RDL PHARMACEUTICAL LABORATORY, INC.,
Petitioner-Appellant,

-versus-

SPLASH MANUFACTURING CORPORATION,
Respondent-Appellee,

x----------x

APPEAL NO. 12-03-01

INTER PARTES CASE NO. 12-2000-00033

Petition for Cancellation:
Letters Patent No. UM-8471
Date Issued: 23 December 1997
Title: A Skin Care Composition for the Treatment of Acne and Pigmentary Disorder

DECISION

This concerns Decision No. 2002-37 dated 23 December 2002 rendered by the Director of the Bureau of Legal Affairs (Director) denying the Petition for Cancellation (of Letters Patent No. UM-8471) filed by RDL Pharmaceutical Laboratory, Inc. (Appellant).

Records show that Appellant filed on 18 September 2000 a Petition for Cancellation of Utility Model Patent No. UM-8471 which was issued in favor of Splash Manufacturing Corporation (Appellee) on 23 December 1997 for a skin care composition for the treatment of acne and pigmentary disorder.[1]

In its Petition, Appellant alleged that the invention of the Appellee is not new or patentable and, therefore, does not qualify or meet the requirements for registration as a utility model, contending that said utility model has been sold in the Philippines more than one year before the Appellee filed its application for registration. According to the Appellant, the products consisting of anti-acne depigmenting agents using Tretinoin and Hydroquinone with percentage by weight composition within the range and/or coverage of the subject utility model have existed and publicly sold in the market, both in the Philippines and in abroad for many years prior to 1996. Said products, Appellant claimed, have been described in printed publications in the Philippines and in foreign countries more than one year before Appellee filed its application for a utility model patent. Appellant also argued that since anti-acne depigmenting agents are in the nature of generic drugs whose use for the purpose of treating acne and pigmentary disorder was widely known for many years prior to 1996, these anti-acne depigmenting agents belong to the general public and not patentable. Even assuming that the subject utility model represent an improvement, the same, Appellant maintains, is merely a clear and obvious result of inventive features introduced by prior art and, therefore, not patentable.

In his Answer, Appellee denied the allegations in the Petition and maintained that the subject utility model was new and patentable under Section 55 of Republic Act No. 165 (RA No. 165), as amended.[2] Appellee claimed that at the time of the filing of its application the subject utility model has not been described in printed publication or publications circulated within the country nor is it substantially similar to any other utility model so known, used or described within the country. The then Bureau of Patents, Trademarks and Technology Transfer (BPTTT)[3] of the Department of Trade and Industry, according to the Appellee, had determined the patentability of its utility model and that the application has undergone prior art search and examination.

On 23 December 2002, the Director rendered the assailed decision. Holding that in cases involving the cancellation of patents for lack of novelty, reference must always be made to the claims, which sets the metes and bounds of patent protection,[4] the Director finds that:

> "A reading of the claim and specification of the 8471 patent shows that the novelty being asserted is in the combination of hydroquinone and retinoic acid, said combination having been found to be more effective than hydroquinone alone in the treatment of specific types of skin disorders… Comparing the 11574 patent with the claims of 8471 patent, there is no anticipation because the novelty being claimed in the 11574 patent is in combination of three major compounds, namely: (a) a bleaching agent such as hydroquinone and hydroquinone monobenzyl ether; (b) an exfoliating agent such as retinoic acid, arachidonic acid, polyoxyethylene lauryl ether and alkylamides containing 5 to 16 carbon atoms; and (c) and an anti-inflammatory cortico-steroid."[5]

On 17 January 2003, Appellant filed Motion for Reconsideration. The Director denied the motion for lack of merit per Resolution No. 2003-10 (D) dated 25 September 2003. Hence, this appeal by the Appellant alleging the following errors of fact and law:

1. The Director of the BLA erred in ruling that a combination that is deemed generic can be the subject of a utility model patent.

2. The Director of the BLA erred in not finding that the hydroquinone and tretinoin combination covered by UM-8471 was already known and used prior to filing of respondent's (Appellee's) application on 11 (sic) February 1996.

In its appeal, Appellant reiterates its contentions that the products are deemed generic and cannot be the subject of appropriation, and that because the formulation protected by the patent in generic, as found by the Bureau of Food and Drugs (BFAD), there is no basis to give legal protection to it, by way of a patent. Appellant claims that it presented sufficient evidence[6] to establish that the hydroquinone and tretinoin combination covered by UM-8471 was known and used prior to Appellee's filing the utility model application and that it has marketed its own hydroquinone and tretinoin combination as early as 1994.[7]

In its comment to the appeal, Appelle argues that while it may be admitted that hydroquinone and tretinoin as independent substances are considered generic, a composition made of these two substances following specific range and percentage composition is not generic. It is the IPO, Appellee contends, that would determine novelty and would resolve the issue of whether a particular patent application is generic or part of the public domain. With respect to the evidence presented by the Appellant, Appellee points out that the invoices presented merely refer to the sale of astringents, sunblock and bleaching creams which do not indicate if said products actually contained hydroquinone and tretinoin. The different printed publications cited by the Apellant, according to the Appellee, do not constitute anticipatory prior arts since a review of the contents of the printed applications show no reference to the date when the said documents were circulated or disseminated in the Philippines to persons skilled in the art. Neither the cited publications, Appellee says, sufficiently describe the utility model of the Appellee.[8]

On 02 December 2003, this Office issued an Order requiring the parties to file their respective memoranda, attaching thereto draft decisions if so desired, within fifteen (15) days from receipt thereof.[9] The Appellant and Appellee filed the required pleadings on 16 January 2004 and 09 February 2004, respectively.

Incidentally, on 19 December 2003 and after filing its Appeal Memorandum, Appellant filed a Motion to Reopen Case for Reception of Additional Evidence alleging that Dr. Rolando B. Hortaleza, registrant and assignor of Utility Model Patent No. 8471 publicly admitted at the Second Management Association of the Philippines CEO Conference that the products covered by said patent had been sold to the public as early as 1991, five (5) years prior to the filing of the application for the issuance of the subject UM Patent. Attaching to the motion a photocopy of a newspaper article, Appellant claimed that Dr. Hortaleza related the early years of SPLASH Corporation, its phenomenal growth of 74% compounded between 1994 and 1999 and achieving P1 Billion in sales in 1996, and the time that Extraderm[10] began to eat up the market in 1991 due

to a demand for a product that controls pimples.[11] Appellant sought the reopening of the case for the taking of the disposition of Dr. Hortaleza and for the reception of additional evidence. Denying said motion per Order dated 15 March 2004, this Office pointed out that the motion is not a remedy provided by the IPO Uniform Rules on Appeals or by the Revised Rules of Court.[12] While the interest of justice may allow the cognizance of facts incidental or connected to the resolution of cases on appeal, the Appellant failed to cite any compelling reason to persuade this Office to deviate from its rules and be convinced that the taking of deposition of Dr. Hortaleza and allowing Appellant additional evidence are justified. Nothing in the said article clearly indicates that the product covered by the Utility Model Patent No. 8471 was sold to the public as early as 1991.[13]

After due consideration of the foregoing and a review of the records, this Office finds this appeal not meritorious.

The Appellee filed the application on 13 February 1996. Under Section 55 of RA No. 165,[14] the applicable at that time, a patentable utility model may be characterized as any new model of implements, tools, industrial product or part of the same, which does not possess the quality of invention and has practical utility. A utility model shall be considered new if before the application for a patent, t has been publicly known or publicly used in the country, or has been described in a printed publication circulated within the country, or if it is substantially similar to any other utility model so known, used or described within the country.

It is not disputed that the Appellee's skin care composition for the treatment of acne and pigmentary disorder is a product of practical utility. The only contentious issue in this case is, whether or not the subject utility model is new and, therefore, patentable under RA 165, as amended.

It may be well to first state that the examination of applications for patent for utility model follows an ex parte proceeding in which the patent examiner determines, among others, whether the claimed utility model satisfies the elements of novelty or newness provided for under Section 55 of RA No. 165. In the case at bar, the patent examiner concluded after examination that the subject utility model[15] is new under RA No. 165, as amended. In view of such conclusion, Utility Model patent No. UM-8471 was issued in favor of the Appellee. There is, therefore, created the legal presumption that the patent is valid. Accordingly, Appellant, which seeks the cancellation of the said patent, has the burden to prove otherwise.

To support its claims that BFAD has held that any combination of hydroquinone and tretinoin is considered generic, Appellant presented Exhibit Z-13.[16] This Office, however, reviewed the said piece of evidence and noted that the BFAD actually has mentioned that the patentability of these drugs is best addressed to the IPO. On this score, it must be stressed that the patent system on discoveries and inventions is a matter which is properly within the competence of the Patent Office, the official action of which has the presumption of correctness and may not be interfered with in the absence of new evidence carrying through conviction that the Office has erred.[17] Accordingly, in this instance, the subject utility model has undergone the examination process and was found to be patentable. The combination of hydroquinone and tretinoin as stated in the claims and specifications of the subject utility model was deemed to be new and not generic.

Appellant offered the testimony of Ms. Zenaida Bugay-Soriano to corroborate its allegations that it has been using a formulation of hydroquinone and tretinoin as early as 1994.[18] It also submitted Exhibits W to W-13[19] to establish that at early as 1994, Appellant has been conducting test marketing of its products, consisting of anti-acne depigmenting agents using tretinoin and hydroquinone with percentage by weight composition within the range and/or coverage of Utility Model Patent No. 8471. However, this pieces of evidence may only show the existence of the generic drugs hydroquinone and tretinoin in the product of the Appellant but do not prove that the Utility Model Patent No. UM-8471 has been publicly known or publicly used in the country prior to the filing of the Appellee's application. Appellant's products is different from

the product of the Appellee as shown by the specification and claims stated in UM-8471. Moreover, Exhibits W to W-3 are only invoices of astringent, bleaching cream and sun block cream products sold by the Appellant but do not indicate anything regarding the product or product formulation of the Appellee. As pointed out by the Director:

> "However, the invoices merely refer to the sales if astringents, sunblock cream and bleaching creams to various customers but do not indicate if the said products actually contained tretinoin and hydroquinone. Absent substantial evidence that the products being sold by Respondent since 1994 are the same as the 8471 patent, the invoices cannot be used as novelty-defeating prior art references."[20]

In the case of Aguas vs. De Leon,[21] the Supreme Court had the occasion to rule that:

> "The validity of the patent issued by the Philippines Patent Office in favor of the private respondent and the question over the inventiveness, novelty and usefulness of the improved process therein specified and described are matters which are better determined by the Philippines Patent Office. The technical staff of the Philippines patent Office, composed of experts in their fields, have by the issuance of the patent in question, accepted the thinness of the private respondent's new tiles as a discovery. There is a presumption that the Philippines Patent Office has correctly determined the patentability of the improvement by the respondent of the process in question."

In this instance, Appellee's utility model for a skin care composition for the treatment of acne and pigmentary disorder was found to be new and useful. While it is composed of two drugs, which independently may be considered as generic drugs, Appellee's claims and specifications on the combination of hydroquinone and tretinoin were found to be something new and useful. Such innovation by the Appellee is the one being rewarded in the patent system with the end in view of encouraging dissemination of information and technology for the promotion and national development and progress and the common good.

The record is also bereft of evidence to any printed publication circulated in the country describing the hydroquinone and tretinoin combination covered by the UM-8471 nor of any other substantially similar utility model known, used or described within the country. While Appellant presented the foreign printed publications[22] describing the combination of hydroquinone and tretinoin used as depigmenting agents with percentages by weight composition within the range and/or coverage of Appellee's utility model, Appellant failed to prove that these publications were circulated within the country. Moreover, as cited by the Director:

> "The phrase 'described in a printed publication' means that it is printed in nearly and any kind of document by any means (including the electronic means) and has been made available to the public… Critical to whether something is a 'printed publication' or not is the question of open dissemination to workers skilled in the art. Where workers skilled in the art are able to get copies of a reference, it may be a 'printed publication'… In this case a review of the contents of the printed publications show no reference to the dated when the said documents where circulated or disseminated in the Philippines to persons skilled in art… a perusal of these documents reveals nothing about the date when the said documents were circulated in the Philippines. Neither do the testimonies of Petitioner's witnesses explain when the said publications were first circulated to persons skilled in art."[23]

Wherefore, premises considered, the appeal is hereby DISMISSED for lack of merit. Accordingly, Decision No. 2002-37 dated 23 December 2002 of the Director of the BLA is hereby AFFIRMED. Let a copy of this Decision be furnished the Director of the BLA. The records of this case are likewise returned to the said Director for appropriate action. Let the Directors of the Bureau of Patents and the Administrative, Financial and Human Resources Development Service Bureau be furnished copies hereof for information and guidance.

SO ORDERED.

December 10, 2004, Makati City.

EMMA C. FRANCISCO
Director General

FOOTNOTES:

1. Appellee filed the application for registration of the subject utility model on 13 February 1996.
2. AN ACT CREATING A PATENT OFFICE, PRESCRIBING ITS POWERS AND DUTIES, REGULATING THE ISSUANCE OF PATENTS, AND APPROPRIATING FUNDS THEREFORE.
3. On 01 January 1998, Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines took effect. Said Act, among other things, abolished the BPTTT and transferred its functions to the newly created Intellectual Property Office (IPO).
4. Decision No. 2002-37, p.4, citing Rule 138, Rules of Practice in Patent Cases.
5. Ibid., pp. 5-6.
6. Appellant claims to have presented evidence consisting of invoices and other documentary and testimonial evidence establishing its products as containing the said formulation.
7. APPEAL MEMORANDUM, pp. 9-10.
8. COMMENT (To Petitioner's Appeal Memorandum) pp.2-4.
9. Section 7 of the IPO Uniform Rules on Appeal provides that:
   "Section 7. Submission of Memoranda and Draft Decision – Within five (5) days after the filing of the comments of both parties or after the clarificatory
   (continuation of footnote 9)
   hearing, the Director General shall require the parties to submit their respective memoranda, attaching thereto draft decisions if so desired. The memoranda and draft decisions must be submitted within fifteen (15) days from notice."
10. This term was used to identify personal care and skin care products of the Appellee.
11. Appellant submitted a photocopy of the said feature article that was published in the business section of the Philippine Daily Inquirer last 09 November 2003.
12. Order, p.2.
13. Ibid, p.3.
14. "Sec. 55. Design patents and patents for utility models – (a)Any new, original and ornamental design for an article or manufacture and (b)any new model of implements or tools or of any industrial product, or of part of the same, which does not possess the quality of invention, but which is of practical utility by reason of its form, configuration, construction, or composition, may be protected by the author thereof, the former by a patent for a design and the latter by a patent for a utility model, in the same manner and subject to the same provisions and requirements as relate to patents for inventions in so far as they are applicable, except as otherwise herein provided.
    xxx
    A utility model shall not be considered "new" if, before the application for a patent, it has been publicly known or publicly used in this country, or has been described in a printed publication or publications circulated within the country, or if it is substantially similar to any other utility model so known, used or describe within the country.
    xxx"
15. A skin care astringent composition for the treatment of acne and pigmentary disorder in liquid form with a pH of 3.5 to 5.5 which comprises the following:

Ingredients	% By Weight
Tretinoin	0.005 to .05%
Hydroquinone	2.0%
Ethyl Alcohol	47.50% to 50.00%
Sodium Metabisulfite	0.10%
Methyl Paraben	0.20%
Demineralized water	Balance to 100%

16. Letter dated 28 may 2001 and signed by Director William D. Torres of the Bureau of Foods and Drugs of the Department of Health.
17. Manzano vs. CA, GR. No. 113388, 05 September 1997.
18. See also Exhibits E, X, Y, and Z inclusive of submarkings.
19. Consisting of invoices issued by RDL Pharmaceutical Laboratory.
20. Decision No. 2002-37, p. 4.
21. G.R. No. L-32160, 30 January 1982.
22. See Exhibits R, S, and T inclusive of submarkings.
23. Decision No. 2002-37, p.6.