IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ERFINDERGEMEINSCHAFT UROPEP GbR,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:15-CV-1202-WCB
	§	
ELI LILLY AND COMPANY,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

In this patent infringement case, the plaintiff Erfindergemeinschaft UroPep GbR ("UroPep"), a German association of urology researchers and physicians, sued the defendant Eli Lilly and Company ("Lilly") for infringement of U.S. Patent No. 8,791,124 ("the '124 patent"). Claim 1 of the '124 patent is to a method of administering an effective amount of a compound known as an inhibitor of the enzyme phosphodiesterase ("PDE") V, in order to treat the condition of benign prostatic hyperplasia ("BPH"). UroPep alleged that Lilly induced infringement of claim 1 by marketing and selling the drug Cialis for the treatment of BPH. Lilly denied infringement and asserted various invalidity defenses. After a trial, a jury found the '124 patent infringed and not invalid. The jury awarded damages in the amount of $20 million.

Pursuant to Rules 50(b) and 59, Fed. R. Civ. P., Lilly now moves for judgment as a matter of law or, in the alternative, a new trial. Dkt. No. 375. The motion is denied.

BACKGROUND

I. The Invention of ’124 Patent

UroPep owns the ’124 patent, entitled “Use of Phosphordiesterase [sic] Inhibitors in the Treatment of Prostatic Diseases.” The disclosure was originally filed as part of a PCT application on July 9, 1997—the undisputed priority date of the ’124 patent. The application under 35 U.S.C. § 371 (“the 371 application”) was filed in April 2000 and later abandoned. The 371 application, in turn, gave rise to a continuation application that issued as U.S. Patent No. 8,106,061 (“the ’061 patent) in January 2012. The ’124 patent is a continuation of the patent application that matured into the ’061 patent. ’124 patent, col. 1, ll. 5-8.

The original specification filed in July 1997 begins by describing BPH, a condition in which the benign growth of the prostate gland in older males causes constriction of the neighboring urethra and results in lower urinary tract symptoms, including difficulties in urinating. See id., col. 1, ll. 9-24. One prior art treatment method for BPH was surgery to reduce the size of the prostate. Id., col. 1, ll. 14-15. Another prior art method was the administration of drugs, such as alpha-receptor blockers or drugs that interfere with hormonal regulation of the prostate, to induce relaxation of human prostatic muscle. Id., col. 1, ll. 20-28. Those drugs, however, were not particularly effective and had significant side effects. Id., col. 1, ll. 24-31; id., col. 1, line 67 through col. 2, line 2.

The inventors of the ’124 patent identified a new drug target: phosphodiesterase (“PDE”) enzymes. ’124 patent, col. 1, ll. 32-35. At that time, it was known that smooth muscle cells contain molecules called cyclic adenosine monophosphate (“cAMP”) and cyclic guanosine monophosphate (“cGMP”), which promote the relaxation of smooth muscle. Id., col. 1, ll. 39-42. It was also known that PDE enzymes break down cAMP and cGMP. Id., col. 1, ll. 43-44.

Finally, it was known that inhibitors of PDEs prevent the breakdown of cAMP and cGMP, which promotes smooth muscle relaxation. Id., col. 1, ll. 44-52.

Those skilled in the art had studied PDEs and knew that PDEs come in different types (subesterases), including PDE1 through PDE5.[1] '124 patent, col. 1, ll. 53-60. Publications reported that those PDE types are distributed differently throughout the body's organs and organ systems, and that the activity of those PDE types varies depending on where they are located. Id., col. 1, ll. 60-65; see also, e.g., Dkt. No. 342, Trial Tr. at 307-08 (a particular PDE type may not be present in a particular tissue; or, even if the PDE type is present in that tissue, the PDE type may not be functionally relevant in that tissue because other conditions in the tissue render the activity of the PDE meaningless).

The prior art also identified compounds that selectively inhibit specific PDE types, i.e., compounds that suppress the activity of a specific PDE type. '124 patent, col. 1, ll. 44-52; see also id., col. 1, ll. 66-67; id., col. 7, ll. 35-40, 43-45. In particular, hundreds of selective inhibitors of PDE5 were known at that time, including the selective PDE5 inhibitor tadalafil, which is the active ingredient in Lilly's product Cialis. Dkt. No. 344, Trial Tr. at 1254 (UroPep's expert describes the advanced state of the art regarding selective PDE5 inhibitors); Dkt. No. 343, Trial Tr. at 791-93 (Lilly's expert acknowledges that tadalafil, as well as 118 other compounds disclosed in a document published in 1995, were known PDE5 inhibitors before the priority date of the '124 patent).

The inventors of the '124 patent performed several experiments. See Dkt. No. 342, Trial Tr. at 316-17 (referencing experiments described in patent disclosure). The first set of

[1] The PDE subesterases were initially identified by Roman numerals, the convention followed in the '124 patent (e.g., PDE V). It is now more common to use Arabic numerals (e.g., PDE5). For consistency, except where quoting record materials, the modern convention will be used throughout.

experiments revealed that PDE1, PDE4, and PDE5 were present and had significant activity in human prostatic tissue. ’124 patent, col. 2, ll. 6-11. The second set of experiments showed that compounds that selectively inhibit PDE1, PDE4, and PDE5 caused the relaxation of strips of human prostatic tissue. Id., col. 7, ll. 11-34. Based on those results, the inventors determined that compounds that selectively inhibit those three PDEs would treat BPH. See id., col. 7, ll. 35-37; id., col. 8, ll. 5-16. The disclosure identifies a number of “preferred selective inhibitors of PDE I, IV, and V,” including 10 discrete chemical compounds and two classes of chemical compounds. Id., col. 2, line 28 through col. 4, line 46.[2] For convenience, those “preferred selective inhibitors of PDE I, IV, and V” will be referred to as “the identified preferred selective inhibitors.” Tadalafil is not among those identified preferred selective inhibitors.

The disclosure also describes and incorporates “known methods” to determine whether any particular compound is a “selective inhibitor” of a specific PDE type. ’124 patent, col. 7, line 35 through col. 8, line 16. If a compound is a selective inhibitor of one of the identified PDE types (PDE1, PDE4, or PDE5), then that compound is “suitable for the purpose according to the invention,” id., col. 7, ll. 35-37—namely, for the prophylaxis and treatment of BPH and other prostatic diseases, id., col. 2, ll. 17-27.

In the original Patent Cooperation Treaty (“PCT”) application, the patentees claimed the “[u]se of [any of the identified preferred selective inhibitors] in the prophylaxis and treatment of prostatic diseases, in particular benign prostatic hyperplasia” and others. PCT Application, at 4 (claim 1); see also id. at 5 (claim 2 covers “medicaments for” the prophylaxis and treatment of BPH and other prostatic diseases using any of the identified preferred selective inhibitors); id. at

[2] The disclosure also identifies, as “preferred selective inhibitors of PDE I, IV, and V,” the “pharmacologically compatible salts” of those 10 compounds and two classes of compounds. ’124 patent, col. 4, line 47.

6 (claim 3 covers the use of the identified preferred selective inhibitors "in the preparation of medicaments for the prophylaxis and treatment of" BPH and other prostatic diseases). The '061 patent, filed in May 2003, claims "[a] method of treating" BPH or prostatism by "administering a selective inhibitor of [PDE] IV and/or [PDE] V," selected from a group of six of the identified preferred selective inhibitors. '061 patent, col. 8, ll. 4-26 (independent claim 1); see also id., col. 8, ll. 29-53 (independent claim 3 is to a method of "relaxing prostatic muscles" by administering, to someone with BPH or prostatism, a selective inhibitor of PDE4 and/or PDE5 selected from a group of nine of the identified preferred selective inhibitors).

In the 1980s and 1990s, some drug companies were investigating PDE5 inhibitors for the treatment of other conditions, such as erectile dysfunction. See, e.g., Dkt. No. 342, Trial Tr. at 314-16 (Pfizer was investigating the PDE5 inhibitor sildenafil (Viagra) in the 1980s and 1990s). Lilly was one of them: Lilly developed Cialis (with tadalafil as the active ingredient) as a drug for erectile dysfunction, and Lilly sought approval of Cialis in the United States and Europe for that indication in mid-2001. See Dkt. No. 343, Trial Tr. at 955. Then, in December 2001, Lilly began discussing other possible indications for Cialis, including whether to develop Cialis as a treatment for BPH. See id., Trial Tr. at 958, 996. Lilly decided to engage in that development and obtained FDA approval for the BPH indication in 2011. Id., Trial Tr. at 1003. Lilly then began marketing and selling Cialis for the treatment of BPH.

The '061 patent was in effect at that time. The claims of the '061 patent, however, do not cover Cialis, because tadalafil is not one of the identified preferred selective inhibitors required by the claims of the '061 patent.

In December 2011, the patentees filed a continuation application that later issued as the '124 patent. During prosecution, the examiner rejected the claims on the basis of nonstatutory

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