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Evaluation of the Patentability of Medicines based on plants produced in Cameroon: Case of Yaounde

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Abstract

Objective: Assess the patentability of medicines based on plants produced in Cameroon.

Materials and Methods: An analytical study, conducted at the Library of the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé I and the Directorate of Pharmacy, Drug and Laboratories (DPML) from November 2021 to June 2022. We conducted a consecutive and non-exhaustive sampling that allowed us to identify 51 drugs and evaluate 16 of them. After that, we proceeded to assess the patentability of our samples exclusively on the criteria of novelty, inventive ability and industrial application.

Results: With regard to patentability, we obtained a patentability percentage of 75%, which shows that the potential for innovation in traditional medicine is enormous.

Conclusion: Cameroon has a rich plant heritage with high therapeutic potential, which it is important to develop. The patent, provides researchers guaranteed and solutions for the protection and enhancement of their inventions.

Keywords: Patents, Intellectual Property, Directorate of Pharmacy, Drug and Laboratories (DPML), WHO, WIPO

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1. Introduction

According to the World Intellectual Property Organisation (WIPO), a patent is an exclusive right conferred on an invention, provided that is new, involves an inventive ability and is capable of industrial application. (1) The patent is the most widely used intellectual property title in the pharmaceutical sector and has a term of 20 years from the date of filing. (2) Patents encourage research, as they allow researchers to exploit their results within a recognised framework, and encourage companies to invest in long-term research programs for the development of innovative medicines. (3) Herbal medicines are widely used in the world for the treatment of many diseases. According to the study "Traditional medicine in the health system: facts and figures" published by Shetty in 2010, 80% of populations use traditional medicines for primary health care in Africa and Asia. (4) According to the World Health Organisation (WHO), the global market for herbal medicines is currently estimated at $60 billion per year. It is therefore essential for African countries to protect their knowledge in order to fully integrate this vast market, hence the importance of patenting herbal medicines.

2. Materials and Methods

Framework of the study

The study carried out is of an analytical nature. It took place from November 2021 to June 2022 in the following places: the Library of the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé 1, at the Directorate of Pharmacy, Drug and Laboratories and at the Cabinet EKEME LISAGHT, representative of African Intellectual Property Organization (OAPI).

Studies conducted on medicines based on plants from Thesis defended at the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé I and the files of applications of medicines based on plants submitted for registration to the DPML for between 2014 and 2021 were studied.

Sampling

The study was conducted on the basis of non-exhaustive consecutive sampling.

Study material

Thesis on medicines based on plants defended at the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé I between 2014 and 2021, the application files for the registration of herbal medicines submitted to the DPML, the legislative and regulatory provisions on the protection of intellectual property by patent and the worldwide databases on patents.

Procedure

Sample Selection and Data Collection

Theses on medicines based on plants produced at the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé I were selected, as well as the files of applications for registration of medicines based on plants at the DPML representing our study population were selected by non-exhaustive consecutive sampling. The collection of our samples took place at the Library of the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé 1 and at the registration service of the DPML. The first stage of sampling at the Library allowed for the systematic sampling of all works on herbal medicines revealing an inventive character, i.e. which included in their titles one or more of the following key words: "Formulation", "Formulation test", "Preparation", "Synthesis and Development". Sampling at the DPML consisted of selecting all medicines based on plants' application files submitted for registration.

The data collected respectively followed the analysis of the criteria of novelty, inventive ability and industrial application, with reference to the provisions of the PCT (Patent Cooperation Treaty), administered by WIPO. (7)

3. Evaluation of the Patentability

- **Evaluation of the Novelty:**

  With regard to the condition of novelty, the search for anteriority was carried out using the Google search engine, the "BOPI" databases of the African Intellectual Property Organisation (OAPI) and the "PATENTSCOPE" platform of the World Intellectual Property Organisation (WIPO).

It should be noted, however, that in the context of our study, the analysis of the various samples was conducted on the assumption that they had not been published by the producer (which would destroy the novelty of the invention). (7)

- **Evaluation of the Inventive Ability:**

  The inventive ability was assessed by demonstrating that for the person skilled in the art, the product was obtained by a non-obvious protocol.

- **Evaluation of the Industrial Application:**

  The assessment of the Industrial Application was conducted by ensuring that each invention had the capacity to be produced on an industrial scale. To this end, it was verified that all industrial scale production of the collected elements successively met three parameters: visual control of the samples, mass uniformity and validation of the manufacturing process. (7)

Ethical considerations

In the framework of our research work, we obtained

- An ethical clearance from the institutional ethics committee of the University of Yaoundé I
- An authorisation to investigate from the Directorate of Drug and Laboratories
- An authorization of training at the Cabinet EKEME LYSAGHT, representative of the AIPO

4. Results

Selection of Samples in the FMSB Library

a) Thesis with inventive character

A total of 36 theses that had an inventive character in the FMSB Library Thesis Register were identified.

Almost all the sample thesis selected were thesis in the Pharmacy stream. Of the 36 samples thesis found in the Library, 34 were from the Pharmacy stream, one from General Medicine and one from Dental Medicine **(Figure 1).** This demonstrates a certain involvement of pharmacists in the processes of innovation through applied research. Of this list, 23 thesis were available on the library shelves and were consulted. This represents a percentage of 61% of the theses listed in the register that were available on the library shelves.

b) Type of thesis selected

The thesis characterised as potentially patentable were those that were inventive and led to the development of a product. In the end, 50% synthesis, 8% preparations, 8% capsule development and 34% formulations were obtained **(Figure 2)**.

Selection of Samples in the DPML

a) List of Herbal Medicines in the DPML

A total of 11 samples at DPML, including one from 2019 and ten from 2020. The majority of locally produced medicines based on plants in Cameroon were found to have been licensed in 2020, during the period of the Coronavirus pandemic. Seven out of the 11 medicines identified by the DPML **(Table 1)** were found to have a patent. This represents a patentability percentage of 64%.

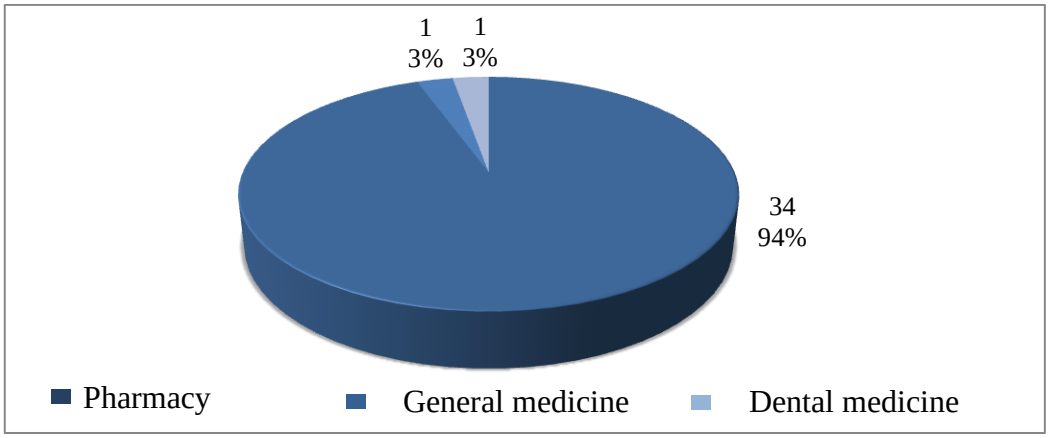

Figure 1. Selected thesis streams

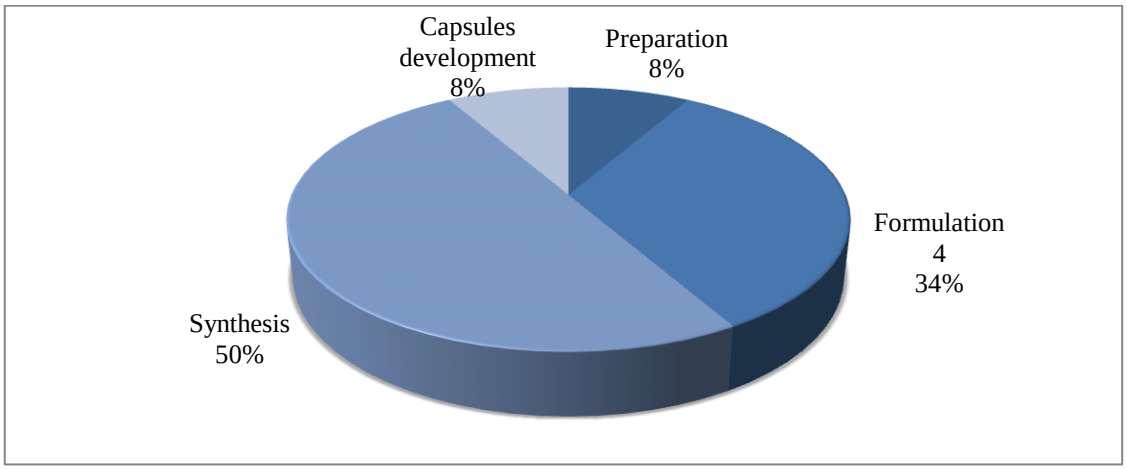

Figure 2. Types of thesis selected

b) Number of evaluated thesis

After the different selection steps in the library, we actually evaluated 12 thesis from those whose results were medicines based on plants, out of a total of 23 thesis samples selected in the library **(Figure 3)**.

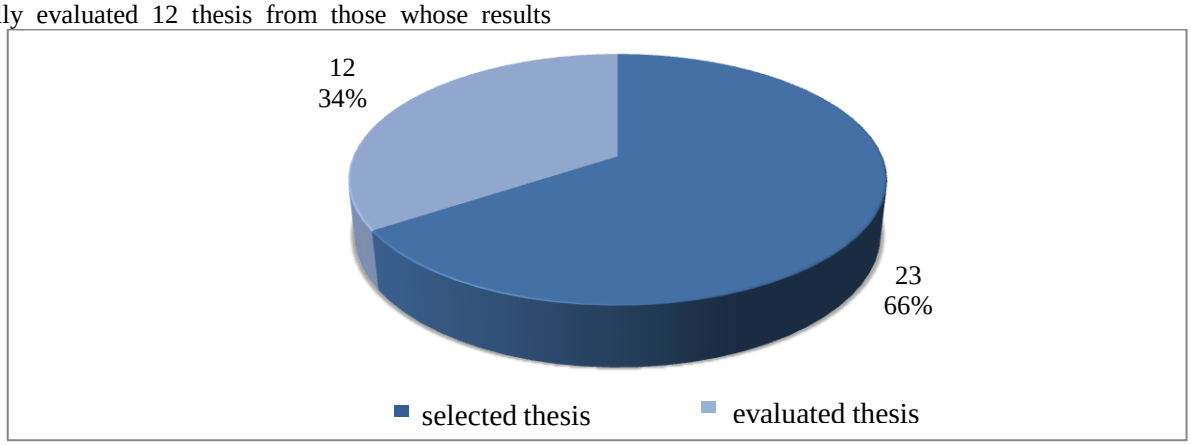

Figure 3. Number of theses evaluated

Table 1. List of herbal medicines registered with the DPML

Sr.no.	Product Name	Manufacturer	Date of MA	PATENT
1.	VENINSERIN	STPN BIO	2020	NO
2.	ADSAK-COVID	Mgr KLEDA	2020	YES
3.	ELIXIR-COVID	Mgr KLEDA	2020	YES
4.	HIVIROL-ANTIBIO BEK'S	LABO.RABBOUNI	2020	YES
5.	VIRO GREEN FORCE	ALT-CIMA & SIL	2020	NO
6.	VIRO LEX BIO	LABOGREEN	2020	NO
7.	COROCUR	Promoteurs de la Bonne Santé	2020	YES

8.	SOUDICOV PLUS	Ets BOBOSSOUDI & Frères	2020	YES
9.	NGUL BE TARA	M & PN RIRCO	2020	YES
10.	PENTAVIR FORTE	AsNO	2020	YES
11.	Tisane *Artemissia afra*	La maison de l'*Artemissia*	2019	NO

c) Medicines based on plants evaluated at the DPML

Four medicines based on plants were evaluated at the DPML. These four medicines selected at the DPML were assessed for novelty, inventive ability and industrial application respectively **(Figure 4)**.

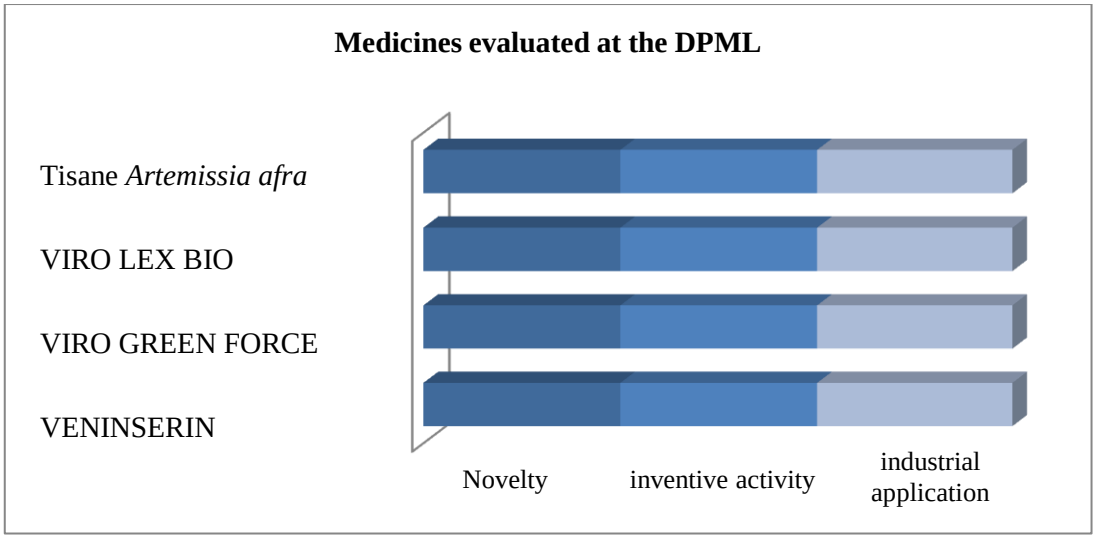

Figure 4. Medicines evaluated at the DPML

Assessment of patentability of samples

- **Novelty assessment:** Of the 12 thesis results on medicines based on plants analysed at the FMSB library, 9 samples met the criterion of novelty. Of the 4 samples evaluated at the Library, 3 met the criterion of novelty. **Table 2** and **3** present this result. This represents for each of the samples 75% novelty.

Table 2. Novelty assessment of the FMBS and DPML library samples

Places of Study	Novelty	YES	NO	Total
FMBS Library	Number of theses with a new character	9	3	12
	Percentage of theses with a new character	75%	25%	100%
DPML	Number of registered drugs of a novel nature	3	1	4
	Percentage of medicines registered as new	75%	25%	100%

- **Assessment of inventive ability:** All 12 theses assessed at the FMSB demonstrated inventive step while at the DPML three out of the four herbal medicines studied met the criteria for inventive step. **Table 3** summarises this result.

Table 3. Inventive step assessment of the FMSB and DPML library samples

Places of Study	Novelty	YES	NO	Total
FMBS Library	Number of theses with a new character	12	0	12
	Percentage of theses with a new character	100%	00%	100%
DPML	Number of registered medicines with inventive step	3	1	4
	Percentage of registered medicines with inventive step	75%	25%	100%

- **Industrial Application Assessment:** With all of our samples having the capacity to be produced on an industrial scale, 100% of our samples met the industrial application criterion **(Table 4)**.

Table 4. Industrial applicability assessment of the FMSB Library and DPML samples

Places of Study	Novelty	YES	NO	Total
FMBS Library	Number of theses with a new character	12	0	12
	Percentage of theses with a new character	100**%**	00%	100%
DPML	Number of registered medicines with inventive step	4	0	4
	Percentage of registered medicines for industrial application	**100%**	0%	100%

5. Discussion

Out of the entire thesis defended at the Faculty between 2014 and 2021, i.e. approximately 1500 for all fields and 210 for the Pharmacy field, only 12 theses were evaluated. This result can be explained by several factors: almost all the thesis in General Medicine and Dentistry and a good number in Pharmacy are *de facto* outside the scope of patentability, as they deal essentially with questions of epidemiological investigation. This would represent an approximate percentage of 90% of thesis, all fields combined, not included in this study. In addition, there is a significant number of thesis that are inventive but cannot be patented because they do not lead to a product or a technical solution. These are mainly thesis on basic research, such as *in vitro* and *in vivo* evaluations of the pharmacological activity of plant extracts. Of what remains, the low sampling yield would be associated with the archiving problems encountered at the FMBS Library. These elements justify that the sample size was limited to 12 thesis. Hoping to obtain a large sample from the Directorate of Pharmacy, Drug and Laboratories, consisting of medicines based on plants registered between 2014 and 2021, only 12 product registration application files, all registered between 2019 and 2021, were retrieved. Medicines based on plants registered between 2014 and 2019 were not retrieved from the DPML. This low sampling result could be attributed to the fact that the Directorate of Pharmacy, Drug and Laboratories does not have an efficient archiving system that can store the processed documents in an organised manner. After the 12 samples from the Directorate of Pharmacy, Drug and Laboratories had been identified, 4 medicines were selected for patentability assessment. During the selection of samples from the Directorate of Pharmacy, Drug and Laboratories, 8 out of 12 medicines met the exclusion criterion. This exclusion was due to the fact that these medicines had already been submitted for patenting. (8) The assessment of the patentability of the two sample batches showed promising results, with an overall patentability percentage of 75%. This represents a huge potential and a valid reason that Cameroonian authorities and researchers should take into account in order to enhance the development of traditional medicine. These findings lend credence to those of Mposhi in 2021, who demonstrated the importance of patenting herbal medicines to enhance their value, by making a point of stopping the patenting strategy for traditional medicines set up by Zimbabwe. (6) As the second African country to have filed more patents for herbal medicines used in the management of the new coronavirus disease after South Africa, (5) Cameroonian researchers have demonstrated their commitment, innovation and entrepreneurial spirit. By positioning itself at the forefront of the response through African therapeutic solutions against the coronavirus, Cameroon has positioned itself as a locomotive of therapeutic innovation through plant-based medicines. This singular progress undoubtedly puts it in a favourable position to integrate the vast and promising world market for plant-based medicines, whose annual economic potential is estimated by the World Health Organisation at 60 billion dollars. (10) With a ratio of 12 patentables medicines based on plant out of 16 evaluated, this study shows that 75% of the medicines based on plants produced by standard protocols in Cameroon meet the conditions for patentability of an invention, and are therefore patentable. (9)

6. Conclusion

The overall objective of this study was to assess the patentability of herbal medicines produced in Cameroon. Of the 47 medicines based on plants identified (36 in the library and 11 in the DPML), we effectively found a sample of 34 (23 in the library and 11 in the DPML) descriptive memoranda of medicines with an inventive character, from which we obtained 16 medicines for analysis. It is important to note that 7 of the 11 herbal medicines identified in the DPML have already been patented. Combined with the results of our work, which showed that 12 out of 16 drugs are patentable (i.e. a patentability percentage of 75%), we can confidently say that medicines based on drugs produced in Cameroon have a high patentability potential.

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Conflict of interest

The authors declare that there are no conflicts of interest.

References

1. World Intellectual Property Organisation. What is intellectual property? [Internet]. WIPO; 2004 [cited 2021 Dec 21]. Available from: http://www.wipo.int/publications/fr/details.jsp?id=99&plang=FR
2. World Trade Organization. TRIPS Agreements [Internet]. WIPO; 2013 [cited 2021 Dec03]. Available from: https://www.wto.org/french/tratop_f/trips_f/ta_docs_f/1_tripsandconventions_f.pdf
3. Drug Companies. Development, patents and trademarks [Internet]. Leem; 2019 Mar 22 [cited 2021 Dec 22]. Available from: http://www.leem.org/developpement-brevets-et-marques
4. Priya Shetty. Place of traditional medicine in the health system: facts and figures. ScienceDevNet [Internet]. 2010 [cited 2021 Nov 07]. Available from: https://www.scidev.net/afrique-sub-saharienne/features/place-de-la-m-decine-traditionnelle-dans-le-syst-me-de-sant-faits-et-chiffres/
5. Beatrice Longmene Kaze. Cameroon: Authorised natural anti-COVID-19 drugs cause debate. ScienceDevNet [Internet]. 2021 [cited 2021 Nov 08]. Available from: https://www.scidev.net/afrique-sub-saharienne/features/cameroun-les-medicaments-naturels-anti-covid-19-autorises-font-debat/

6. Archibold Mposhi. The importance of patenting Traditional medicine in Africa: the case of Zimbabwe. International Journal of Humanities and socialSciences. 2021; 3(N°2):236.
7. WIPO. PCT Annual Review 2017 - Summary The international patent system [Internet]. 2017 [cited 2021 Dec 24]. Available from: http://www.wipo.int/publications/fr/details.jsp?id=4221&plang=FR
8. African Intellectual Property Organization. Revised Bangui Agreement. 14 December 2015 [Internet]. OAPI 2015 [cited 2021 Dec 20];3(2):236. Available from: http://www.oapi.int/index.php/fr/oapi/cadre-juridique/accord-de-bangui
9. WTO. Implementation of paragraph 6 of the Doha Declaration [Internet]. WTO; 2003 Sept 01 [cited 2022 Jan 15]. Available from: https://www.wto.org/french/tratop_f/trips_f/implem_para6_f.htm
10. World Health Organization. WHO strategy for traditional medicine 2014-2023 [Internet]. Geneva Switzerland: WHO; 2013 [cited 2021 Jan 08]. Available from: https://apps.who.int/iris/bitstream/handle/10665/95009/9789242506099_fre.pdf