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Natural Products for Cancer Therapy – Is Economic Success Reachable?

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Scientific and Economic Success Perspectives

Each year, 13 million people are diagnosed with cancer worldwide. Of those, 8 million deaths are recorded making cancer the second cause of death on the globe. In recent years, a significant prognostic benefit for cancer patients has been achieved through the development of new forms of therapy especially for many hematological malignancies. Unfortunately, the hope to transfer this success to the field of solid tumors is yet to be fulfilled. Economically speaking, the market of chemotherapeutics represents one of the largest sectors of health care with an annual sales rate of 180 billion $ per year. It is noteworthy that the market-leading scientific and biotechnological companies were developed in cooperation with universities.

Research projects based on chemical substances extracted from medicinal plants have paved their way into fields of pharmaceutical research, biotechnology and cancer therapy. According to the Federal Statistical Office in Germany, pharmaceutical industry belongs to the most dynamic branches of industry with positive future growth prospects. Responsible for this boom are the following factors: (1) the advances achieved in developing new technologies, (2) the higher demands in budding societies, e.g., in Asia and (3) the demographical dominance of an older population in western industrial countries. In Germany, the export rates of pharmaceutical industry are above 50%.

Natural products have an enormous impact on the economy and markets of our societies, and this trend is largely increasing during the past four decades (Figure 1). This can be illustrated by a literature survey performed with the PubMed database (http://www.ncbi.nlm.nih.gov/). A restricted search for medicinal plants or herbals resulted, however, in much less publications (Figure 1). The reason may be that other products than medicinal plants and herbals also belong to natural products, e.g., antibiotic drugs from microbial organisms, natural products from marine organisms as well as therapeutic peptides and antibodies. It could be concluded at this point that the economic potential of natural products in general has been recognized by the scientific community. The full potential of medicinal herbs has still be realized and developed, but represents a promising strategy for the future.

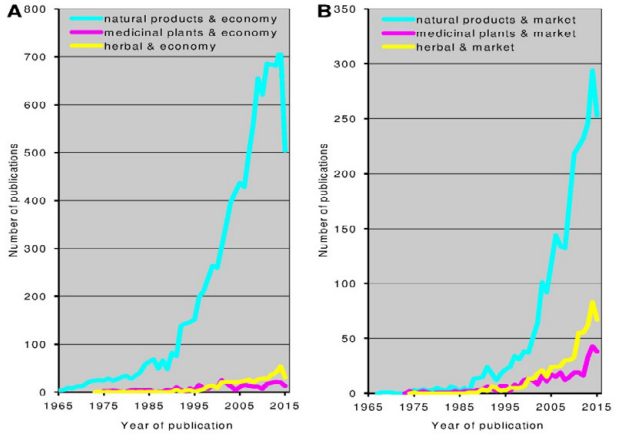

Figure 1: Survey of the literature deposited in the PubMed database from 1965 to 2015 with the keyword combinations (A) natural products/medicinal plants/herbal and economy and (B) natural products/medicinal herbs/herbal and market.

Biotechnology as interdisciplinary field also contributes to the development of medicinal plant research not only in the pharmaceutical industry, but also in all fields of life sciences. Therefore, economics experts also forecast a significant growth potential. In the field of oncology, this so called "red" biotechnology is becoming interesting due to an aging population that it is more prone to cancer on the one hand. On the other hand, the present therapy approaches have proven inadequate in terms of cure rates and tolerability. Considering the previous facts, a research project focusing on substances isolated from medicinal plants fits perfectly into the overall constellation of promising economic aspects in pharmaceutical research.

Besides being urgently needed in the field of medicine, novel cancer therapies are considered attractive and innovative not only in both scientific and technical research fields. The application of modern bioinformatics-based screening tools to identify novel lead compounds, whose effects are later experimentally validated, is considered a very promising approach.

In addition to the objectively high demand on more and better medications in cancer therapy comes the fact that the pipeline of new medications in clinical trials is inadequate, and investments in the healthcare sector are continuously declining. Therefore, new intelligent strategies have to be developed to cope with both medical and economic necessities. In this context, a profitable market niche can be created using targeted therapy with the aid of biomarkers in turn identifying subpopulations of patients that are predicted to successfully respond to a selected therapy. Through this approach, both higher efficiencies and lower toxicities can be achieved at the same time, due to the prior pre selection of patients, who would benefit from the selected therapy and those who would not.

A proof-of-principle of this concept was provided several years ago after launching the drug Gleevec for the treatment of specific types of leukemia (CML and ALL) that carry the BCR-ABL gene as a biomarker. Meanwhile, many targeted antibodies and small molecules exist on

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the market speaking for the validity of this concept. This trend along with sequencing of the human genome and evolving technique of high throughput sequencing will open endless doors to new therapies, since various target protein can be discovered thereby.

Even though peptides and proteins can be isolated from plants, their therapeutic relevance is still to be researched. Therefore, it makes more sense to concentrate on innovative technical concepts to identify small to medium-sized molecules from plants.

Keeping in mind the declining R&D budgets, it can be predicted that small molecules may outrun biopharmaceuticals considering their significantly lower costs of manufacture.

Following preclinical studies phase I and II clinical trials have to be conducted on cancer patients. Therefore, the previously mentioned research concepts must carried out in cooperation between universities and pharmaceutical industry, thereby constructing strong ties between the innovative academic ideas and their application and contribution in pharmaceutical development. To achieve economic success in this process, wide spectrum of technical methods from basic research that accompany the development process from the preclinical to the clinical stage is needed. This cooperation has to be tightly and optimally designed that long-term research and development strategies can be built.

Scientific Connectivity

After the identification and validation of potential inhibitors from medicinal plants, the next step is to develop diagnostic tools to screen which patients are going to benefit from the sought therapy. Since this step comes at the very end of a specific project and because personalized is still being intensively discussed at the moment, many phytochemicals would be identified. Therefore, the goal is to develop tightly linked diagnostic and therapeutic strategies to avoid ineffective drugs with high risk of side effects to optimize cancer therapy. To accomplish this, target proteins with prognostic relevance have to be recognized. Highly aggressive tumors are often characterized by the expression of proteins that are responsible for metastasis and resistance against classical chemotherapy. Hence, to assess the success of a specific therapy, it is important to identify these target proteins. This process is not only important for the prognosis of the therapy outcome, but also contributes to the discovery of natural and synthetic small molecules that can specifically inhibit these targets. Therefore, it is of high importance to combine these diagnostic and therapeutic tools to target molecules playing a key role in cancer biology.

Economic Connectivity

These inhibitors have to be clinically investigated on a long term, in order to be readily launched on the market. As previously mentioned, a parallel process is to develop diagnostic tools, in order to individually predict the success of a selected therapy with a specific inhibitor. Therefore, mixed concepts of drug development depending on both diagnosis and therapy should be developed. This combination will allow the application of target-specific inhibitors on an individualized scale. Accordingly, a patient would only receive drugs with positive outcomes based on results from predictive diagnostic tests. With the long term application of this concept, more precise personalized therapy approaches with natural plant products can be achieved.

In this context, it is of high importance to flexibly plan these projects, in order to cope with constantly changing market environment and still be able to compete. *In silico* screening approaches provide numerous natural and synthetic small molecule candidate drugs that have wide application spectra. Thus, in case of fluctuations in the market environment or emergence of new competitors, a switch to another application field is possible through this method. This flexibility can also be experimentally applied, since cytotoxicity tests and experiments majoring binding capacity to a target protein are considered to be universal techniques. Therefore, the whole presented concept of synthetic or natural small molecules development remains flexible and competitive.

Through this flexibility and the universal applicability of these techniques, a benefit in various fields can accomplished due the various possibilities of cooperation in various fields (neuro-degenerative diseases, heart diseases, infections such as malaria, sleeping sickness, etc.), where further research topics and therapy concepts are tabulated.

Natural compounds represent an enormous source with an economic potential. The realization of research projects on natural compounds in the context of cancer therapy depends substantially on intelligent coping with changing environments of both local and international markets.