIS J. GABLE, C.S.R., R.M.R.
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MR. JACKSON: Unless the Court has questions for Dr. Miller, that concludes the tutorial about the gram negative killing and the bactericidal effect. We thought it would be useful to go through the disease with Dr. White, the bacteria, and then the other patent, which is the actual synthesis of the molecule next. Unless the Court has questions for Dr. Miller.

THE COURT: No, I think I've got it. Thank you.

DR. MILLER: Thank you.

(Dr. Miller excused.)

MR. CARSTEN: So, your Honor, Dr. White started out with the whole body, the patient if you'll have it, the medical doctor talking about the disease and talking about the manner in treating that disease.

Dr. Miller just talked about smaller scale, the cells, the bugs as he called them, and the effect of the particular diluents or buffers on the growth or killing of those particular bugs.

Now, if we, you know, take off our microscope glasses and get down to sort of even smaller, you know, molecule level, we're going to be talking about some chemistry. And we brought with us here Professor Robert Williams, from Colorado State University, a synthetic organic chemist, who's going to talk to you about the '117 patent and the chemistry involved in that patent.

So, Professor Williams?

PROFESSOR WILLIAMS: Good afternoon, your Honor.

THE COURT: Good afternoon. How are you today?

PROFESSOR WILLIAMS: Good.

00:50 So, my name is Robert Williams from Colorado State University, I'm a professor there. And on behalf of plaintiff I've been asked to give a simple tutorial, a basic tutorial on some organic chemistry basics, we're going to hear a lot about organic chemistry in the coming days. And I'll tell you a

00:51 little bit about treprostinil and treprostinil sodium, and I'll also talk a little bit about the novel aspects of the '117 patent invention.

THE COURT: All right, thank you.

PROFESSOR WILLIAMS: So first on chemical bonding

00:51 and molecular structures we're going to see a lot of chemical structures with respect to the '117 patent. And treprostinil is an organic molecule, and most organism molecules are composed of the elements carbon, hydrogen, nitrogen and oxygen atoms, and organic compounds sometimes contain additional

00:51 elements, like sulphur, phosphorous, chlorine and so on. Treprostinil itself only contains carbon, hydrogen and oxygen.

And chemistry is a convention to draw three dimensional molecules on two dimensional surfaces, and so there's an example here. And because the skeletons of organic

00:51 molecules are composed of carbon, instead of drawing little Cs

all over the place we've adopted a convention where the intersection of lines represent carbon atoms. And then other elements like oxygen and so forth we would specifically label at their appropriate position.

00:52 And so the lines in these structures represent chemical bonds connecting the atoms in the molecular structure. So, a line like this, just one line is a single bond; between those two carbons, and sometimes carbon engages in more than one bond to another carbon so we draw two lines,

00:52 that would be a so-called double bond. Sometimes carbon atoms engage in three bonds between each other, so we draw three lines like shown here, that's a triple bond.

Organic molecules sometimes have linear portions like this chain here, and sometimes there's ring structures

00:53 like there aromatic ring.

THE COURT: Where's the aromatic ring?

PROFESSOR WILLIAMS: That's the six membered ring right here, and it's three double binds inside the ring. And so for example here I said other elements would be

00:53 specifically identified, so there's an oxygen atom, it's bonded with the hydrogen, that's called an hydroxyl group; and we also -- chemists have lots of acronyms unfortunately, but -- and we'll hear about some of those, so Me is an acronym for a methyl group or a CHe group. And we'll hear about this

00:53 acronym a little bit later in the litigation, THP, is a

so-called alcohol protecting group that's connected to an oxygen atom.

Now, also in this figure chemists have a convention where because molecules are three dimensional we want to represent their three dimensional structures on a two dimensional surface, we have a convention where straight lines indicate projection of that bond in the plane of the paper or surface; a darkened wedge would indicate projection away from the plane of that surface toward you; and a hashed line would indicate projection of that bond behind the screen or away from you.

Now, another term we're going to hear a lot about in the trial is the issue of stereoisomers, and what are stereoisomers. Well, stereoisomers are molecules, related molecules that have the same connectivity of atoms, but they're arranged in a different three dimensional configuration in space. Another term we're going to hear -- and I'll illustrate this for you in just a minute with a little movie clip, another term we're going to hear is a terms called enantiomers, and this is an term chemists have used to describe molecules that are non-superimposable mirror images of each other, just like our left hand is a non-superimposable mirror image of our right hand. You know, if you try to put your left hand into a right-handed glove, it just doesn't feel quite right, it doesn't fit in there.

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