

Judge McMahon

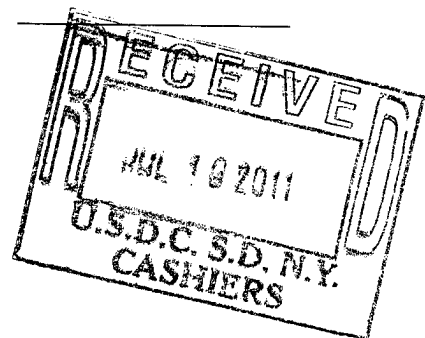
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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

MEDICIS PHARMACEUTICAL CORPORATION,)
)
)
 Plaintiff,)
)
 v.)
)
 PERRIGO COMPANY, INC.)
)
)
 Defendant.)

11 CIV 4963

C.A. No. _____



COMPLAINT

Plaintiff Medcis Pharmaceutical Corporation (“Medcis”), for its complaint against Defendant Perrigo Company (“Perrigo”), alleges as follows:

PARTIES

1. Medcis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medcis is a leading independent specialty pharmaceutical company in the United States, focusing primarily on the treatment of dermatological and aesthetics conditions. Since its inception in 1988, Medcis has developed and commercialized numerous brand-name prescription medications in the therapeutic categories Medcis serves. Because of their clinical effectiveness and high quality, Medcis’ products have earned wide acceptance by both physicians and patients.

2. Upon information and belief, Perrigo is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 515 Eastern

Avenue, Allegan, Michigan 49010. Perrigo also maintains offices and a manufacturing facility within this judicial district located at 1700 Bathgate Avenue, Bronx, NY 10457.

JURISDICTION AND VENUE

3. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)–(c).

6. This Court has personal jurisdiction over Perrigo by virtue of, *inter alia*, the physical presence within this judicial district of a Perrigo office and manufacturing facility, transaction of business and derivation of substantial revenue from services or things used or consumed in this judicial district, its substantial and continuous contacts with this judicial district, and its purposeful availment of the rights and benefits of New York law. Upon information and belief, Perrigo engages in the manufacture, sale, and distribution of pharmaceutical products within the United States generally and the state of New York specifically.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,981,909

7. Medicis incorporates by reference the averments set forth in paragraphs 1–6 as if fully set forth herein.

8. United States Patent No. 7,981,909 (“the ‘909 patent”), entitled “Use of 1-Hydroxy-2-Pyridones for the Treatment of Seborrheic Dermatitis,” was duly and lawfully issued on July 19, 2011. A true and correct copy of the ‘909 patent is attached to this Complaint as Exhibit 1.

9. The '909 patent resulted from Application No. 13/018,417, filed on Jan. 31, 2011.

10. Medicis is the owner of all rights, title, and interest in the '909 patent, including the right to sue and recover for infringement thereof.

11. The '909 patent recites four (4) claims directed to a "method of treating seborrheic dermatitis." For example, Claim 1 of the '909 patent recites:

A method of treating seborrheic dermatitis of the scalp comprising administering to the scalp of a human seborrheic dermatitis patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising only one active ingredient, the active ingredient consisting of ciclopirox, and at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is a single composition and is a shampoo.

12. Medicis is the holder of New Drug Application No. 21-159 approved by the United States Food and Drug Administration for Loprox® Shampoo (ciclopirox) 1%. Loprox® Shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

13. On or about February 16, 2010, Perrigo received FDA approval for a generic ciclopirox 1% shampoo.

14. Upon information and belief, Perrigo's generic ciclopirox 1% shampoo is indicated for treating seborrheic dermatitis of the scalp.

15. Pursuant to federal regulation, including, without limitation, 21 C.F.R. Sections 314.94(a)(4) and (a)(8), Perrigo's ANDA seeking approval of its generic ciclopirox 1% shampoo was required to contain a statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for its generic product had been previously approved for the reference listed drug, Loprox® Shampoo, and that its labeling is the same as the labeling of Loprox® Shampoo, except for certain differences not relevant here.

16. Because Loprox® Shampoo is only indicated for the topical treatment of seborrheic dermatitis of the scalp in adults, upon information and belief, subject to Fed. R. Civ. P. 11(b)(3), the label for Defendant Perrigo's generic ciclopirox 1% shampoo contains the same indication and instructions for use as the label for Loprox® Shampoo.

17. Upon information and belief, Perrigo's generic ciclopirox 1% shampoo comprises the active ingredient ciclopirox and at least one surfactant and has a pH in the range of about 4.5 to about 6.5.

18. The package insert for Perrigo's generic ciclopirox 1% shampoo includes instructions for dosage and administration of the shampoo.

19. Upon information and belief, Perrigo has infringed, and is still infringing, the '909 patent, either directly and/or indirectly, literally or under the doctrine of equivalents, by its activities, including making, using, offering for sale, selling in the United States or importing, without authority, ciclopirox 1% shampoo.

20. Perrigo's infringing activities have caused and will continue to cause Medicis irreparable harm, for which it has no adequate remedy at law, unless Perrigo's activities are enjoined by this Court in accordance with 35 U.S.C. § 283.

21. Medicis has been and continues to be damaged by Perrigo's infringement of the '909 patent in an amount to be determined at trial.

22. On or about June 4, 2011, Medicis notified Perrigo of the application that resulted in the '909 patent and provided a copy of the published application to Perrigo.

23. Upon information and belief, Perrigo's infringement of the '909 patent is willful and deliberate, and justifies an increase in damages of up to three times in accordance with 35 U.S.C. § 284.

24. Upon information and belief, Perrigo's infringement of the '909 patent is exceptional and entitles Medicis to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

25. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Medicis demands a trial by jury of this action of all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Medicis respectfully requests that:

(a) Judgment be entered that Perrigo has infringed one or more claims of the Asserted Patent;

(b) Judgment be entered permanently enjoining Perrigo, its directors, officers, agents, servants and employees, and those acting in privity or in concert with them, and its subsidiaries, divisions, successors and assigns, from further acts of infringement of the Asserted Patent;

(c) Judgment be entered awarding Medicis all damages adequate to compensate it for Perrigo's infringement of the Asserted Patent including all pre-judgment and post-judgment interests in the maximum rate permitted by law;

(d) Judgment be entered that Perrigo's infringement of the Asserted Patent is willful and deliberate, and therefore, that Medicis is entitled to treble damages as provided by 35 U.S.C. § 284;

(e) Judgment be entered that Perrigo's infringement of the Asserted Patent is willful and deliberate, and, therefore, that this is an exceptional case entitling Medicis to an award of its attorneys' fees for bringing and prosecuting this action, together with interest, and costs of the action, pursuant to 35 U.S.C. § 285; and

(f) Judgment be entered awarding Medicis such other and further relief as this Court may deem just and proper.

Dated: July 19, 2011

Respectfully submitted,

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Exhibit 1



US007981909B2

(12) United States Patent
Bohn et al.**(10) Patent No.: US 7,981,909 B2****(45) Date of Patent: Jul. 19, 2011****(54) USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC DERMATITIS****(75) Inventors: Manfred Bohn, Hofheim (DE); Karl Theodor Kraemer, Langen (DE); Astrid Markus, Liederbach (DE)****(73) Assignee: Medicis Pharmaceutical Corporation, Scottsdale, AZ (US)****(*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.**(21) Appl. No.: 13/018,417****(22) Filed: Jan. 31, 2011****(65) Prior Publication Data**

US 2011/0112153 A1 May 12, 2011

Related U.S. Application Data**(60)** Continuation of application No. 12/563,774, filed on Sep. 21, 2009, which is a continuation of application No. 10/606,229, filed on Jun. 26, 2003, now abandoned, which is a division of application No. 09/077,194, filed as application No. PCT/EP97/05070 on Sep. 16, 1997.**(30) Foreign Application Priority Data**

Sep. 27, 1996 (DE) 196 39 818

(51) Int. Cl.**A01N 43/40** (2006.01)
A61K 31/44 (2006.01)
C07D 211/72 (2006.01)
C07D 211/84 (2006.01)**(52) U.S. Cl.** 514/345; 514/277; 514/352; 514/852; 514/861; 514/863; 514/864; 514/881; 546/290; 546/294; 546/295; 546/300; 546/301; 546/302**(58) Field of Classification Search** 514/336, 514/348, 351, 852, 861, 863, 864, 881, 345, 514/277, 352; 546/290, 294, 295, 300, 301, 546/302

See application file for complete search history.

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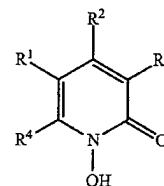
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Primary Examiner — Michael G Hartley**Assistant Examiner** — Leah Schlientz**(74) Attorney, Agent, or Firm** — Reed Smith LLP; William J. McNichol**(57) ABSTRACT**

Compounds of the formula (I) are disclosed and are suitable for the treatment of seborrheic dermatitis.



(I)

4 Claims, No Drawings

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isolated systems as such, which are derived from biphenyl, diphenylalkanes, diphenyl ethers and diphenyl thioethers.

In the formula I, the hydrocarbon radical R^4 is an alkyl or cyclohexyl radical which can also be bonded to the pyridone ring via a methylene or ethylene group or can contain an endomethyl group. R^4 can also be an aromatic radical which, however, is preferably bonded to the pyridone radical via at least one aliphatic carbon atom:

Important representatives of the class of compounds characterized by the formula I are:

6-[4-(4-chlorophenoxy)phenoxyethyl]-1-hydroxy-4-methyl-2-pyridone, 6-[4-(2,4-dichlorophenoxy)phenoxyethyl]-1-hydroxy-4-methyl-2-pyridone, 6-(biphenyl-4-oxyethyl)-1-hydroxy-4-methyl-2-pyridone, 6-(4-benzylphenoxyethyl)-1-hydroxy-4-methyl-2-pyridone, 6-(4-(2,4-dichlorobenzoyloxy)phenoxyethyl)-1-hydroxy-4-methyl-2-pyridone, 6-[4-(4-chlorophenoxy)phenoxyethyl]-1-hydroxy-3,4-dimethyl-2-pyridone, 6-[4-(2,4-dichlorobenzyl)phenoxyethyl]-1-hydroxy-3,4-dimethyl-2-pyridone, 6-[4-cinnamylphenoxyethyl]-1-hydroxy-4-methyl-2-pyridone, 1-hydroxy-4-methyl-6-[4-(4-trifluoromethylphenoxy)phenoxyethyl]-2-pyridone, 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone, 1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridone, 1-hydroxy-4-methyl-6-n-hexyl-, -6-iso-hexyl-, -6-n-heptyl- or -6-isoheptyl-2-pyridone, 1-hydroxy-4-methyl-6-octyl- or -6-isooctyl-2-pyridone, in particular 1-hydroxy-4-methyl-6-cyclohexylmethyl- or -6-cyclohexylethyl-2-pyridone, where the cyclohexyl radical can in each case also carry a methyl radical, 1-hydroxy-4-methyl-6-(2-bicyclo[2,2,1]heptyl)-2-pyridone, 1-hydroxy-3,4-dimethyl-6-benzyl- or -6-dimethylbenzyl-2-pyridone or 1-hydroxy-4-methyl-6-(β -phenylethyl)-2-pyridone.

The term "saturated" in this case designates those radicals which contain no aliphatic multiple bonds, i.e. no ethylenic or acetylenic bonds.

The abovementioned compounds of the formula I can be employed either in free form or as salts, use in free form is preferred.

If organic bases are used, poorly volatile bases are preferably employed, for example low molecular weight alkanolamines such as ethanolamine, diethanolamine, N-ethylethanolamine, N-methyldiethanolamine, triethanolamine, diethylaminoethanol, 2-amino-2-methyl-n-propanol, dimethylaminopropanol, 2-amino-2-methylpropanediol, triisopropanolamine. Further poorly volatile bases which may be mentioned are, for example, ethylenediamine, hexamethylenediamine, morpholine, piperidine, piperazine, cyclohexylamine, tributylamine, dodecylamine, N,N-dimethyldodecylamine, stearylamine, oleylamine, benzylamine, dibenzylamine, N-ethylbenzylamine, dimethylstearylamine, N-methylmorpholine, N-methylpiperazine, 4-methylcyclohexylamine, N-hydroxyethylmorpholine. The salts of quaternary ammonium hydroxides such as trimethylbenzylammonium hydroxide, tetramethylammonium hydroxide or tetraethylammonium hydroxide can also be used, furthermore guanidine and its derivatives, in particular its alkylation products. However, it is also possible to employ as salt-forming agents, for example, low molecular weight alkylamines such as methylamine, ethylamine or triethylamine. Suitable salts for the compounds to be employed according to the invention are also those with inorganic cations, for example alkali metal salts, in particular sodium, potassium or ammonium salts, alkaline earth metal salts such as, in particular, the magnesium or calcium salts, as well as salts with bi- or tetravalent cations, for example the zinc, aluminum or zirconium salt.

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The active compounds to be employed in the preparations of the compound of the formula I can be prepared, for example, according to processes given in U.S. Pat. No. 2,540, 218.

For the use according to the invention of the compounds mentioned, liquid to semisolid pharmaceutical preparations, in particular hair lotions, shampoos, liquid soaps, as well as cream, ointment and gel preparations, are suitable.

In this case, these are always preparations which, depending on their actual intended use, are applied to the skin and/or to the scalp for a shorter or longer time. Due to the addition of the compounds according to the invention, an effective treatment of the seborrheic dermatitis is brought about.

If the preparations according to the invention are present as shampoo, they can be in clear liquid or opaque liquid form, in cream form or even gelatinous. The surfactants on which these shampoos are based can be of anionic, cationic, non-ionic or amphoteric nature and can also be present as a combination of these substances.

Preferably, however, anionic surfactants are employed on their own or as a mixture with other anionic surfactants as base surfactants—if appropriate with addition of amphoteric surfactants as cosurfactant.

As the sole detergent substances, amphoteric surfactants are virtually insignificant, since their foaming behavior, thickenability and partly also skin and eye mucous membrane tolerability are only moderate. In combination with various anionic surfactants, however, precisely these properties are synergistically improved. This explains the relatively great importance of the amphoteric surfactants for the optimization of anionic shampoo bases.

Nonionic surfactants can also be employed as cosurfactants.

Examples of anionic detergent substances of this type which may be mentioned are: (C_{10} - C_{20})-alkyl- and -alkylenecarboxylates, alkyl ether carboxylates, fatty alcohol sulfates, fatty alcohol ether sulfates, alkylolamide sulfates and sulfonates, fatty acid alkylamide polyglycol ether sulfates, alkanesulfonates and hydroxyalkanesulfonates, olefinsulfonates, acyl esters of isothionates, α -sulfofatty acid esters, alkylbenzosulfonates, alkylphenol glycol ether sulfonates, sulfosuccinates, sulfosuccinic acid hemiesters and diesters, fatty alcohol ether phosphates, protein-fatty acid condensation products, alkylmonoglyceride sulfates and sulfonates, alkylglyceride ether sulfonates, fatty acid methyltaurides, fatty acid sarcosinates or sulforicinoleates. These compounds and their mixtures are used in the form of their water-soluble or water-dispersible salts, for example the sodium, potassium, magnesium, ammonium, mono-, di- and triethanolammonium as well as analogous alkylolammonium salts.

Examples of amphoteric surfactants which can be added to the shampoos are: N-((C_{12} - C_{18})-alkyl)- β -aminopropionates and N-((C_{12} - C_{18})-alkyl) β -iminodipropionates as alkali metal and mono-, di- and trialkylolammonium salts; N-acylamidoalkyl-N,N-dimethylacetobetaine, preferably N-((C_8 - C_{18})-acyl)amidopropyl-N,N-dimethylacetobetaine; (C_{12} - C_{18})-alkyldimethylsulfopropylbetaine; amphoteric surfactants based on imidazoline (trade name; Miranol®, Steinapon®), preferably the sodium salt of 1-(β -carboxymethoxyethyl)-1-(carboxymethyl)-2-laurylimidazolinium; amine oxides, e.g. (C_{12} - C_{18})-alkyldimethylamine oxide or fatty acid amidoalkyldimethylamine oxide.

Suitable nonionic surfactants which can be employed as detergent substances are, for example: fatty alcohol ethoxylates (alkyl polyethylene glycols); alkylphenol polyethylene glycols; alkylmercaptan polyethylene glycols; fatty amine ethoxylates (alkylamino polyethylene glycols); fatty acid

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EXAMPLE 4

A preparation according to the invention has the following composition:

Liquid soap	
1-Hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone	1.00%
Sodium lauryl diglycol ether.sulfate (27% strength solution)	35.00%
Cocamidopolyglycol ether sulfate magnesium salt (30% strength. solution)	8.00%
Cocamidopropylbetaine (30% strength solution)	10.00%
Lauryl alcohol glycol ether	2.00%
Sodium chloride	2.00%
Water	42.00%

EXAMPLE 5

A preparation according to the invention has the following composition:

Hair lotion	
1-Hydroxy-4-methyl-6-[4-(4-chlorophenoxy)phenoxyethyl] 2(1H)pyridone	0.05%
2-Propanol	60.00%
Water	39.95%

EXAMPLE 6

A preparation according to the invention has the following composition:

Gel preparation	
1-Hydroxy-4-methyl-6-cyclohexyl-2(1H)pyridone	0.75%
2-Propanol	15.00%
2-Octyldodecanol	7.5%
Carbomer 4,000,000	0.50%
Polysorbate 60	1.50%
Sodium hydroxide	0.18%
Water	74.57%

EXAMPLE 7

A preparation according to the invention has the following composition:

Cream preparation	
1-Hydroxy-4-methyl-6-cyclohexyl-2(1H)-pyridone, aminoethanol salt 1:1	1.00%
2-Octyldodecanol	7.5%

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-continued

Cream preparation	
Liquid paraffin	7.50%
Stearyl alcohol	7.50%
Cetyl alcohol	7.50%
Polysorbate 60	3.00%
Sorbitan monostearate	2.00%
Lactic acid, 90% strength	0.51%
Water	63.49%

EXAMPLE 8

In a clinical study with a total of 180 patients, it was possible to show that the symptoms of seborrheic dermatitis of the scalp (severe scaling, inflammation, itching) can be effectively treated by a 1-2x weekly treatment with a 1% strength ciclopirox shampoo preparation over a period of 4 weeks.

EXAMPLE 9

In a clinical study, it was possible to successfully treat 180 patients with seborrheic dermatitis of the scalp, of the face and of the upper body by application of a 0.77% strength ciclopirox gel preparation over a period of 4 weeks.

The invention claimed is:

1. A method of treating seborrheic dermatitis of the scalp comprising administering to the scalp of a human seborrheic dermatitis patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising only one active ingredient, the active ingredient consisting of ciclopirox, and at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is a single composition and is a shampoo.
2. A method of treating seborrheic dermatitis as claimed in claim 1 in which the composition further comprises at least one additional surfactant chosen from anionic, cationic, non-ionic, and amphoteric surfactants.
3. A method of treating seborrheic dermatitis comprising administering to a human seborrheic dermatitis patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising only one active ingredient, the active ingredient consisting of ciclopirox and at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; wherein the composition has a pH ranging from about 4.5 to about 6.5; and wherein the composition is a single composition, which is a shampoo.
4. A method of treating seborrheic dermatitis as claimed in claim 3 in which the composition further comprises at least one additional surfactant chosen from anionic, cationic, non-ionic, and amphoteric surfactants.

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