

Practical implementation of the patent and innovation strategy of the Homeopathic medical and social center in the field of inventions

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In recent years, in modern scientific and practical medicine, more and more attention is paid to the search for effective and safe drugs. In this regard, it is of interest to use complex homeopathic medicines available without a prescription and for the purpose of which no detailed knowledge of the homeopathic method is required, which makes it possible to use these medicines by doctors of academic clinics. The effectiveness of homeopathic treatment in modern conditions is explained by the harmful influence of the ecological situation and aggressive social environment on the activity of immune processes in living organisms. A decrease in the activity of immune functions in humans leads to a change in the clinical picture of diseases, the predominance of asymptomatic forms of diseases and their chronicity. A competent combination of the means and methods of academic medicine with homeopathic effects allows you to achieve a quick and pronounced effect in the treatment of any pathology; significantly reduce the dose of allopathic drugs, reduce the toxicity of drugs, and significantly prolong their action.

The traditional opinion is that the effect of complex homeopathic medicines is purely symptomatic, with each component in the composition complementing each other, corresponding to the symptoms of a certain stage of the pathological process. However, the analysis of clinical studies on the efficacy and safety of homeopathic complex preparations suggests that the effectiveness of a homeopathic complex preparation is the higher, the more "homeopathic" the disease is (S. Hahnemann) and represents a single complex, which basically corresponds to the structure of a homeopathic recipe. It should be pointed out that when compiling a prescription for a homeopathic complex preparation, it is necessary to take into account that the differentiation of the principle of similarity is reflected in the concept of Breuer's so-called "similarity layers" (cited by T.M. Drozdova),

1 layer - the coincidence of the picture of the disease and drug pathogenesis in the most common, uncharacteristic symptoms, such as fever, asthenia, etc. ; Layer 2 - organ match - and tissue-tropicity for a specific effect on a certain organ or tissue(for example, heart, liver, mucous membranes, osteoarticular apparatus, etc.); Layer 3 - coincidence in organ symptomatology, i.e. not only structural, but also functional organotherapy means; Layer 4 - a more integrated coincidence not only in organs, but also in organ and tissue systems, associated symptoms, modalities; 5th layer - coincidence also at the level of the constitution, the individual psychosomatic habitus of the patient.

Thus, sequentially moving from superficial to ever deeper levels of homeostasis of the body, we see that symptomatic, organotropic and pathogenetic agents lie in 1–3 layers of Breuer's similarity, and typological (constitutional or personotropic) - in 4–5 layers [14] ... It is not possible to include a typological (constitutional) means in the complex, since complex drugs have specific nosologically verified indications. But it should be noted that in some cases the components of a complex preparation are polychrests

- may be constitutional for a number of patients.

Therefore, the monopreparations included in the homeopathic prescription must have symptomatic, organotropic and pathogenetic effects, which can

be a formula for the preparation of an original homeopathic medicinal product. An analysis of the literary sources available to us allows us to conclude that when compiling a prescription for a complex homeopathic preparation, the following points must be taken into account:

The first is the quantitative composition. According to a number of authors [1, 4, 18, 19], the fewer drug components in the complex, the wider the indications for its use and the less opportunities to cause unforeseen complications.

The second is the quality composition. Homeopathic complex drug includes monopreparations that have symptomatic, organotropic, pathogenetic effects.

The third is the choice of dilutions. According to N.A. Koroleva. et al. 1999, it is rational to use potencies from 3 CH - 12 CH, since it is these dilutions of the starting substances that have more indications and fewer restrictions on their use.

Currently, the market for complex homeopathic remedies with indications for various nosologies is widely represented by both domestic and foreign drugs. In connection with the expansion of the pharmaceutical market of homeopathic preparations, there is a need to form a patent and innovative strategy for developers and manufacturers of homeopathic medicines for the legal protection of intellectual property, taking into account the specifics of the complex of works on the development, mastering of production and market launch of a competitive original homeopathic medicine (Bykov V. A., Val E.V., Gromakova A.I., Gorlenko S.A. and others).

Since 1992, patenting of new developments in the field of creating complex homeopathic medicines has been carried out in accordance with new legislation. As a result of this, since 1996, we have prepared descriptions of inventions and drawn up claims to ensure the protection of the rights of the patent owner, and have submitted applications to the Patent Office.

The claims were drawn up by us in such a way that it was possible to implement patent rights in further work, namely: the claims covered the widest but reasonable scope of rights, and the fact of its violation could be easily established.

Based on the results of the examination carried out at the Federal Institute of Industrial Property, 8 patents for medicinal products (compositions, formulations) were received (Table 1).

Table 1

Data on the practical implementation of the enterprise's patent and innovation strategy  
in the field of invention

№ п/п	Название изобретения	Номер охранного документа (Патент РФ)
1	Гомеопатическое лекарственное средство для лечения костно-суставной патологии (Остеоартроз, остеохандроз, артрозы, артриты)	№2162334
2	Гомеопатическое лекарственное средство для лечения паразитарного холецистита, вызванного возбудителем « <i>Opistorchis felineus</i> »	№2144372
3	Гомеопатическое лекарственное средство для лечения паразитарного холецистита	№2144371
4	Гомеопатическое лекарственное средство для лечения гипертрофии предстательной железы	№2144370
5	Гомеопатическое лекарственное средство желчегонного действия	№2225217
6	Гомеопатическое лекарственное средство «Э-сан» для лечения энуреза	№2225216
7	Гомеопатическое лекарственное средство для лечения в комплексной терапии ишемической болезни сердца, начальной стадии сердечной недостаточности, транзиторной гипертензии, миокардиострофии, нарушения ритма, кардионеврозе.	№2162332
8	Гомеопатическое лекарственное средство для лечения атеросклероза коронарных и церебральных сосудов	№2162333

As an example of drawing up the formula of the invention (the composition of a complex homeopathic medicine), we propose to consider the prescription of the homeopathic medicine "Prostatosan", which is used in the complex therapy of benign prostatic hyperplasia of the I-II degree in combination with chronic prostatitis. Each of the above ingredients is an independent homeopathic remedy, which has long and proven itself in the treatment of pathology of the genitourinary system.

The direction of action of individual components can be characterized as follows: the truly symptomatic component in the "Prostatosan" preparation is *Pulsatilla pratensis*, the pathogenesis of which was described by Hahnemann in 1813. Symptoms: frequent, painful urination, "straining" before urinating, because the thickness of the stream decreases, urine is excreted drop by drop [2, 6, 17].

The components acting on the pathogenetic prostate are: mechanisms increase *Serenoa serrulata* and *Thuja occidentalis*.

*Serenoa serrulata* is used for enlarging the prostate gland [2]. In "... conducting a double-blind, placebo-controlled study in men with prostatic hyperplasia, the state of androgenic, estrogenic and progesterone receptors from prostate tissue samples was assessed using two different methods. The results of the steroid evaluation found that the men who received the *Serenoa serrulata* extract had significantly lower values of the cytosolic (cellular) and nuclear (control center in the cell) receptors for estrogen and progesterone compared with the placebo group. Since the capacity of the progesterone receptor is related to estrogen activity, the results of this assessment indicate that *Serenoa serrulata* extract has significant anti-estrogenic activity. Numerous studies of *Serenoa serrulata* extract have shown that it is effective in approximately 90% of patients with prostatic hyperplasia, usually between the fourth and sixth weeks "(cited by Vermeulen F., 2002). This is one of the main agents in the treatment of prostatic hyperplasia [2, 8, 11, 17].

The next component is *Thuja occidentalis* (*Thuja western*) - "tree of life" according to Hahnemann [2] - has a resorbing effect on enlarged glands due to the content of essential oil containing thujone in fresh leaves of the plant [11, 15]. Characteristically obstructed

urination - the patient must wait before urine appears, sharp pains when urinating, the urine stream doubles.

The next component - *Clematis recta* (straight clematis) - has an organotropic effect, it is recommended to prescribe it for prostatic hyperplasia, which is accompanied by involuntary urination, pain, burning sensation at the beginning of urination. The stream of urine is intermittent [2, 17].

The last component - *Vitex agnus-castus* (*Vitex sacred*) - is recommended in the treatment of prostatic fluid emission, due to its organotropic action on the prostate gland.

Thus, the components of "Prostatosan", having organotropy, affect both the symptoms of the disease and the pathogenetic processes in prostatic hyperplasia.

As a result of the work carried out, the formula of the invention is as follows: *Pulsatilla pratensis* C30; *Serenoa serrulata* (*Serrata serrata*) C12; *Thuja occidentalis* (*Thuja western*) C12; *Clematis recta* (straight clematis) C12; *Vitex agnus-castus* (*Vitex sacred*) C 12.

Information about the patent search, the pathogenesis of homeopathic single-component drugs as components of the complex, the positive results obtained in clinical trials, data from the analysis of the literature and departmental materials, allowed the drug "Prostatosan" to be registered with the Federal Service for Surveillance in Healthcare and Social Development and to protect the manufacturer's rights RF patent No. 2144370.

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