

Environmental Investigation Agency comment on “Guidance for Reviewing Patent Applications from the Field of Traditional Medicine (draft for public consultation)”

21 April 2020

EIA is an international non-governmental organization committed to investigating environmental crime and abuse and advocating for effective laws, enforcement and criminal justice responses to combat it. Since its establishment in 1984, EIA has played a key role in contributing to international and national decision-making in relation to combating environmental crimes such as illegal wildlife trade, including through the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). EIA’s work on wildlife trade focuses on trade in elephant ivory, tigers and other Asian big cats, rhinoceroses, pangolins and totoaba, although our investigation findings and policy recommendations are of relevance to many other wildlife species.

EIA has contributed comments and recommendations during multiple revisions of the Wildlife Protection Law of the People’s Republic of China and to consultation drafts of implementing regulations.

Key recommendation

With regard to the public consultation process for the “Guidance for Reviewing Patent Applications from the Field of Traditional Medicine”, EIA recommends:

Amend section 1.1.2 to state that, in line with Article 5 of the Patent Law which states that patent rights shall not be granted for inventions and creations that violate socially recognised ethical standards or hinder public interest, patents shall not be issued to TCM products which contain ingredients sourced from wild animal species that are threatened by trade (defined as wildlife species subject to special state protection within China, and/or listed on CITES Appendix I, and/or listed as Critically Endangered, Endangered or Vulnerable on the International Union for the Conservation of Nature Red List), including from captive sources.

Use of threatened wild animal species in TCM hinders public interest

According to the first paragraph of Article 5 of the Patent Law, patent rights shall not be granted for inventions and creations that “violate the law or socially recognised ethical standards, or harm public interest”.

The current draft Guidance recognises that consideration should be given as to whether use of a rare ingredient harms public interest, and that this determination is not simply limited to whether its use is prohibited by law:

“If the invention involves the use of rare Chinese medicinal ingredients, toxic Chinese medicinal ingredients, or forbidden Chinese medicinal combinations, one needs to consider whether the invention will seriously waste resources, disrupt ecological balance, endanger public health or similar, thereby harming public interests.”

Rare ingredients which may disrupt ecological balance and thereby harm public interest are not limited to those whose use is currently prohibited by Chinese law. In order to fully implement the first paragraph of Article 5 of the Patent Law, the present Guidance should therefore be amended to recommend against acceptance of any applications which involve use of threatened wild animal species (including from captive bred specimens).

EIA commends the recommendation in Section 1.1.1 and Case Study 1 in the draft guidance that patents should not be granted for applications for patents for products which use tiger bone and rhino horn. However, medicinal use of body parts of many other wildlife species which are threatened due to demand for use in medicine is not currently prohibited under Chinese law, for example pangolin scales, leopard bones, saiga horn, elephant skin and bear bile.

In our recommendations for the 2020 revision of the Wildlife Protection Law ([enclosed](#)), EIA recommended that the Law should be amended to prohibit the use of all specimens of wild animal species that are threatened by trade (including from captive sources), because of risks that the current legal trade is exacerbating poaching and illegal trade, thereby disrupting ecological balance. We suggest defining 'wildlife that is threatened by trade' as any species subject to special state protection in China, and / or which are listed on Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and/or which are listed as Critically Endangered, Endangered or Vulnerable on the International Union for the Conservation of Nature Red List.

The results of EIA's investigations and research indicate that 'utilisation' or legal domestic trade in wildlife that is threatened by trade such as tigers and other big cats, elephants, rhinos, bears and pangolins, including in parts and derivatives of captive bred specimens, is a high-risk approach that exacerbates the trade threat faced by these species in the wild. EIA has obtained evidence that demonstrates that the current "special marking" scheme implemented under the Wildlife Protection Law to regulate legal trade in wildlife under special state protection, including in medicine, in effect enables laundering of illegal wildlife specimens, undermines enforcement efforts and stimulates demand for the species thereby threatening their survival in the wild.

Use of captive-bred specimens of wild animal species that are threatened by trade should also be regarded as disrupting ecological balance and thereby harming public interest. Taking tigers as an example, large-scale commercial breeding of species such as tigers has not lessened pressure on wild populations and by extension poaching and biodiversity loss, but has instead perpetuated and stimulated demand for all big cat products, reduced stigma of consumption of tiger products, and has provided traders with opportunities to launder illegally-sourced tiger specimens.

Loss of biodiversity poses a grave threat to the natural systems upon which all societies and economies depend and increases the risk of catastrophic events such as

pandemics. Over-exploitation of biodiversity has been highlighted by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services as the second greatest driver of biodiversity loss. Therefore, preventing excessive exploitation and utilization of biodiversity is essential to safeguard public interest and to realise the vision of ecological civilization.

In addition to exacerbating biodiversity loss, continued use of threatened wildlife in TCM hinders public interest in various other ways and should not be condoned through granting of patents, in accordance with Article 5 of the Patent Law:

- Concern regarding link between wildlife trade and emerging infectious diseases

Following the emergence of the novel coronavirus SARS-CoV2, suspected to have originated from trade in wildlife, the Standing Committee of China's National People's Congress adopted decisions in February 2020 to restrict wildlife trade and ban trade in and commercial breeding of most terrestrial species for consumption as food. However, the risk of pathogen crossover is also inherent in breeding and utilisation of wild animal species for medicinal use. As such, in the interests of public health and safety and to allay the concerns of the public regarding further potential crossover events, the Guidance should be amended so that utilisation of wildlife for medicinal purposes is discouraged.

- Going against public opinion

A survey conducted in January 2020 by Peking University and a number of non-governmental organisations to gauge the attitudes of the Chinese public in China regarding consumption of and trade in wildlife found that, of 101,172 responses, 79 per cent opposed the use of wildlife for purposes such as traditional medicine and fur. Only one per cent were fully in favour.

Continued use of wildlife that is threatened by trade such as leopard bones and pangolin scales has also been the subject of a significant degree of public criticism and debate in China. Ending such use, including by not considering patent applications for products which use threatened wildlife, would help to eliminate this controversy and so promote social harmony.

- Harming the international image of traditional Chinese medicine

Although the majority of TCM products do not contain any wildlife ingredients, the continued use of rare wildlife ingredients such as pangolin scales, leopard bones and bear bile in TCM regularly attracts criticism in other countries, resulting in much negative coverage of TCM in foreign media.

Ending use of wildlife that is threatened by trade in TCM would conversely lead to significant positive press coverage in foreign media, which would benefit the international image of TCM and its international development.

- Failing to encourage innovation in TCM

Quoting the “Opinions on Promoting the Inheritance and Development of Traditional Chinese Medicine” from the Party Central Committee and the State Council, the draft Guidelines state that, “we should follow the pattern of TCM development, grasp the characteristics and directions of innovation in traditional Chinese medicine”. In recent years, much progress has been made in development of artificial substitutes for wildlife ingredients used in TCM, such as artificial bear bile, which could eliminate the perceived need for the highly controversial practice of bear bile farming.

If the Guidelines are to follow the direction of innovation in TCM, they should help to do so by not supporting the continued use of threatened wildlife, and instead encourage the rapid development and adoption of artificial or sustainable herbal alternatives.

Suggested text amendments

In conclusion, Section 1.1.1 should be amended as follows:

1.1.1 Rare TCM ingredients that are banned from medicinal use or which derive from threatened wild animal species

The use of such rare Chinese medicinal materials will exacerbate the depletion of wild or natural resources, disrupt ecological balance, and thereby cause damage to public interests, ~~and that the country has banned the medicinal use of such ingredients and removed the relevant pharmaceutical standards.~~ Therefore, inventions involving the use of rare Chinese medicinal materials that are prohibited from being used in medicine or which derive from threatened wild animal species, defined as species under special state protection, species listed on CITES Appendix I, and/or listed as Critically Endangered, Endangered or Vulnerable on the International Union for the Conservation of Nature Red List, including captive specimens, fall within the scope of applications for which patent right should not be issued as stipulated in Article 5, paragraph 1, of the Patent Law, because they hinder public interest.

Section 1.1.2 should be amended as follows:

1.1.2. Rare TCM ingredients not currently banned from medical use and which do not derive from threatened wild animal species

If the invention using rare Chinese medicinal ingredients does not cause the depletion of wild or natural resources, does not disrupt the ecological balance, the ingredients are not prohibited by the state from medical uses, and the rare ingredients do not derive from threatened wild animal species defined as species under special state protection, species listed on CITES Appendix I, and/or listed as Critically Endangered, Endangered or Vulnerable on the International Union for the Conservation of Nature Red List, including captive specimens, the patent application should not be rejected as a situation that interferes with public interest under Article 5, paragraph 1, of the Patent Law.

Case Study 2 should also be amended to specify that the patent would only be granted if the application specified the formulation would use only artificial musk, as natural musk is a product derived from a threatened wild animal species.

Section 2.1 Recommendations regarding full disclosure of ingredients used in traditional medicine

Another issue we would like to draw your attention to is the use of non-specific terms in labelling of TCM products that contain wildlife ingredients.

The term used for “leopard bone” in TCM (豹骨 / bao [leopard] gu [bone]) is ambiguous, as the generic character for leopard - 豹 (bao) - could be used to refer to leopard, snow leopard, clouded leopard or even other species such as jaguar (which translates literally as “American leopard”). The TCM term “bao gu” is sometimes translated into Latin as “Os pardi” on product labelling, this being a non-scientific term used by the industry which has no taxonomic meaning. A similar issue exists with so-called ‘bone strengthening wine’. Several tiger breeding facilities in China sell “bone strengthening wine”, which is labelled in Latin as containing lion. It is marketed however, as having been made using tiger. Such situations do not reflect the “full and clear disclosure of medicinal ingredients” as required in Section 2.1 of the draft Guidance.

We recommend ensuring that Section 2.1 of the Guidance clearly require applications to fully and clearly state what ingredients they propose to use, including using Latin names for species.