

2009 Giles Sutherland Rich Memorial Moot Court Competition

The United States District Court for the District of Galapagos (a fictitious 51st archipelago state off the coast of Louisiana and within the jurisdiction of the Court of Appeals for the Fifth Circuit) dismissed a patent infringement action brought by Temple Drug Company (“Temple”) against Crystal Pharmaceuticals, Inc. (“Crystal”). In its complaint, Temple had alleged that Crystal infringed U.S. Patent No. 5,431,007 (“the ’007 patent”) by making, offering for sale, and selling the “MoGRO” hair loss treatment patch within the United States.

Temple timely filed a Notice of Appeal in the United States Court of Appeals for the Federal Circuit. The appeal was docketed as Appeal No. 08-2001. All of the facts recited herein are supported by substantial evidence of record. Any facts not recited herein are without support in the record.

***Temple Drug Co. v. Crystal Pharmaceuticals, Inc.* Case No. 08-2001**

Appeal from the District of Galapagos, Santa Rosalía Division

Temple sued Crystal for infringement of Claim 1 of the ’007 patent on April 15, 2007. Crystal stipulated to infringement and did not challenge the validity of the ’007 patent. Nevertheless, Crystal asserted that it was not liable on two separate grounds. First, Crystal argued that Temple’s patent rights have been exhausted with respect to MoGRO because Crystal purchases the active ingredient in MoGRO (red-banded cobra venom) from a licensed supplier, Snake Oil Farms (“Snake Oil”). Second, Crystal argued that it had a non-exclusive, fully paid-up license to the ’007 patent executed by a certain Mr. Bond, who Crystal argued was a proper (but unnamed) joint inventor of the subject matter of Claim 1 of the ’007 patent.

After a short bench trial, the District Court ruled for Crystal on both grounds.¹ First, the District Court held that the sale of red-banded cobra venom by a licensed supplier to Crystal exhausted Temple’s patent rights. The District Court also found that Mr. Bond was a proper joint inventor of the subject matter of Claim 1 of the ’007 patent and that, as a result, the Bond License is enforceable. As a result, the District Court ruled that Temple lacked standing to

¹ The District Court decided the exhaustion issue in the alternative and at the parties' joint request.

proceed against Crystal and entered a final judgment dismissing the lawsuit with prejudice. Shortly thereafter, Temple appealed the judgment on both grounds. The District Court's findings of fact and conclusions of law are set forth below.

Findings of Fact

1. The venom of a red-banded cobra is extremely poisonous to humans. In fact, the bite of one red-banded cobra is sufficiently potent to kill an average-size person within 12 hours. Without administration of an anti-venom serum, such a bite is fatal 95% of the time. Luckily, the red-banded cobra avoids most encounters with humans and bites are extremely rare, occurring only once or twice per year.
2. Somewhat serendipitously in May of 1995, Dr. Illinois Jones discovered that, in the right dosage, the venom of the red-banded cobra is an extremely effective treatment for male pattern baldness. Specifically, Dr. Jones discovered that a solution comprising about 0.3 percent saline and about 0.1 percent red-banded cobra venom is extremely effective in treating this condition.
3. While the venom of the red-banded cobra was well-known, prior to Dr. Jones' discovery others in the art believed that any amount of the venom was deadly. No one ever suspected that it might also be useful for cosmetic applications, such as hair growth.
4. The key to Dr. Jones' method of treatment was that the red-banded cobra venom must be administered in very small doses at precisely 20 minute intervals for 48 hours. In his initial experiments, Dr. Jones achieved this by using an IV with a digital control unit, which was well-known in the art for administering other dosage-sensitive treatments. The downside to using a digitally-controlled IV is that the patient must be hooked up to that IV for the full length of the procedure. Up until September of 1995, all of Dr. Jones' other attempts to develop a more convenient delivery system failed.
5. A few months later, Dr. Jones' long-time friend, Mr. Bond, arrived in town to visit Dr. Jones over Labor Day weekend. Dr. Jones shared his discovery with Mr. Bond and explained the problem of finding a safe and more convenient delivery system.

6. This problem intrigued Mr. Bond, and he decided to assist Dr. Jones in developing a better delivery system. Over the next six weeks, the two of them conceived of and built a specially-designed ridged patch for delivery of the red-banded cobra venom. But before the ridged-patch could be properly tested, Mr. Bond was called away by the British government on an urgent mission to the Far East.
7. Dr. Jones subsequently tested the ridged-patch and discovered that it worked well because the ridges allow for very precise control over the timing and amount of venom released into the bloodstream. Indeed, Dr. Jones confirmed that a solution comprising about 0.3 percent saline and about 0.1 percent red-banded cobra venom is just as effective in the ridged patch as in the IV.
8. While the above solution yielded excellent results, Dr. Jones also discovered that the use of a solution additionally comprising about 3.3 percent dextrose had the unexpected benefit of improving patient safety in the unlikely event that the ridged patch provided too large a dose.
9. The chances of the ridged patch providing too large a dose are small (only about 1 in a thousand), but the side effects of an overdose can be severe and permanently debilitating. The dextrose ameliorates those side effects. The dextrose has no effect when the solution is administered using an IV and digital control unit.
10. In March of 1996, Dr. Jones filed a patent application titled “Method of Using Red-Banded Cobra Venom to Treat Hair Loss,” naming himself as the sole inventor. That application had one claim:
 1. A method for treating male pattern baldness, the method comprising the steps of:
 - administering to a patient by means of a ridged patch applied to the skin of the patient about 1.0 milliliters of a solution comprising, by volume,
 - about 3.3 percent dextrose,
 - about 0.3 percent saline, and
 - about 0.1 percent red-banded cobra venom;

and repeating the administering step at intervals of about 20 minutes for a period of about 48 hours.

11. The specification disclosed the precise dosage regimen discovered by Dr. Jones and taught that both an IV and a ridged-patch can be used as a delivery system. The specification also disclosed that, while a solution comprising about 0.3 percent saline and about 0.1 percent red-banded cobra venom is extremely effective in treating male pattern baldness, the use of a solution also comprising about 3.3 percent dextrose has the unexpected benefit of improving patient safety in the unlikely event that the ridged patch provides too large a dose. The specification had two figures. FIG. 1 showed the solution being administered to a patient by means of an IV and digital control unit. FIG. 2 showed the solution being administered to a patient by means of a ridged patch applied to the skin of the patient.
12. Three months after Dr. Jones filed his patent application, he filed a preliminary amendment adding the following claim:
 2. A method for treating male pattern baldness, the method comprising the steps of:
 - administering to a patient about 1.0 milliliters of a solution comprising, by volume,
 - about 3.3 percent dextrose,
 - about 0.3 percent saline, and
 - about 0.1 percent red-banded cobra venom;
 - and repeating the administering step at intervals of about 20 minutes for a period of about 48 hours.
13. A year later, the U.S. Patent and Trademark Office mailed an election of species requirement. Specifically, the patent examiner stated that the patent application contained claims directed to two patentably distinct species. Species 1 corresponded to FIG. 1 (showing the solution being administered to a patient by means of an IV and digital control unit). Species 2 corresponded to FIG. 2 (showing the solution being administered to a patient by means of a ridged patch applied to the skin of the patient).

The patent examiner stated that the species were independent or distinct, and that the species were not obvious variants of each other based upon the record. The patent examiner preliminarily indicated that Claim 2 was generic to the species.

14. In response to the election of species requirement, Dr. Jones elected to proceed with Species 2 for examination in his patent application. Dr. Jones indicated that Species 2 was covered by both Claims 1 and 2.
15. The application, with claims 1 and 2 as originally filed, issued as U.S. Patent No. 5,431,007 (“the ’007 patent”) on September 1, 1999.
16. While the use of red-banded cobra venom in these dosages for baldness treatment was undoubtedly novel, dextrose and saline were common ingredients in many types of hair loss treatments. Indeed, other than the use of cobra venom and the application regimen for administering it, Dr. Jones’s percentages for dextrose and saline were almost identical to a prior art hair growth product called Glare-B-Gone.
17. In 2000, Dr. Jones assigned the ’007 patent to Temple Drug Company (“Temple”) for several million dollars. Temple subsequently obtained FDA approval and began selling a ridged-patch infused with red-banded cobra venom according to the invention disclosed in the ’007 patent under the brand name “RegenX.” When it was released in 2004, RegenX was an immediate blockbuster drug.
18. Snake Oil Farms (“Snake Oil”) is a combination medical spa and snake farm. Its primary business before RegenX’s FDA approval was to harvest and sell snake venom to medical companies that used it to make antivenom.
19. Included among its many snake varieties were several red-banded cobras from which Snake Oil harvested and sold venom for antivenom production. But the sales of red-banded cobra venom were remarkably low compared to other snake species, such as rattlesnakes, due to the relatively low frequency of red-banded cobra attacks. In fact, red-banded cobra venom sales in 1998 amounted to only 0.1 % of Snake Oil’s venom sales, which ranked 24th (by volume of sales) out of Snake Oil’s top 25 best-selling snake venoms.

20. After reading the '007 patent, Snake Oil decided that it would like to offer a red-banded cobra venom baldness treatment, administered through an IV as taught in the '007 patent, to its spa customers. In late 2001, Snake Oil approached Temple seeking to license the '007 patent.
21. At that time, Temple was still in the process of obtaining FDA approval for RegenX. Anxious to recoup some of its costs, Temple granted Snake Oil a non-exclusive license as follows:

“Snake Oil is hereby granted a license under any Temple patent to make, use, or sell red-banded cobra venom at any Snake Oil facility for purposes of hair loss treatment.”
22. Between 2004 and 2007, Snake Oil’s use of the IV treatment was relatively low. Although the RegenX patch was popular, no one wanted to have a similar treatment administered by IV for 48 hours. Nonetheless, there were enough sales to move Snake Oil’s red-banded cobra venom sales from 24th to 18th on its list of its best-selling snake venoms.
23. In early 2007, a generic version of RegenX called “MoGRO” was introduced by Crystal Pharmaceuticals (“Crystal”).
24. To make MoGRO, Crystal first purchases red-banded cobra venom at Snake Oil’s facility outside of Dallas, Texas. Snake Oil harvests this venom from cobras raised on its farm and purifies it using its own proprietary techniques.
25. Crystal then manufactures ridged-patches and infuses them with the venom it purchased from Snake Oil. Crystal accomplishes this by following the techniques disclosed in the '007 patent, of which its scientists and executives were well aware.
26. Not surprisingly, Snake Oil’s sales of red-banded cobra venom skyrocketed in 2007, making red-banded cobra venom Snake Oil’s number one venom by sales volume. In fact, red-banded cobra venom sales outpaced rattlesnake venom sales (the prior number one seller) by almost 500%. The growth has only been slowed by the limited availability of red-banded cobras, whose natural non-captive populations have been decimated since

the release of RegenX. At present, Snake Oil still sells some red-banded cobra venom for antivenom purposes, but this antivenom use currently amounts to less than 1% of its total sales of red-banded cobra venom. Interestingly, the only reported uses of red-banded cobra antivenom between 2005 and late 2007 were from bites at snake farms that supply either Crystal or Temple with venom.

27. In January 2007, Snake Oil stopped offering the IV treatment at its Spa facilities due to an unfortunate accident where a customer was accidentally given a fatal amount of venom and died. Snake Oil settled the lawsuit quickly, but the accident received nationwide attention.
28. After Snake Oil stopped offering the IV treatment in January 2007, Crystal tried offering the IV treatment at a spa facility in Calistoga, California. Crystal promoted the treatment in Bay Area radio advertisements as part of a weekend “Relax and Regrow” vacation package, wherein customers would sip premium Napa Valley wines while lounging in warm mud baths, all the while hooked up to the IV. While the “Relax and Regrow” package attracted a handful of wealthy Silicon Valley customers, interest was low—so low that, by March, Crystal concluded that it had no hope of ever recouping its costs. In March 2007, Crystal scrapped the “Relax and Regrow” package and focused its marketing efforts exclusively on its successful MoGRO ridged patches.
29. Temple sued Crystal in April 2007, accusing Crystal of indirectly infringing the ’007 patent by selling MoGRO.
30. News of the lawsuit was so widespread that even Mr. Bond— who now lived on a beach in Indonesia—heard about it.
31. This was the first time Mr. Bond had ever heard of the ’007 patent. After reading the ’007 patent, he contacted Crystal and explained to the company that he should have been named as a joint inventor on Dr. Jones’ patent application. Crystal was initially skeptical of Mr. Bond’s claim. However, Mr. Bond explained the events of Labor Day weekend 1995 and the ensuing six weeks of rigorous joint research involving himself and Dr. Jones.

32. To further prove his story, Mr. Bond showed Crystal a notarized drawing dated September 15, 1995, attached hereto as Exhibit A. The drawing is in Mr. Bond's handwriting and clearly depicts a ridged-patch having the same specifications disclosed in the '007 patent. After seeing the drawing, Crystal was convinced and paid Mr. Bond \$250,000 for a non-exclusive, fully paid-up license to the '007 patent (the "Bond License"). As part of that license, Mr. Bond also agreed that he would not join as a plaintiff in the lawsuit against Crystal.
33. In June 2008, the District Court conducted a bench trial at which both Dr. Jones and Mr. Bond testified. On the stand, Dr. Jones conceded that Mr. Bond helped him out in the laboratory for about six weeks in the fall of 1995. But Dr. Jones testified that the ridged-patch was entirely his idea. Dr. Jones had no explanation for Mr. Bond's September 15, 1995 drawing, other than asserting that Mr. Bond had merely illustrated, after-the-fact, the same ridged-patch idea Dr. Jones had shared with Mr. Bond more than a week earlier. There is, however, nothing in Dr. Jones' own lab notebook that shows a ridged-patch prior to the September 15, 1995 date on Exhibit A.
34. Temple offered the testimony of Dr. Jones' daughter, Ohio Jones, to corroborate Dr. Jones' testimony. Ohio testified that she distinctly remembered a lunchtime conversation between Dr. Jones and Mr. Bond, during which her father slapped his forehead, exclaimed "That's it!" and proceeded to describe a ridged patch for delivering some sort of venom. On cross examination, in response to an improvidently asked open-ended question, Ohio explained at some length that the meal was so memorable because it was her first time to dine on chilled monkey brains and live baby snakes. Ohio was even able to recall the specific date on which the conversation took place—September 5, 1995—because it was her 16th birthday and, by Jones family tradition, such exotic lunches were only allowed upon turning 16.
35. The Court also heard from two experts in the field of biochemistry.
36. Dr. Steve Snape, a professor of biochemistry at Hogwarts University in Scotland, testified that the only reasonable use of Snake Oil red-banded cobra venom is to practice Claim 1 of the '007 patent. He based this opinion on the following facts: (1) at least

99% of red-banded cobra venom sales are for venom used in the methodology of Claim 1; (2) the only alternative venom use is for antivenom, which is primarily used to treat people bitten while harvesting the venom for the use described in Claim 1 (and is thus indirectly related to Claim 1); and (3) Snake Oil was the only inventive feature of Claim 1 because the mixture was otherwise well known for other hair loss treatments, such as Glare-B-Gone.

37. Dr. Miles Python, a professor of biochemistry at Holy Grail University in London, testified that Snake Oil red-banded cobra venom has significant uses other than use in a ridged patch. He based that opinion on the use of the venom in an IV treatment form and the use of red-banded cobra venom to make antivenom. Dr. Python admitted the low usage rate of antivenom, but explained that the low use should not be discounted since the antivenom use is far more important (i.e., to save lives) than the use of venom to fight male pattern baldness. Dr. Python also testified that transdermal patches to release chemicals into the body through the skin predate Mr. Bond's work in September 1995. The nicotine patch, for example, first became available in the United States in 1992. If a chemical has the ability to permeate human skin, then it is a relatively straightforward process to combine that chemical with a transdermal patch in order to deliver the chemical through the skin and into the bloodstream.

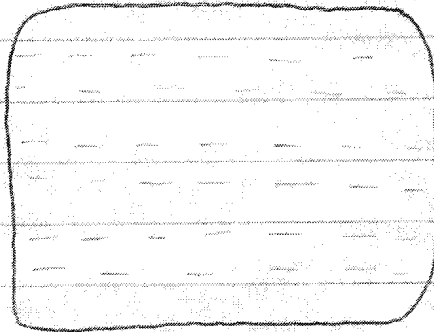
Conclusions of Law

1. The District Court ruled for Crystal on the exhaustion issue, citing Quanta Computer, Inc. v. LG Electronics, Inc., 128 S. Ct. 2109 (2008), for the proposition that the authorized sale of an article is a relinquishment of the patent monopoly with respect to the article sold when the article's sole reasonable and intended use is to practice the patent.
2. In support of its exhaustion determination, the District Court explained that the claims of the '007 patent are directed to a method of treatment using red-banded cobra venom, and that the purified venom that Crystal purchased from Snake Oil substantially embodied the invention.
3. The District Court further found that the purified venom does not have reasonable and intended uses other than in practicing the patent. The District Court stated that use in making antivenom was not a reasonable and intended use. The District Court also stated that use in a solution lacking dextrose and delivered to a patient by means of an IV with a digital control unit was not a reasonable and intended use.
4. Because the purified venom substantially embodied the invention and because the venom does not have reasonable and intended uses other than in practicing the patent, the District Court held that Snake Oil's sale of the venom exhausted Temple's patent rights.
5. The District Court ruled in favor of Crystal on the inventorship issue, citing Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456 (Fed. Cir. 1996) for the proposition that an alleged joint inventor need only contribute to the conception of a single claim in order to properly be considered a joint inventor for the entire patent.
6. In support of its inventorship determination, the District Court found that Mr. Bond had overcome the presumption of validity as to correct inventorship of the '007 patent with clear and convincing evidence. Specifically, referring to Ethicon, the District Court found that Mr. Bond's September 15, 1995 drawing corroborated his testimony that he contributed to the invention by conceiving of the ridged-patch delivery system.

7. Further, the District Court determined Dr. Jones' testimony was not as credible as Mr. Bond's. The District Court pointed out that Dr. Jones had no substantive explanation for Mr. Bond's drawing, had no documents to support his claim that the ridged patch was his idea, and could only offer the testimony of his daughter to support his story. The District Court cited Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728 (Fed. Cir. 2002), and Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368 (Fed. Cir. 1998) as evincing skepticism of interested witness testimony, particularly testimony from family members.
8. Finally, the District Court concluded that because Mr. Bond was a joint inventor, he was a co-owner of the patent, and thus a necessary plaintiff in the infringement action against Crystal. Relying again on Ethicon, the Court held that absent all co-owners joined as plaintiffs, Temple lacked standing to bring the action and dismissed the case.

9/15/95 (MB)

TOP



SEDS



APPLICATION



Venom dosed into skin
over time

Mr. Bond did appear before me, this 15th day of September, 1995.

Miss Moneypeeny
Notary Public
1995
Miss Moneypeeny
Galapagos

Miss Moneypeeny
Notary, State of Galapagos
Reg. No. 329-9792