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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MITCHELL F. BRIN,
JOSEPH FRANCIS and KEI ROGER AOKI

Appeal 2013-002503
Application 12/255,369
Technology Center 1600

Before JEFFREY N. FREDMAN, ULRIKE W. JENKS, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving claims to a method of treating urogenital-neurological disorders. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] Appellants identify the Real Party in Interest as Allergan, Inc. (*see* App. Br. 3).

Statement of the Case

Background

"The ability of Clostridial toxins . . . to inhibit neuronal transmission [is] being exploited in a wide variety of therapeutic and cosmetic applications" (Spec. ¶ 2). "There is a great desire by the pharmaceutical industry to expand the use of Clostridial toxin therapies . . . to treat sensory nerve-based ailment, such as . . . urogentital disorders" (Spec. ¶ 4). "One approach that is currently being exploited to expand Clostridial toxin-based therapies involves modifying a Clostridial toxin so that the modified toxin has an altered cell targeting capability for a non-Clostridial toxin target cell" (Spec. ¶ 4).

"The present specification discloses modified Clostridial toxin compositions and methods for treating an individual suffering from a nociceptive sensory neuron-mediated urogenital disorder" (Spec. ¶ 5).

The Claims

Claims 1–5 and 7–12 are on appeal. Independent claim 1 is representative and reads as follows:

> 1. A method of treating urogenital-neurological disorder in a human, the method comprising the step of administering to the human in need thereof a therapeutically effective amount of a composition including a modified Clostridial toxin comprising an opioid peptide binding domain, a Clostridial toxin translocation domain and a Clostridial toxin enzymatic domain, wherein the urogenital-neurological disorder is selected from the group consisting of urinary incontinence, overactive bladder, detrusor dysfunction, lower urinary tract dysfunction, urinary retention and urinary hesitancy, wherein administration of the composition reduces a symptom of the urogenitalneurological disorder, thereby treating the human.

The Issue

The Examiner rejected claims 1–5 and 7–12 under 35 U.S.C. § 103(a) as obvious over Schmidt[2] and Foster[3] (Ans. 4–6).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Schmidt and Foster render claim 1 obvious?

Findings of Fact

1. Schmidt teaches that:

> Three patients with recalcitrant voiding dysfunction were treated with injections of botulinum toxin BOTOX® (Allergan) as follows.
>
> Patient 1 . . . received four weekly 200 IU botulinum toxin injections into the bladder neck for total dose of 800 IU. Post-injection, his bladder capacities ranged from 300-400 cc with oxybutinin and 150-200 cc without oxybutinin. . . . The patient was continent with a penile clamp after treatment with botulinum toxin. . . .
>
> Patient 2 . . . received injections into the lateral bladder wall in two weekly injections of 200 IU each for a total of 400 IU of botulinum toxin. . . . Post injection, diary data indicated bladder capacity increased to 300-400 cc. In addition, the patient no longer had annoying constant urge type dysfunction . . .
>
> Patient 3 . . . was treated with one 200 IV injection of botulinum toxin into the external urethral sphincter. The patient experienced dramatic relief of testicle pain and had far less severe pain in the shaft of the penis.

(Spec. ¶¶ 52–55).

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[2] Schmidt, R., US 2005/0159337 A1, published July 21, 2005.
[3] Foster et al., WO 2006/059093 A2, published June 8, 2006.

2. Foster teaches "a system for preparing non-cytotoxic conjugates" (Foster 6, ll. 1–2) with three domains, a first "non-cytotoxic protease component [that] . . . is a botulinum neurotoxin" (*id.* 6, ll. 18–20), a second "translocation component [that] . . . is preferably a clostridial neurotoxin H-chain" (*id.* 6, l. 32 to 7, l. 1), and a third targeting moiety where "[o]pioids represent a preferred group of [targeting moieties] of the present invention" (*id.* 8, l. 28).

3. Foster teaches that "the target cell is a nociceptive sensory afferent, preferably a primary nociceptive afferent . . . In use, the conjugates reduce or prevent the transmission of sensory afferent signals (e.g. neurotransmitters or neuromodulators) from peripheral to central pain fibres, and therefore have application as therapeutic molecules for the treatment of pain, in particular chronic pain" (Foster 7, ll. 12–21).

Principles of Law

To establish a prima facie case of obviousness, the Examiner must find "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Analysis

We begin with claim interpretation because before a claim is properly interpreted, its scope cannot be compared to the prior art. In this case, claim 1 is limited, by its express language, to urogenital-neurological disorders "selected from the group consisting of urinary incontinence, overactive bladder, detrusor dysfunction, lower urinary tract dysfunction,

urinary retention and urinary hesitancy." Thus, claim 1 does not encompass pain alone as a urogenital-neurological disorder.

Schmidt teaches treatment of urological-neurological conditions including those recited in claim 1 by injection of native botulinum toxin (FF 1). Foster teaches modification of the native botulinum toxin to incorporate an opioid targeting moiety (FF 2) in order to treat nociceptive pain (FF 3), but the Examiner does not establish a teaching or suggestion in Foster for treatment of the disorders recited in claim 1.

The Examiner finds the combination of references obvious because "both Schmidt (see paragraphs 0054-0055) and Foster et al (see p. 7; p. 21) teach that the clostridial neurotoxin and modified clostridial toxin respectively are useful in the treatment of pain, which is a symptom of a urogenital-neurological disorder" (Ans. 11).

Appellants contend that the "Schmidt reference treats a urogenital-neurological disorder by paralyzing a muscle, while the Foster reference controls pain by targeting sensory nerve while not having any affect of a muscle" (Br. 11). Appellants contend that "where there are two references being combined, each of which show the treatment of different diseases or conditions by a ***different mechanism of action***, there is no reasonable expectation of success" (Br. 12).

We find that Appellants have the better position. Pain is not one of the recited conditions in claim 1. Foster's modified clostridium toxin would have been expected to treat pain (FF 3), not the conditions recited in claim 1. We therefore agree with Appellants that there would have been no reason, based on Foster, to expect that a modified clostridium toxin with an opioid

targeting moiety would have any efficacy on muscle based urogenital-neurological disorders "selected from the group consisting of urinary incontinence, overactive bladder, detrusor dysfunction, lower urinary tract dysfunction, urinary retention and urinary hesitancy" (Claim 1). Schmidt also provides no reason to modify the clostridial toxin with an opioid targeting moiety because Schmidt is focused on treatment of voiding dysfunction, not pain (FF 1). Neither Foster nor Schmidt provide any suggestion that an opioid targeting moiety designed for nociceptive pain would have any efficacy treating the conditions recited in claim 1.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that Schmidt and Foster render claim 1 obvious.

SUMMARY

In summary, we reverse the rejection of claims 1–5 and 7–12 under 35 U.S.C. § 103(a) as obvious over Schmidt and Foster.

REVERSED

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