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Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARIANNE FLOWERS
AND BASILIO TAVARES

Appeal No. 94-0706
Application 07/620,145¹

ON BRIEF

Before WINTERS, WILLIAM F. SMITH and TURNER, Administrative
Patent Judges.

W. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1 through 10, all the claims in the application. Claims 1 and 7 are illustrative of the subject matter on appeal and read as follows:

1. A composition packaged for use in the treatment of topical infections of the skin, comprising a mixture of at least 0.5% by weight of each of the following ingredients: an alkali metal carbonate; an alkali metal phosphate; and an alkali metal hypochlorite, in a pharmaceutically acceptable topical carrier.

¹ Application for patent filed November 30, 1990. According to applicants this application is a continuation-in-part of Serial No. 07/389,689 filed August 3, 1989.

Appeal No. 94-0706
Application 07/620,145

method for treating topical infections of the skin by applying the present composition to the skin at the site of the infection.

Mihalovits is directed to a cosmetic facial preparation which contains aloe vera. The reference does not in and of itself teach or suggest the use of an alkali metal carbonate, an alkali metal phosphate or an alkali metal hypochlorite in that composition. Rather, the examiner relies upon The Merck Index for its disclosure of uses for these compounds.

While we would agree that The Merck Index disclosure of using calcium carbonate in cosmetics would have been sufficient suggestion to use that substance in the composition of Mihalovits, we do not find that The Merck Index entries for sodium carbonate, calcium hypochlorite and sodium phosphate relied upon by the examiner provide such a suggestion.

The suggested use of sodium carbonate in veterinarian applications to soften scabs of ringworm does not suggest the use of that compound in Mihalovits since that composition is not directed toward treatment of ringworm. Nor has the examiner established any reason why the use of calcium hypochlorite in the specific composition of Mihalovits would have been considered

Appeal No. 94-0706
Application 07/620,145

obvious by one of ordinary skill in this art. Nor does the disclosed utility of sodium phosphate in tanning suggest the use of this compound in the composition of Mihalovits.

The examiner's reliance upon appellants' admission concerning the commercial cleanser sold under the trademark "Comet" containing the claimed active ingredients does not help the rejection. The examiner has not established that one of ordinary skill in the cosmetic facial preparation art routinely consults household cleansers when determining appropriate ingredients for facial preparations.

The decision of the examiner is reversed.

Under the authority of 37 CFR § 1.196(b), we make the following new grounds of rejection.

I. Claims 1 through 4 are rejected under 35 U.S.C. § 102 as anticipated by appellants' admission regarding "Comet" cleanser or, in the alternative, under 35 U.S.C. § 103 as unpatentable over this admission.

As set forth above, appellants have admitted that the cleanser sold under the trademark "Comet" contains the active ingredients of the claimed compositions. In making this admission, appellants seek to distinguish the claimed compositions from that cleanser by noting that the claims require

Appeal No. 94-0706
Application 07/620,145

the presence of a pharmaceutically acceptable topical carrier. However, the specification indicates that this carrier can be water. Since the normal use of the cleanser sold under the trademark "Comet" involves placing that composition in water, appellants' admission amounts to an anticipation of claims 1 through 4.

In the event the actual composition of "Comet" brand cleanser differs from that required by the claims on appeal, it would have been prima facie obvious to one of ordinary skill in the art to optimize the relative amounts of these ingredients for the purposes of providing an effective cleanser. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

We have not included claims 5 and 6 in this rejection since we do not find evidence of record which establishes that one of ordinary skill in the art would have found it obvious to use either corn starch or aloe lotion in combination with a typical household cleanser such as that sold under the trademark "Comet." Upon return of this application to the examiner, appellants and the examiner should investigate this matter further.

II. Claims 1 through 10 are rejected under 35 U.S.C. § 101 as lacking utility and 35 U.S.C. § 112, first paragraph, as being nonenabled.

Appeal No. 94-0706
Application 07/620,145

The claimed composition is stated to be a pharmaceutical composition and the use of that pharmaceutical composition for topical treatment of infections of the skin such as herpes simplex 1 and ringworm is claimed.

The Merck Manual entries for ringworm and oral herpetic manifestations such as cold sores or fever blisters indicate that these conditions are difficult to treat and that known treatments do not involve any of the claimed active ingredients of the present composition.

The Merck Manual provides an evidentiary basis upon which one can reasonably conclude that those skilled in this art would doubt the asserted utility and enablement of the claimed invention. In re Langer, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974), In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). On this record, it is reasonable to shift the burden of proof to appellants to establish in the first instance that one of ordinary skill in the art would accept that the claimed pharmaceutical composition is in fact useful for broadly treating infections of the skin and specifically treating herpes simplex 1 and ringworm.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date

Appeal No. 94-0706
Application 07/620,145

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med. A purulent pocket should be opened cautiously with the point of a scalpel. Infection extending along the tendon sheaths requires prompt surgical incision and drainage.

In chronic recurrent inflammation, it is important to keep the hands dry. The subungual debris should be cultured. If *Candida* is not present on several cultures, cutting the nail to the point of its detachment from the underlying skin and applying a 2% tincture of iodine, 2 drops bid, will help to keep the subungual and paronychia dry and free of infection. If *Candida* is present, an antifungal lotion (eg, ciclopirox, miconazole, or tioconazole) should be applied to the paronychia and subungual areas after the nail is cut back. As the GI tract is a likely source of contamination with *Candida*, oral nystatin 500,000 u. qid may also be advisable. Women should be examined for an accompanying candidal vaginitis, which should also be treated. Distorted nail plates may have to be removed.

ERYTHRASMA

A superficial skin infection caused by *Corynebacterium minutissimum*, found most commonly in adults. The incidence is higher in the tropics. Erythrasma resembles a chronic fungus infection or intertrigo. In the toe webs, scaling, fissuring, and slight maceration occur, usually confined to the 3rd and 4th interspaces. In the genitocrural region, principally where the thighs contact the scrotum, patches are irregular and pink, later becoming brown with a fine scale. Erythrasma may widely involve the axillas, trunk, and perineum, particularly in obese middle-aged women or in patients with diabetes mellitus. Differentiation from ringworm is essential. Diagnosis is established readily with a Wood's light, under which erythrasma shows a characteristic coral-red fluorescence. Prompt clearing follows oral erythromycin or tetracycline 250 mg qid for 14 days. Recurrences 6 to 12 mo later are usual. Antibacterial soaps may also control the infection.

ERYSIPELOID

(See in BACTERIAL DISEASES CAUSED BY GRAM-POSITIVE BACILLI in Ch. 8)

32. SUPERFICIAL FUNGAL INFECTIONS

DERMATOPHYTE INFECTIONS

(Ringworm)

Superficial infections caused by dermatophytes—fungi that invade only "dead" tissues of the skin or its appendages (stratum corneum, nails, hair). *Microsporum*, *Trichophyton*, and *Epidermophyton* are the genera most commonly involved. Fomites are probably responsible for transmission of infection. Some dermatophytes produce only mild inflammation; in such cases, the organism may persist indefinitely, causing intermittent remissions and exacerbations of a gradually extending lesion with a scalloped, slightly raised border. In other cases an acute infection may occur, typically causing a sudden vesicular and bullous disease of the feet; or an inflamed boggy lesion of the scalp (kerion) may occur, which is due to a strong immunologic reaction to the infection and is usually followed by remission or cure.

Types and Diagnosis

The clinical differentiation of the related dermatophytes is difficult, these infections are conveniently discussed according to the sites involved. Diagnosis is con-

firmly by demonstrating the pathogenic fungus in scrapings of lesions, either by direct microscopic examination or by culture (see also SPECIAL DIAGNOSTIC METHODS in Ch. 227).

Tinea corporis (ringworm of the body) is usually caused by a *Trichophyton*. The characteristic papulosquamous annular lesions have raised borders, expand peripherally, and tend to clear centrally. Differential diagnosis includes pityriasis rosea, drug eruptions, nummular dermatitis, erythema multiforme, tinea versicolor, erythrasma, psoriasis, and secondary syphilis.

Tinea pedis (ringworm of the feet athlete's foot) is particularly common. *Trichophyton mentagrophytes* infections begin in the 3rd and 4th interdigital spaces and later involve the plantar surface of the arch. The lesions often are macerated and have scaling borders; they may be vesicular. Acute flare-ups, with many vesicles and bullae, are common during warm weather. Infected toenails become thickened and distorted. *T. rubrum* produces scaling and thickening of the soles, often extending just beyond the plantar surface in a "moccasin" distribution. Inflammation or vesiculation may be slight or severe. *Tinea pedis* may be confused with maceration (from hyperhidrosis and occlusive footwear), with contact dermatitis (from sensitivity to various materials in shoes, particularly adhesive cement), with eczema, or with psoriasis.

Tinea unguium (ringworm of the nails), a form of onychomycosis, is usually caused by a *Trichophyton* species. Toenail involvement is common in longstanding *tinea pedis*; infections of the fingernails are less common. The nails become thickened and lusterless, and debris accumulates under the free edge. The nail plate becomes separated, and the nail may be destroyed. Differentiating a *Trichophyton* infection from *Candida* infection and psoriasis is particularly important because chemotherapy is specific and prolonged treatment is required.

Tinea capitis (ringworm of the scalp) mainly affects children. It is contagious and may become epidemic. *Trichophyton tonsurans* infection has become the common cause in the USA; other *Trichophyton* species, such as *T. violaceum*, are common in other parts of the world. *T. tonsurans* infection of the scalp is subtle in onset and characteristics. Inflammation is low-grade and persistent; the lesions are not annular or sharply marginated; and the hairs do not fluoresce under Wood's light. Affected areas of the scalp show characteristic black dots resulting from broken hairs. The fungus, an endothrix, produces within the hair chains of arthrospores that can be seen microscopically.

Trichophyton species may persist in adults. *Microsporum audouinii* and *M. canis*, once predominant, are much less common. *M. audouinii* lesions are small, scaly, semi-bald grayish patches with broken, lusterless hairs. Infection may be limited to a small area or extend and coalesce until the entire scalp is involved, sometimes with ringed patches extending beyond the scalp margin. *M. canis* and *M. gypseum* usually cause a more inflammatory reaction, with shedding of the infected hairs. A raised, inflamed, boggy granuloma (kerion) may also occur; it is followed shortly by healing. Diagnosis of a *Microsporum* infection is facilitated by examining the scalp under a Wood's light; infected hairs may fluoresce a light bright green. The organism is an ectothrix, producing spores to form a sheath around the hair. The sheath can be seen on microscopy. Culture of the fungus is also important in establishing the diagnosis.

Tinea cruris (jock itch) may be caused by various dermatophyte or yeast organisms. Typically, a ringed lesion extends from the crural fold over the adjacent upper inner thigh. Both sides may be affected. Scratch dermatitis and lichenification are often seen. Lesions may be complicated by maceration, miliaria, secondary bacterial or candidal infection, and reactions to treatment. Recurrence is common, since fungi may persist indefinitely on the skin or may repeatedly infect susceptible individuals. Flare-ups occur more often during the summer. Tight clothing or obesity tends to favor growth

of the organisms. The infection of erythrasma, or candidiasis. The tinea, whereas in dermatophyte slight.

Tinea barbae, a mycotic infection more commonly bacterial (see FOOT in agricultural workers. The caus

Dermatophytids or "id" eruptions the body during an acute vesiculi thought to result from hypersensiti is most commonly due to some oth FEET (in Ch. 230).

Treatment

Griseofulvin is effective in treating onychomycosis caused by *Trichophyton* species, *T. verrucosum*, *T. interdigitale*, *M. canis*, or *M. gypseum*; but it deep-seated mycoses (eg, histoplasma microsize griseofulvin 250 mg orally fat meal. The micronized form is infections, especially those involving drug occasionally causes GI distress, reported. Headaches, vertigo, and, rare imidazoles with oral griseofulvin, imidazoles (miconazole, clotrimazole, clotrix olamine cream have recently the first effective topical cream for the imidazoles are about equal in efficacy the treatment of certain types of dermatitis or onychomycosis. **Ketoconazole** broad-spectrum agent for systemic infections. Although it is also effective oral toxicity that can be severe or even fatal safer measures fail (see also General

Tinea corporis: For small to moderate pirox creams or lotions should be rubbed disappear. For extensive or resistant tinea griseofulvin. *Tinea corporis* usually responds but may be extensive and resistant to diseases.

Tinea pedis: Griseofulvin, the most acute inflammatory infection. It is useful exacerbations, but cure may require therapy if the toenails are involved. Consider reduce recurrences.

Good foot hygiene is essential. Interdigital skin rubbed away, and a bland, comfortable footwear is recommended, especially from going barefoot. During acute vesiculation, but the keratinous tops should dry.

of the organisms. The infection may be confused with contact dermatitis, psoriasis, erythrasma, or candidiasis. The scrotum is often acutely inflamed in candidal intertrigo, whereas in dermatophyte infections scrotal involvement is usually absent or slight.

Tinea barbae, a mycotic infection of the beard area, is rare. Infections in this area are more commonly bacterial (see FOLLICULITIS in Ch. 231), but may be fungal, especially in agricultural workers. The causative agent is established by microbiologic study.

Dermatophytids or "id" eruptions are fungus-free skin lesions that occur elsewhere on the body during an acute vesicular or inflammatory ringworm infection; they are thought to result from hypersensitivity to the fungus. Vesicular dermatitis of the hands is most commonly due to some other cause (see CHRONIC DERMATITIS OF HANDS AND FEET in Ch. 230).

Treatment

Griseofulvin is effective in treating tinea capitis, corporis, pedis, and unguium (onychomycosis) caused by *Trichophyton rubrum*, *T. mentagrophytes*, *T. stipitatum*, *T. verrucosum*, *T. interdigitale*, *Epiormonaxton floccosum*, *Microsporum audouinii*, *M. canis*, or *M. gypseum*; but it is worthless in candidiasis or tinea versicolor and deep-seated mycoses (eg, histoplasmosis, coccidioidomycosis). The adult dosage is 500 mg of griseofulvin 250 mg orally bid to qid and the drug is best given with a high-fat meal. The micronized form is better absorbed than the nonmicronized form. Some infections, especially those involving the nails, may require 7 mo of therapy. The drug occasionally causes GI distress, skin rashes, or leukopenia. Angioedema has been reported. Headaches, vertigo, and, rarely, transient hearing reduction may occur. Topical imidazoles with oral griseofulvin increase the cure rate. A number of related imidazoles (miconazole, clotrimazole, toconazole, econazole, bifonazole) as well as ciclopirox olamine cream have recently been marketed. The latter has been found to be the first effective topical cream for many (but not all) cases of onychomycosis. All of the imidazoles are about equal in efficacy and are very effective topical medications for the treatment of certain types of dermatophyte infections of the skin (but not tinea capitis or onychomycosis). Ketoconazole, an oral imidazole derivative, is an effective broad-spectrum agent for systemic therapy of candidiasis and some deep fungal infections. Although it is also effective orally for dermatophyte infections, occasional liver toxicity that can be severe or even fatal limits its use for superficial infections unless other measures fail (see also General Therapeutic Principles in Ch. 9).

Tinea corporis: For small to moderately sized lesions, one of the imidazole or ciclopirox creams or lotions should be rubbed in bid until at least 7 to 10 days after lesions disappear. For extensive or resistant tinea corporis, the most effective therapy is oral griseofulvin. Tinea corporis usually responds readily to specific antifungal medication, but may be extensive and resistant to treatment in persons with debilitating systemic diseases.

Tinea pedis: Griseofulvin, the most effective treatment for mycologically proven tinea pedis, should be started even though it may have little immediate effect on the acute inflammatory infection. It is useful in chronic infections and in preventing acute exacerbations, but cure may require therapy for many months and is especially difficult if the toenails are involved. Concomitant topical imidazole or ciclopirox may reduce recurrences.

Good foot hygiene is essential. Interdigital spaces must be dried after bathing, macerated skin rubbed away, and a bland, drying dusting powder applied. Light permeable footwear is recommended, especially during warm weather; many patients benefit from going barefoot. During acute vesicular flare-ups, bullae may be drained at the origin, but the keratinous tops should not be removed. Tap-water soaks bid are helpful.

pemphigus, accompanying skin lesions are common. *Erythema multiforme* (see in Ch. 237) may be discerned by more marked constitutional symptoms and widespread hemorrhagic lesions. In *pemphigus* (see also in Ch. 238), constitutional symptoms usually persist for several weeks, and the patient often recalls a prior episode of large painless bullae without accompanying prodromal symptoms.

Diagnosing the solitary lesion of *herpes labialis* is usually not difficult because of its characteristic appearance and location.

Treatment

In *primary herpetic stomatitis*, a topical analgesic relieves temporary pain; 2% lidocaine viscous, 5 mL (1 tsp) as an oral rinse q 3 h, or diphenhydramine elixir, 5 mL (1 tsp) as an oral rinse q 2 h is used as needed. A sodium bicarbonate mouthwash of 2.5 mL (0.5 tsp) in 250 mL (8 oz) warm water qid soothes and cleanses. Since children tend to decrease fluid intake, they must be watched for dehydration. Supportive therapy consists of increasing fluids and giving diet supplements (see TABLE 79-5 in Ch. 79). Systemic antibiotics may be used to guard against secondary infection.

Recurrent herpetic labialis (lip lesions) can be reduced in frequency by using a sunscreen containing amino benzoic acid during sun exposure. *All proposed treatment is more effective if started in the prodromal stage*, ie, at the first symptoms of local change in sensations.

Topically, antiviral agents such as vidarabine or acyclovir ointments will discourage spreading and act as lubricants. Applying ice locally will reduce swelling. Petrolatum will tend to prevent cracking, bleeding, and self-inoculation from manual spread.

Systemic treatment is directed toward improving resistance to the virus. A combination of equal parts of citrus bioflavonoids and ascorbic acid tablets 400 mg tid for 3 days may abort or greatly reduce the duration of the lesions. Where frequent recurrences interfere with daily function or nutrition, acyclovir 200-mg capsules 5 times/day will give relief.

Desiccating agents such as alcohol, ether, and chloroform are thought to fractionate the virus, thereby inviting resistant and mutagenic strains. Corticosteroids can spread the virus, especially on mucosal tissue.

There is no cure for herpes simplex.

TONGUE

Infants may have *mucocutaneous lymph node syndrome* (*Kawasaki syndrome*—see in Ch. 191) in which there is a bright red tongue and face, edema of the extremities, and thrombocytosis. *Ankyloglossia* (tongue-tie) may be diagnosed if the tip of the tongue cannot contact the alveolar ridge or the tips of the teeth or sweep from one corner of the mouth to the other. To increase mobility of the tongue, the lingual frenum may need cutting. Untreated tongue-tie may affect speech and interfere with mastication and passive cleansing of the teeth. A *burning sensation* is a frequent postmenopausal symptom in association with poor keratinization, or may be a symptom of diabetic neuropathy; both require treatment of the underlying endocrine disorder. In the absence of physiologic or anatomic abnormalities, depression or an anxiety state should be considered. Amitriptyline 25 mg at bedtime with a weekly increase of dosage is usually effective in 3 to 4 wk.

GLOSSITIS

An acute or chronic inflammation of the tongue.

Etiology

Glossitis may be either a primary disease or a symptom of disease elsewhere. The many and varied causes include the following:

Local: Infection, ill-fitting teeth, ill-fitting primary irritants, toothpaste, mouthwash, or restorative

Systemic: Pernicious anemia, erythema multiforme.

Symptoms, Signs

Clinical manifestations of lesions may indicate infection or a tooth with swollen, and of the tongue is painless lesions, erythema multiforme, or patch of syphilitic areas, if not moderately painful may be the lesion rhomboid glossitis, reddish, nodular, the tongue. Hair asymptomatic mouthwash tobacco stain the underlying

Severe acute may develop and cause protrusion. Mastication, swelling, and submandibular gland treatment

Patients may be without obvious. Incipient candidiasis shows

Each case of may disclose a symptoms of disease. Evidence of pernicious anemia, mild diabetes

Prognosis

When the cause may be delayed that persistent inflammation. Aphthodically. Solitary biopsied.

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NOTICE OF REFERENCES CITED

APPLICANT(S)

Marianne Flouris et al

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R	Berkow et al., The Merch Manual, 15 Edition, pgs 2267-2270 + 2327-2328 (1987)					
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James Smith

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