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(54) **APPARATUS AND METHOD FOR TREATMENT OF INFECTED NAIL**

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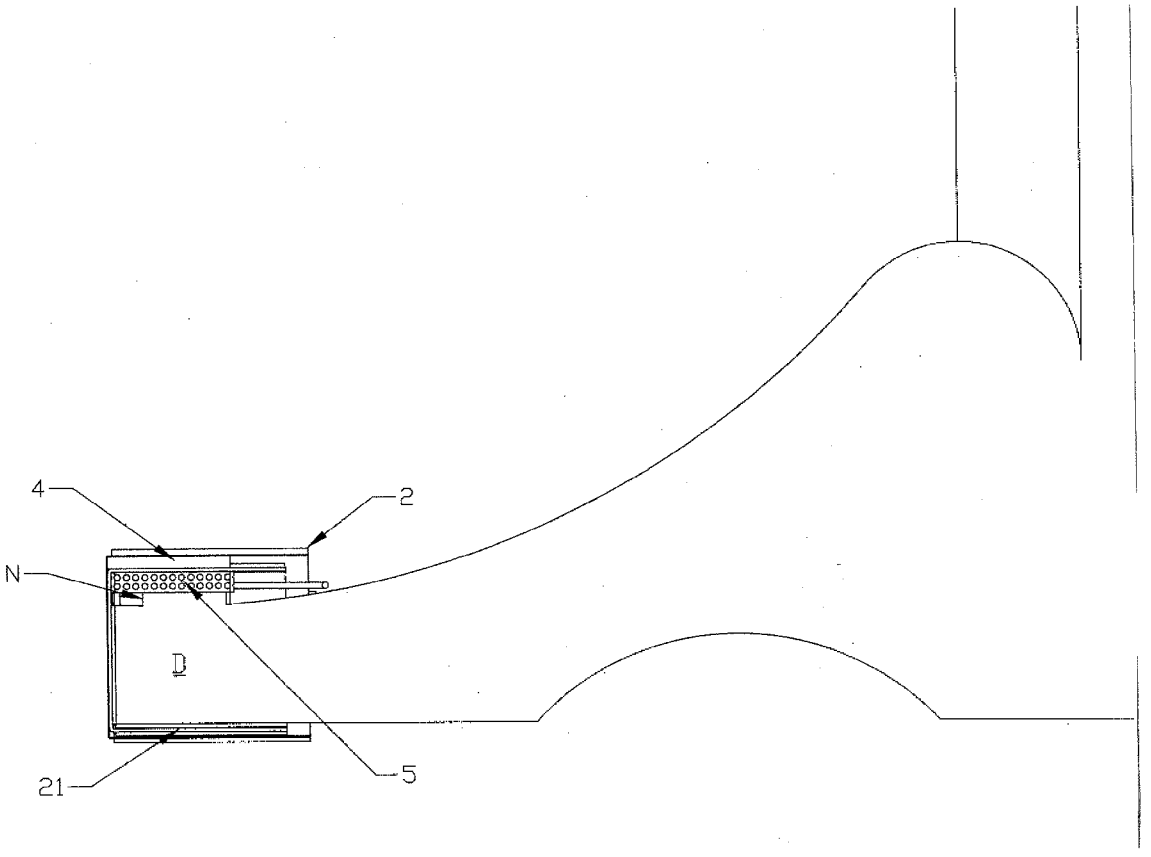
(57) **ABSTRACT**

An infected nail of a digit of a patient is treated using apparatus including an enclosure capable of housing at least a distal end of at least one digit of a patient having an infected nail. The apparatus also includes a heater and a nail infection agent-containing member housed within the enclosure and positionable against an infected nail at the distal end of a digit housed within the enclosure. The heater is in heat-transfer relationship with the nail infection agent. In this way heated nail infection agent can be maintained against an infected nail by the nail infection agent-containing member.



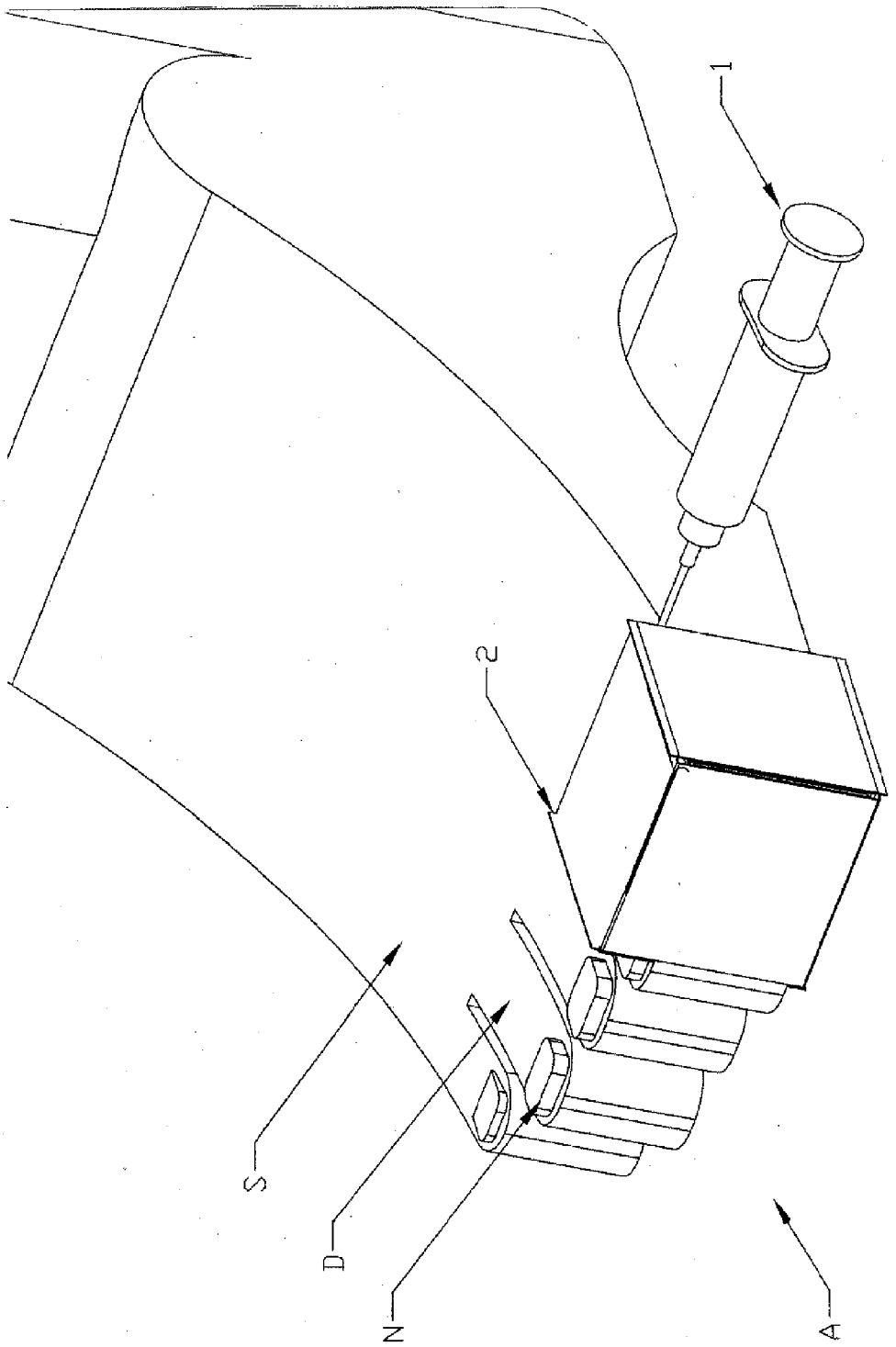


FIGURE 1

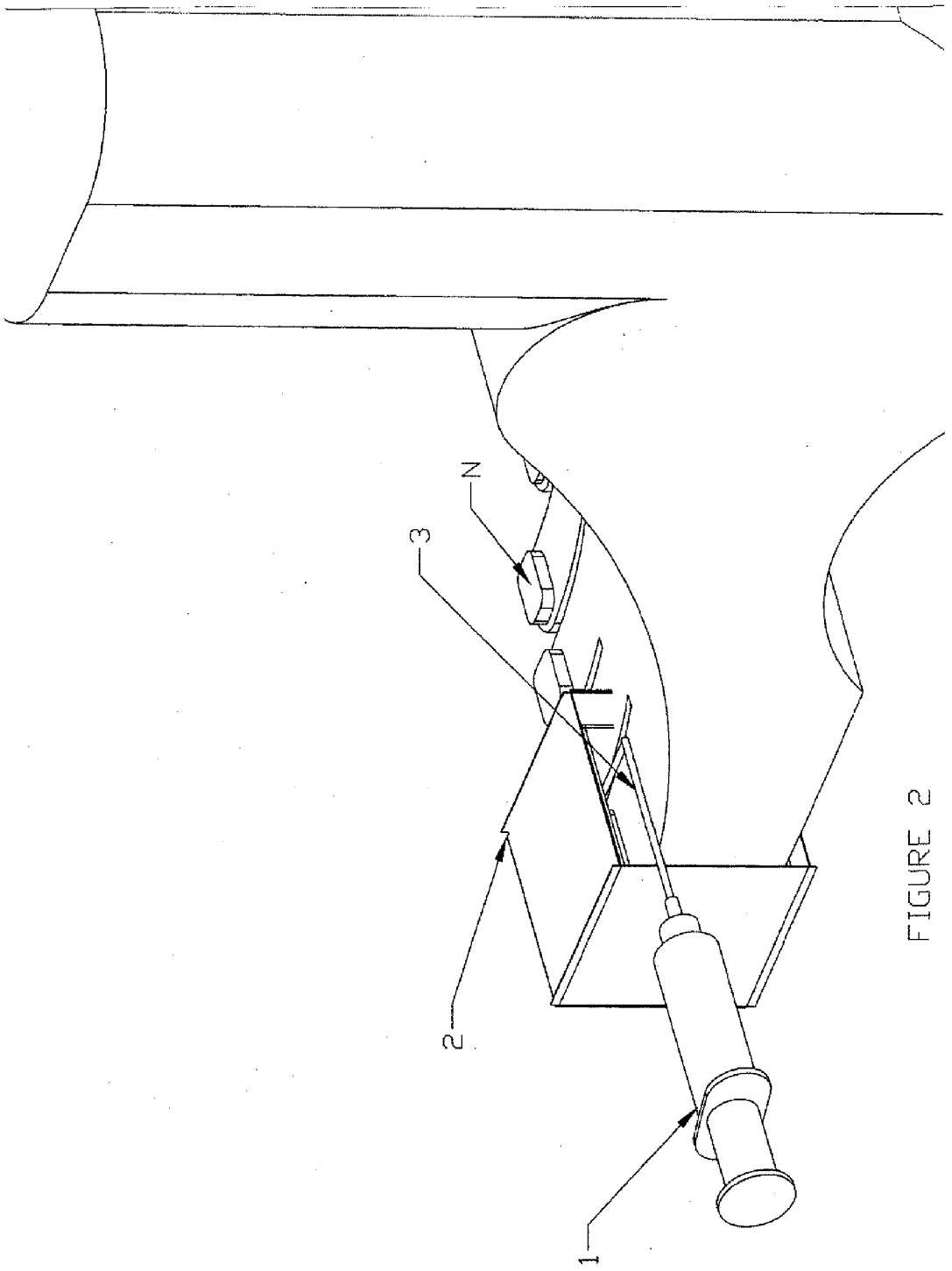


FIGURE 2

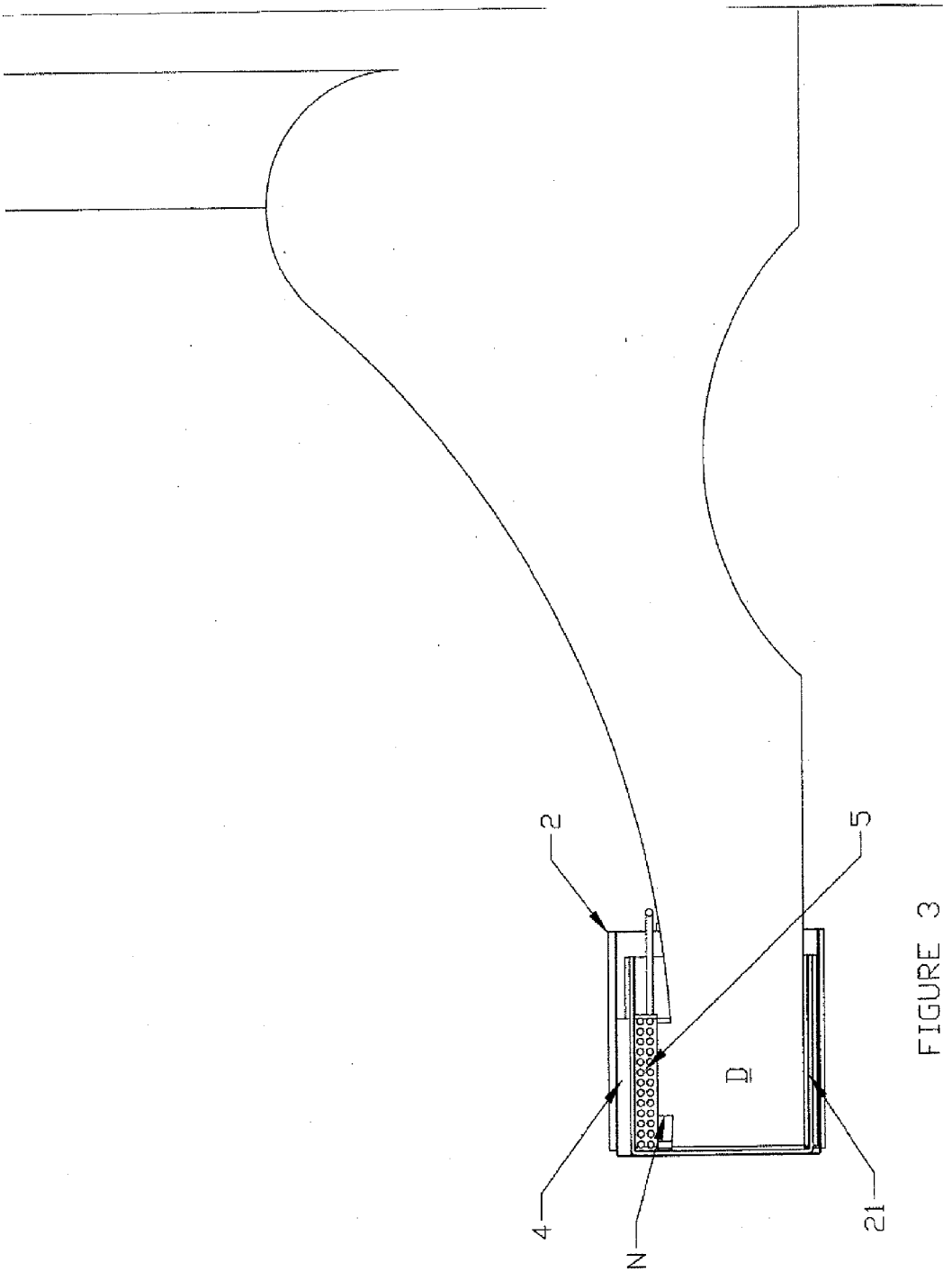


FIGURE 3

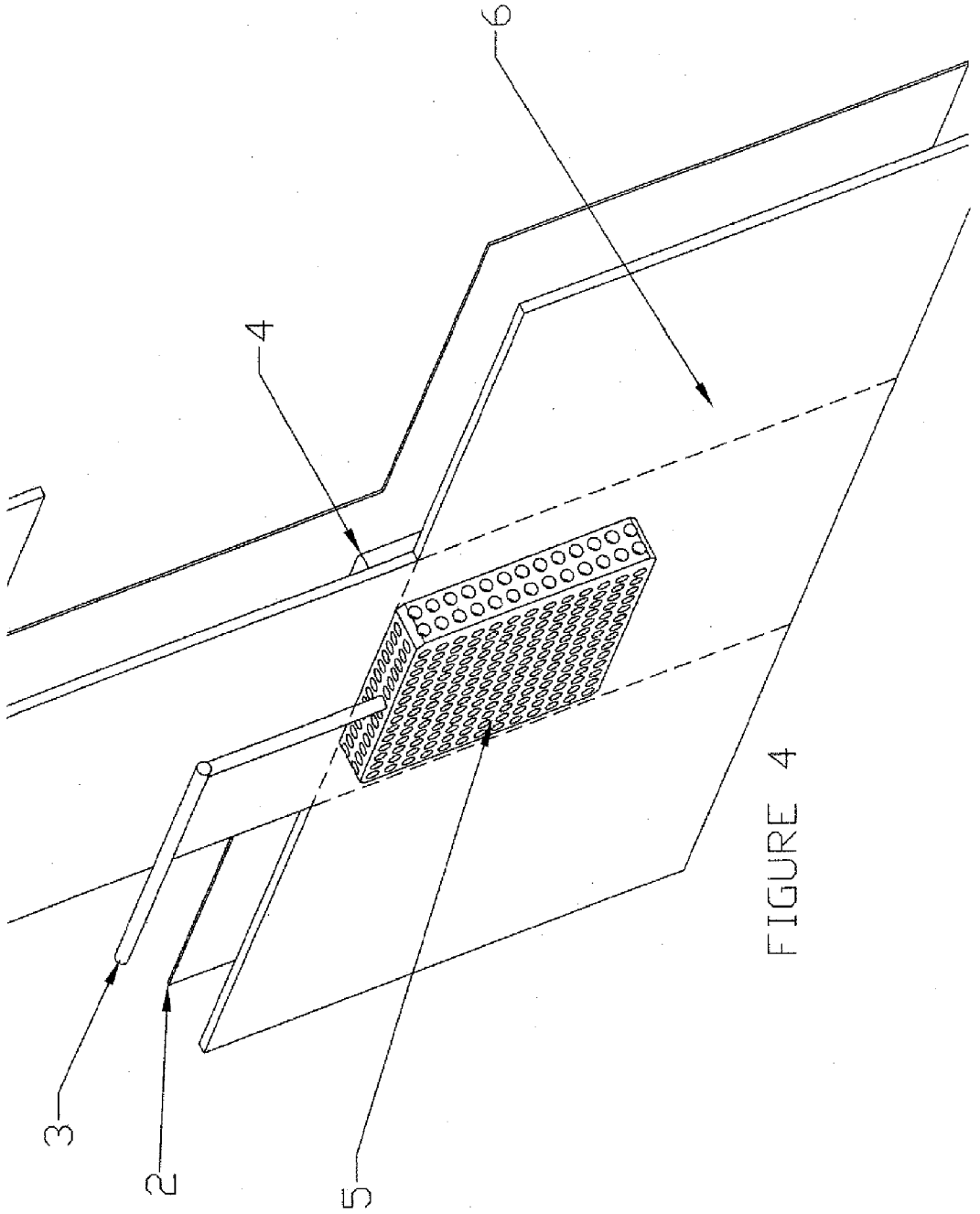
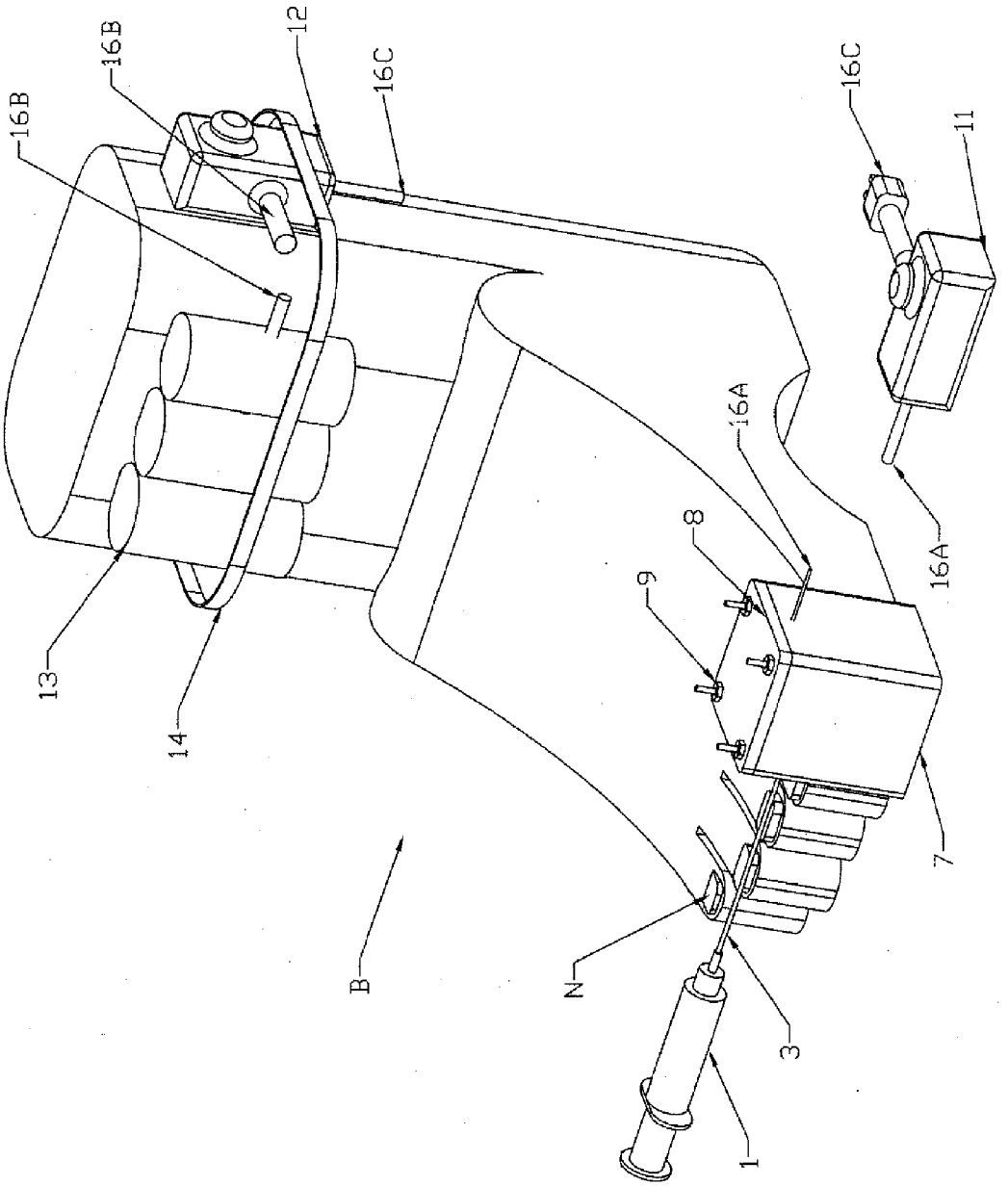


FIGURE 4

FIGURE 5



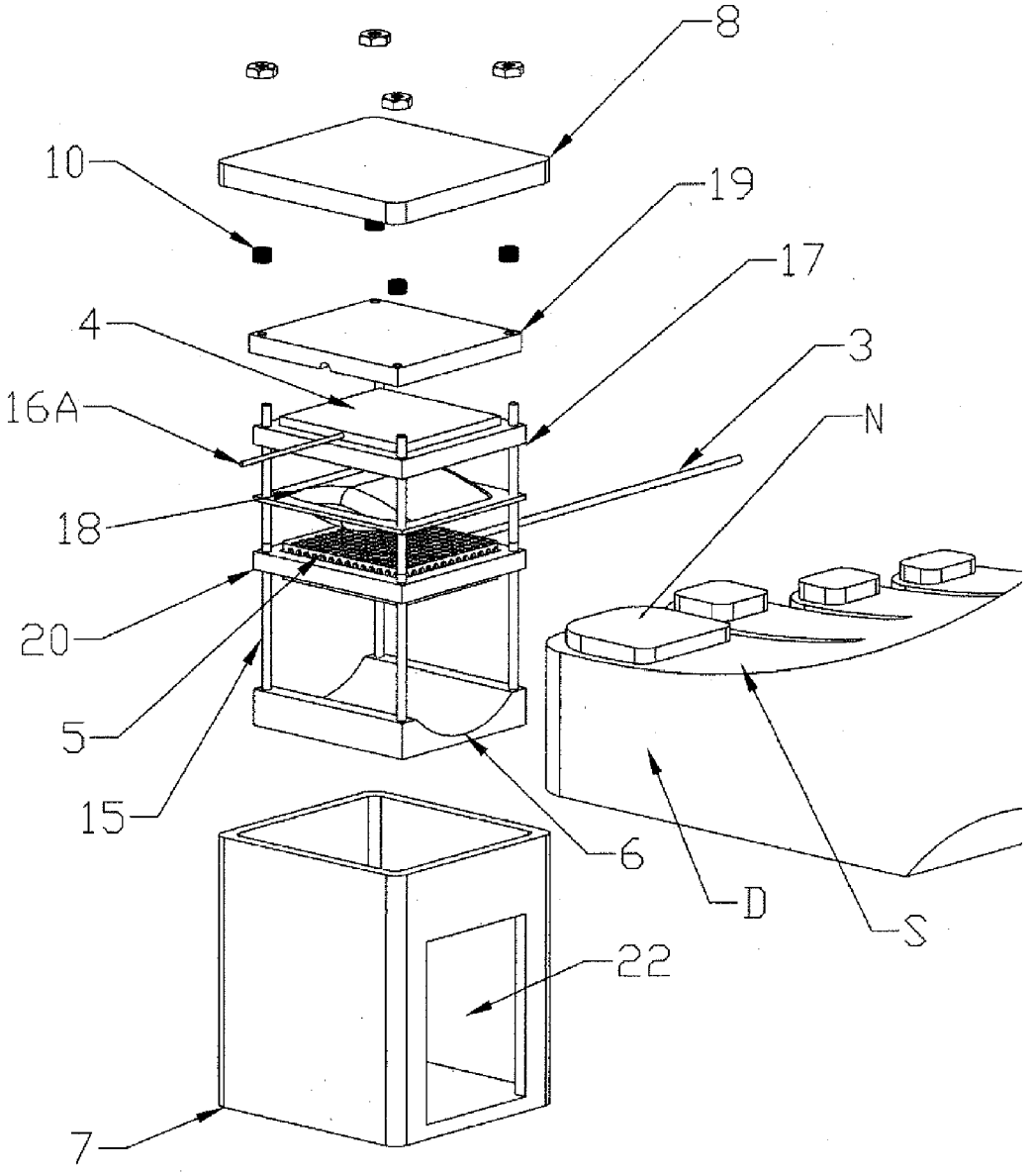


FIGURE 6

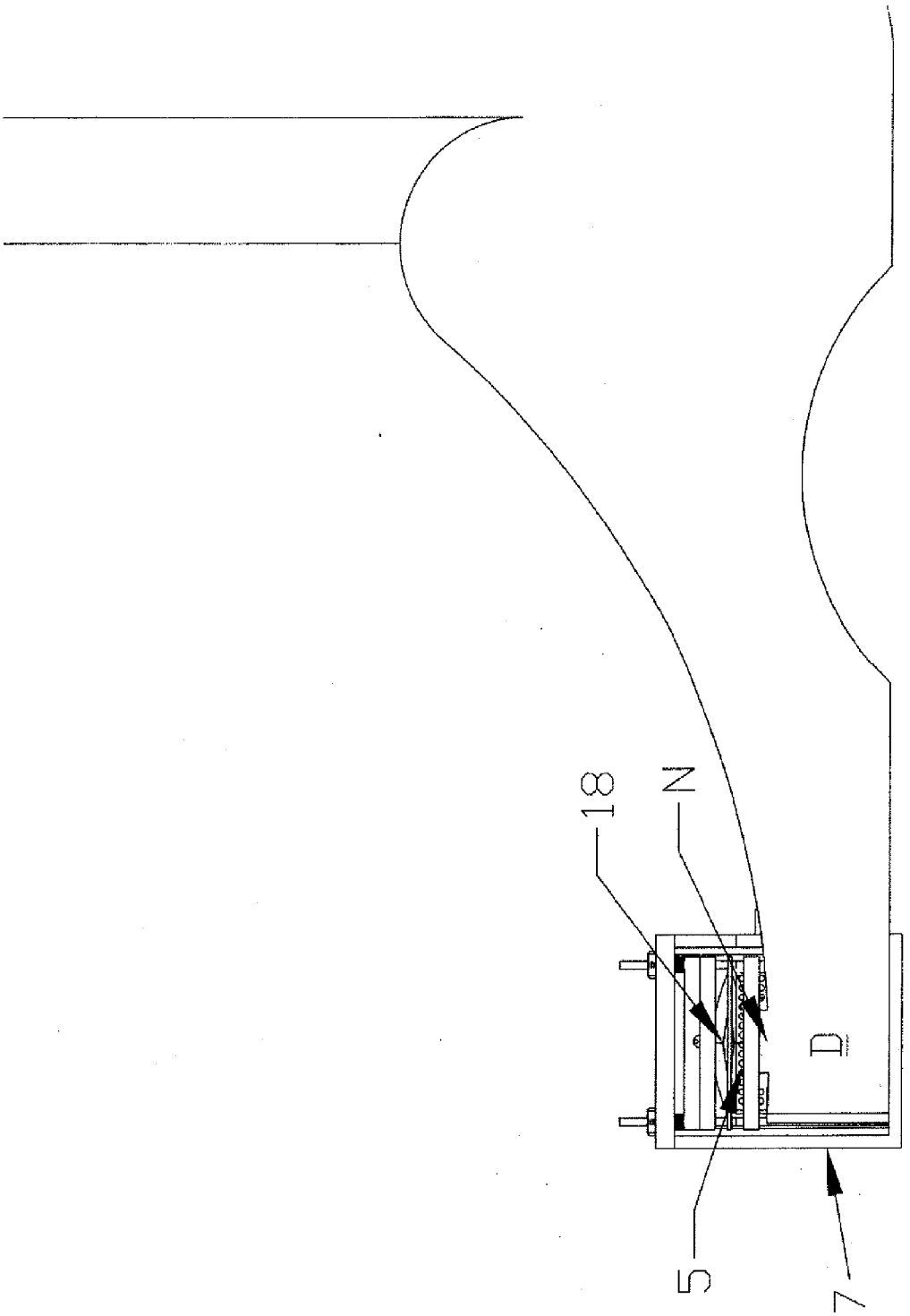


FIGURE 7

APPARATUS AND METHOD FOR TREATMENT OF INFECTED NAIL

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 11/423,874, filed Jun. 16, 2006, which claims the benefit of U.S. Provisional Application Nos. 60/704,230, filed Jul. 28, 2005; 60/709,602, filed Aug. 8, 2005; and, 60/731,754, filed Oct. 30, 2005; each application of which is hereby incorporated herein in it's entirety by reference.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] None.

BACKGROUND OF THE INVENTION

[0003] Tinea unguium or onychomycosis (nail fungus) has long been a medical challenge to cure. While there are topically applied reagents which effectively control fungal growth (e.g., cyclopirox) getting the reagent to thoroughly contact the fungus has long been the challenge. The nail provides a seemingly impenetrable membrane protecting the fungus from outside elements as Quintanar-Guerrero et al from Universidad Nacional Autónoma de México have shown in their paper, *The effect of keratolytic agents on the permeability of three imidazole antimycotic drugs through the human nail* (Drug Dev Ind Pharm, Jul. 1, 1998; 24(7): 685-90).

[0004] Current topical treatment research has focused on developing a single reagent which both penetrates the nail and destroys the fungus. Unfortunately, to date such research has not produced this cure. Ciclopirox (Penlac, Loprox) alone has a cure rate of just 20% after one year, however, this rate may include data for Ciclopirox' primary purpose, that is, tinea corporis. Part of the challenge is developing a single treatment for the 119 known strands of tinea.

[0005] Quintanar-Guerrero et al also found that keratolytic substances such as papain, and salicylic acid used in combination did enhance the permeability of the antimycotic.

[0006] Patents with methods, formulae, and apparatus to increase the permeability of the antimycotic through the nail into the nail bed dominate this art. See, for example, the following U.S. Pat. Nos. and patent application publications: U.S. Pat. Nos. 6,821,508; 6,921,529; 5,795,314; 5,098; 4,331,137; patent application publications 2004/0161452 A1; 2006/0013862; U.S. Pat. Nos. **6,727,401**; **6,465,709**.

BRIEF SUMMARY OF THE INVENTION

[0007] A first aspect of the invention is directed to apparatus for treating an infected nail of a digit of a patient. The apparatus includes an enclosure capable of housing at least a distal end of at least one digit of a patient having an infected nail. The apparatus also includes a heater and a nail infection agent-containing member housed within the enclosure and positionable against an infected nail at the distal end of a digit housed within the enclosure. The heater is in heat-transfer relationship with the nail infection agent. In this way heated nail infection agent can be maintained against an infected nail by the nail infection agent-containing member.

[0008] A second aspect of the invention is also directed to apparatus for treating an infected nail of a digit of a patient. The apparatus includes means for housing at least a distal end of at least one digit of a patient having an infected nail. The apparatus also includes means, within the housing means, for positioning a nail infection agent-containing member against an infected nail at the distal end of a digit housed within the enclosure. In addition, the apparatus includes means for heating the nail infection agent. The nail infection agent can thereby be maintained against an infected nail by the agent-containing member.

[0009] A third aspect of the invention is directed to a method for treating an infected nail of a digit of a patient. At least a distal end of at least one digit of a patient, having an infected nail, is housed within an enclosure. A nail infection agent-containing member is positioned against an infected nail at the distal end of a digit housed within the enclosure. The nail infection agent is heated to enhance the effectiveness of the nail infection agent. The heated nail infection agent is maintained against the infected nail for a therapeutically effective time period. In some embodiments the nail infection agent is restrained or prevented from coming into contact with a patient's skin. The nail infection agent may also be restrained or prevented from escaping from the enclosure.

[0010] Various features and advantages of the invention will appear from the following description in which the preferred embodiments have been set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. **1** is a first simplified isometric view of a first preferred embodiment of an infected nail treatment apparatus mounted to a digit of a user;

[0012] FIG. **2** is a second simplified isometric view of the apparatus of FIG. **1**;

[0013] FIG. **3** is a simplified cross-sectional view of the apparatus of FIG. **1**;

[0014] FIG. **4** is a simplified isometric view of the apparatus of FIG. **1** in an unfolded state;

[0015] FIG. **5** is a first simplified isometric view of a second, alternative embodiment of an infected nail treatment apparatus mounted to a digit of a user;

[0016] FIG. **6** is an exploded isometric view of the apparatus of FIG. **5**; and

[0017] FIG. **7** is a simplified cross-sectional view of the apparatus of FIG. **5**.

DETAILED DESCRIPTION OF THE INVENTION

[0018] The following description of the invention will typically be with reference to specific structural embodiments and methods. It is to be understood that there is no intention to limit the invention to the specifically disclosed embodiments and methods but that the invention may be practiced using other features, elements, methods and embodiments. Preferred embodiments are described to illustrate the present invention, not to limit its scope, which is defined by the claims. Those of ordinary skill in the art will recognize a variety of equivalent variations on the description that follows. Like elements in various embodiments are commonly referred to with like reference numerals.

The Treatment Apparatus of Preferred Embodiment

[0019] The design intent for the embodiment of FIGS. **1-4** is to facilitate the contact between the solution, that is the nail infection agent, and the infected nail(s) N while minimizing the contact between skin S and the solution; and to provide a convenient, portable, and disposable, and/or reusable means to apply solution to the infected nails.

[0020] Treatment apparatus A includes a reservoir **1** which supplies sponge **5** with solution. Reservoir **1** may be designed as a container which supplies sponge **5** with solution via

gravity feed through fluid tubing **3**, or (as illustrated in FIGS. **1** and **2**) as an electronically controlled pump feed system through fluid tubing **3**, or as syringe feed through fluid tubing **3**. See Table A for an example of syringe feed which may be purchased as a commercial part. Although sponge **5** may be provided filled with solution, the use of some sort of solution reservoir permits sponge **5** to be supplied and re-supplied with solution as needed during a procedure.

[0021] Treatment apparatus A also includes an enclosure **21** which acts as the compress which holds all of the components together including pressing and keeping sponge **5** on top of the infected nail. Enclosure **21** is made of flexible, stretchy hook and loop type of material which adheres to itself similar to a diaper to fasten the invention around the toe(s), and to provide a thermal barrier between sodium acetate heater **4** and the outside. Enclosure **21** also acts to force heater **4** and sponge **5** against infected toe or finger nail(s) to provide an even distribution of both heat and solution and as a liquid barrier between the entire assembly and its surroundings. Enclosure **21** may be designed to accommodate only one nail or as many as ten.

[0022] Fluid tubing **3** is the conduit through which reservoir **1** supplies sponge **5** with solution. Corrosion resistant material choices for fluid tubing **3** include ETFE, PTFE, PFA, FEP, and Chemfluor. See Table A for an example of fluid tubing **3** available for purchase in ETFE material.

[0023] Sodium acetate heater **4** is a flexible plastic enclosure that contains sodium acetate disk and water. When the sodium acetate disk is clicked (fingernail tap) to mix with the water, the mixture changes to its solid state in an exothermic reaction to freeze at 130 F thereby heating the solution enclosed in sponge **5**. The process is reversible by boiling the solid back into the liquid state. Sodium acetate is a food additive and is non-toxic. An example of a sodium acetate heater that may be purchased as a commercial part is included in table A. Other types of heaters may be used and may also be affixed to reservoir **1** or between reservoir **1** and sponge **5** to perform the same function.

[0024] The purpose of sponge **5** is to absorb and saturate heated solution onto the infected nail(s), to maintain the solution on the surface of the nail, to isolate the surrounding skin from the solution as much as possible, and to apply heated solution to an irregularly shaped nail (not flat). Sponge **5** receives solution from reservoir **1** through tubing **3**. For this reason, sponge **5** may be made from a variety of absorbent sponge/cloth type materials, an example of which is included in Table A. It may be desired to use some type of seals surrounding sponge **5** to help prevent the heated solution from contacting the user's skin.

[0025] Sodium polyacrylate liner **21** is the liner between sponge **5** and heater **4** having the same outline as diaper enclosure **2** and may be made from a variety of sponge/cloth type materials (including sodium polyacrylate to absorb excess solution) an example of which is included in Table A. Sodium polyacrylate is the chemical in baby diapers to absorb moisture.

Intended Use of Preferred Embodiment

[0026] Treatment apparatus A creates a volume which contains and heats a solution around infected nail(s) to amplify the keratolytic properties of the solution to theoretically imbed the solution within the nail molecular structure, in addition to etching the nail from the top.

[0027] To use treatment apparatus A, infected nail(s) are wrapped into diaper enclosure **2** shown in FIGS. **1-3**, preferably creating a liquid tight seal, to force solution-saturated sponge **5** against the infected nail(s). The appropriate chemistry solution (see the discussed below) is added to reservoir **1** which fills sponge **5** with solution. The sodium acetate heater is clicked with a fingernail to heat the solution in sponge **5**. Solution is removed from sponge **5** using aspiration of reservoir **1** as necessary.

The Treatment Apparatus of Alternative Embodiment

[0028] Treatment apparatus B of FIGS. **5-7** includes a sponge **5** is to absorb and saturate heated solution onto the infected nail(s), to maintain the solution on the surface of the nail, to isolate the surrounding skin from the solution as much as possible, and to apply heated solution to an irregularly shaped nail (not flat). Sponge **5** receives solution from reservoir **1** through tubing **17**. For this reason, sponge **5** may be made from a variety of absorbent sponge/cloth type materials, an example of which is included in Table A. Sponge harness **20** is a frame which surrounds and captures sponge **5** for vertical adjustable mounting to threaded rods **15**.

[0029] The center of sponge harness **20** is open to allow sponge **5** to extend beyond sponge harness **20** to allow sponge **5** to contact the nail with solution. This design allows for vertical adjustment of sponge **5** and sponge harness **20** within enclosure **7** perpendicular to the nail to provide pressure between the nail plate and sponge **5** for thorough distribution of solution onto the nail. Likewise a variety of materials would be appropriate for sponge harness **20**, preferably corrosion resistant ones such as 316 L stainless steel or chemically resistant plastics as polycarbonate.

[0030] The design intent for fluid-containing, conformable heat transfer device **18** is to evenly distribute heat from the flat regular surface of heater plate **17** to the irregular surface of sponge **5** as it conforms to the irregular nail surface. Device **18** can be made from most flexible water tight plastics (see example in Table A) with a heat transfer fluid such as water trapped inside. The heat transfer fluid inside device **18** contacts the walls of its plastic enclosure and flows inside the plastic evenly distributing the heat from heater **4** and heater plate **17** to sponge **5**. The flexible plastic of device **18** is smoothed, hardened and flattened at its edges with holes added for vertical adjustment on threaded rods **15**.

[0031] Heater **4** is a standard flexible heater available from many suppliers and is usually made by embedding resistance wires inside a thermally flexible rubber material (see Table A) and its temperature is controlled with a heater controller such as item **11** or **12**. Heater **4** may be purchased with a pressure sensitive adhesive on one side to secure the heater and for a good thermal connection with heater plate **17**. Heater **4** may also be affixed to reservoir **1** to perform the same function.

[0032] Heater cover **19** is made from a high temperature thermally isolating material such as polyamide-imide. The center portion of heater cover **19** is scalloped so only the edges contact heater plate **17** to limit heat transfer even further. Heater cover **19** is designed to thermally isolate heater **4** from enclosure cover **8**. Heater cover **19** includes holes through which travel threaded rods **15** for vertical adjustment.

[0033] Toe harness **6** is designed to comfortably secure toes or fingers within enclosure **7**. Materials of choice for toe harness **6** include corrosion resistant metals such as 316 L stainless steel and plastics such as polycarbonate. Threaded rods **15** are permanently and perpendicularly fixed to toe harness **6** using an appropriate adhesive, sonic, solvent bond, or internal or external fastener, and do not move. Toe harness **6** is permanently attached to enclosure **7** using an appropriate fastener means as above and likewise does not move.

[0034] Enclosure **7** surrounds, thermally isolates, and preferably creates a liquid barrier between the entire assembly and its surroundings. Enclosure **7** should be made of a corro-

sion resistant metal such as 316 L stainless steel or plastic such as polycarbonate. Enclosure **7** includes an opening **22** for receipt of digit(s) D, that is the finger(s) or toe(s), with the infected nail(s). Enclosure components may be designed to accommodate only one digit or as many as ten.

[0035] Enclosure cover **8** further seals enclosure **7** and the entire assembly from its surroundings and may be made from a semi-high temperature semi-hard rubber material such as EPDM rubber (Shore A 60). Enclosure cover **8** does not move relative to enclosure **7**.

[0036] Hex nut **9** should be made from a corrosive resistant metal such as 316 L stainless steel to keep threads from galling (see Table A). When hex nut **9** is tightened on threaded rods **15** against enclosure cover **8**, it compresses springs **10** forcing heater **4**, heater plate **17**, fluid **18**, sponge **5** and sponge harness **20** against the infected toe nail(s) to provide an even distribution of both heat and solution to the nail(s).

[0037] Spring **10** should be made of 316 L stainless steel or other material to withstand both corrosion and repeated tension and compression. The design intent for spring **10** is to provide the spring tension force that compresses the above components into a good thermal and liquid contact with the infected nail(s) against enclosure cover **8**.

[0038] AC heater controller **11** regulates heater **4** (by modulating power from the wall outlet to heater **4**) to selected temperatures. AC heater controller **11** is purchased as a commercial part as shown in Table A. Regulating the temperature in AC heater controller **11** also regulates the temperature of heater plate **17**, device **18** and sponge **5**. Sponge **5** controls the temperature of the solution on the infected nail which is optimized according to the selected treatment chemistry.

[0039] Battery heater controller **12** performs the same function as AC heater controller **11**, with the exception that it draws its power from battery pack **13** instead of the wall outlet and is purchased as a commercial component and modified to operate to use battery power instead of AC power. Battery heater controller **12** coupled with battery pack **13** enables the entire assembly to be portable.

[0040] Battery pack **13** supplies the power to operate the assembly when in portable mode and may be purchased from a supplier as shown in Table A. Battery pack **13** may be made from a variety of rechargeable battery technologies including NiMH, Lithium Ion, or a hydrogen fuel cell.

[0041] Leg harness **14** removeably attaches battery heater controller **12** and battery pack **13** to the limb for portable operation. Leg harness **14** may be made from a variety of materials including nylon fabric, leather, or plastic straps. See Table A for an example of a harness which may be purchased as a commercial part.

[0042] Reservoir **1** supplies sponge **5** with solution. Reservoir **1** may be made of a variety of corrosion resistant materials including polycarbonate and 316 L stainless steel. Reservoir **1** may be designed as a container which supplies sponge **5** and the above volumes with solution via gravity feed through fluid tubing **3**, or as an electronically controlled pump feed system through fluid tubing **3**, or as syringe feed through fluid tubing **3**. See Table A for an example of syringe feed which may be purchased as a commercial part.

[0043] Threaded rod **15** is the shaft on which the entire assembly travels in a vertical direction perpendicular to the nail. Threaded rod **15** should be made of corrosion resistant material such as 316 L stainless steel. See Table A for an example of a threaded rod which is available for purchase as a commercial component.

[0044] Fluid tubing **3** is the conduit through which reservoir **1** supplies sponge **5** and the volumes above with solution. Corrosion resistant material choices for fluid tubing **3** include ETFE, PTFE, PFA, FEP, and Chemfluor. See Table A for an example of fluid tubing **3** available for purchase in ETFE material.

[0045] Electrical wire **16** is subdivided into three groups **16** A, **16** B, and **16** C depending on the electrical connection. **16**A electrical wire designates the connection between heater **4** and AC heater controller **11**. **16** B designates the connection between battery pack **13** and battery heater controller **12**. **16** C designates the connection between AC heater controller **11** and the wall outlet. Electrical wire **16** (all groups) varies in diameter depending on the intended current it carries—an example of which (copper wire insulated with PTFE) is in Table A and is purchased as a commercial component.

[0046] Heater plate **17** is designed to support and evenly disburse heat from heater **4** (flexible heater with pressure sensitive adhesive on one side). Heater **4** should be made from a good thermally conductive material such as aluminum, which has been anodized (plated) to resist corrosion.

Intended Use for Alternative Embodiment

[0047] Treatment apparatus B creates a volume which contains and heats a solution around infected nail(s) to amplify the keratolytic properties of the solution to theoretically imbed the solution within the nail molecular structure, in addition to etching the nail from the top.

[0048] To use treatment apparatus B, infected nail(s) are inserted into enclosures shown in FIGS. **5-7**. All fasteners are tightened, preferably creating a liquid tight seal, to force saturated sponge **5** against the infected nail(s). The procedure is preferably continued for a therapeutically effective time period, typically about 20 to 30 minutes daily. The appropriate nail infection agent is added to reservoir **1** which fills sponge **5** and the appropriate volumes formed inside the enclosures with the agent.

[0049] For portable operation, battery pack **13** and battery heater controller **12** are strapped to the appropriate limb using leg harness **14**. Electrical connection **16** B is made between battery pack **13** and battery heater controller **12**. Electrical connection **16** A is also made between battery heater controller **12** and heater **4**. The appropriate temperature is selected by rotating the dial on the battery heater controller **12**. To remove the invention, the battery heater controller **12** is turned off. Solution is removed from the volumes using aspiration or gravity. Fasteners are loosened and the nail(s) are removed.

[0050] For stationary operation, heater controller **11** is plugged into a standard wall outlet using electrical connection **16** C. Electrical connection **16** A is also made between heater controller **11** and heater **4**. The appropriate temperature is selected by rotating the dial on the heater controller **11**. To remove the invention, the heater controller **11** is turned off. The solution is removed from the volumes using aspiration or gravity. Fasteners are loosened and the nail(s) are removed.

Discussion of Typical Nail Infection Agents, Times and Temperatures

[0051] The terms tinea unguium and onychomycosis specifically refer to fungal infections of the toe nails. These infections, however, may be caused by different fungi such as: *Trichophyton rubrum* and *Trichophyton mentagrophytes,* which are the major two.

[0052] Most successful antifungal agents such as ciclopirox and Anacor AN2690 are broadband antifungal agents which means they are effective in treating a wide range of fungi responsible for onychomycosis.

[0053] However, even a broad band antifungal agent is ineffective in treating onychomycosis without contacting the

fungus. To facilitate this contact, the antifungal agent (and a keratolytic agent such as salicylic acid) are dissolved in warm water (45 degrees C.).

[0054] The infected nails are submerged in the warm solution mixture for 20 to 30 minutes daily. Since human nails are made of keratin, and keratin absorbs water, the antifungal agent becomes embedded inside the nail, contacting the fungus.

[0055] Additional topical treatments (such as a topical antibiotic ointment over undecyclenic acid) are applied after the water has evaporated to further create a toxic environment for the fungi.

TABLE A

ITEM NO	DESCRIPTION	QUANTITY	MFG/SUPPLIER	REF PART NO
1	Reservoir	1	mcmaster.com	7510A656
2	Diaper Enclosure	1	mcmaster.com	58435T11
3	Fluid Tubing	A/R	mcmaster.com	50375K41
4	Heater	1	mcmaster.com	35765K126
5	Sponge	1	mcmaster.com	7271T32
6	Toe Harness	1	custom	N/A
7	Enclosure	1	custom	N/A
8	Enclosure Cover	1	custom	N/A
9	Hex Nut	4	mcmaster.com	90730A003
10	Spring	4	mcmaster.com	9657K81
11	AC Heater Controller	1	mcmaster.com	35655K89
12	Battery Heater Controller	1	mcmaster.com/custom	mod of 35655K89
13	Battery Pack	1	sears.com	911022000
14	Leg Harness	1	mcmaster.com	8062T211
15	Threaded Rod	4	mcmaster.com	93250A105
16	Electrical Wire	A/R	mcmaster.com	1749T23
17	Heater Plate	1	custom	N/A
18	Heat Transfer Device	1	mcmaster.com	7789A11
19	Heater Cover	1	custom	N/A
20	Sponge Harness	1	custom	N/A
21	Sodium Polyacrylate Liner	1	mcmaster.com	7271T32
22	Opening	1	custom	N/A

[0056] The above descriptions may have used terms such as above, below, top, bottom, over, under, et cetera. These terms are used to aid understanding of the invention are not used in a limiting sense.

[0057] While the present invention is disclosed by reference to the preferred embodiments and examples detailed above, it is to be understood that these examples arc intended in an illustrative rather than in a limiting sense. It is contemplated that modifications and combinations will occur to those skilled in the art, which modifications and combinations will be within the spirit of the invention and the scope of the following claims.

[0058] Any and all patents, patent applications and printed publications referred to above are incorporated by reference.

We claim:

1. An system for treating an infected nail, comprising:

a nail-infection-agent-containing member having a surface positionable for contacting a nail-infection agent against a surface of an infected nail; and,

a heater operable to heat the nail-infection agent while the agent is in contact with the surface of the infected nail during a treatment of the infected nail;

wherein,

the nail-infection-agent-containing member is adjustable relative to the surface of the infected nail to provide a localized application of pressure between the nail-infection-agent and the surface of the infected nail; and,

the treatment of the infected nail occurs in a warm, dark, and moist environment.

2. A method for treating an infected nail of a patient, comprising:

applying a nail-infection agent to a surface of an infected nail, wherein the agent is applied from a surface of a nail-infection-agent-containing member that is positionable for contacting the nail-infection agent against the surface of the infected nail;

heating the nail-infection agent with a heater operable to heat the nail-infection agent while the agent is in contact with the surface of the infected nail during a treatment of the infected nail to enhance penetration of the agent into the infected nail; and,

maintaining the nail-infection agent, heat, and pressure against the surface of the infected nail for a therapeutically effective time.

wherein,

the nail-infection-agent-containing member is adjustable relative to the surface of the infected nail to provide a localized application of pressure between the nail-infection-agent and the surface of the infected nail;

the treatment of the infected nail occurs in a warm, dark, and moist environment; and,

the penetration of the nail-infection agent is enhanced relative to a penetration that does not include the heat and the pressure in the warm dark, and moist environment.

* * * * *