10 CASE REPORT FROM PVA-MV

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FAST AND COST-EFFICIENT METHOD FOR IMMOBILIZING ENZYMES

Summary

The innovation is a novel method for immobilizing enzymes of the classes esterase, lipase and oxygenase. Enzymes are proteins that function as biocatalysts speeding up specific reaction in the human (and other organisms') body. According to international agreements, enzymes can be divided into six main classes: oxidoreductase, transferase, hydrolase, lyase, isomerise and ligase.

Due to their extreme ability of speeding up a specific chemical reaction, enzymes are frequently used in industrial production of for example foods, fine chemicals, pharmaceuticals, etc. Through means of modern biotechnology artificial enzymes can be manufactures whose properties are optimized for a certain reaction. It is estimated that about 50 % of all enzymes used in industrial production have been artificially manufactured through the means of bio and gene technological methods.

Enzymes can in principle be utilized in two different ways, bound to a stable matrix (immobilized) or free in a liquid phase. In industrial applications with high through-put, free enzymes in a liquid are difficult to retain and reuse. Thus, immobilizing enzymes on a carrier material either covalently or non-covalently is the most frequently used strategy.

Technology

There are different ways of immobilizing an enzyme onto a carrier material. Chemical and physical methods are most commonly used. A third method is by means of plasma. Plasma in this sense is an ionized nitrogen containing gas that provides a favourable environment for the enzymes concerning their immobilization.

In conventional immobilization methods utilizing plasma so called spacers, being small molecules functioning as a linker, are required for enabling the binding of the enzyme onto the surface of the carrier material. The procedure of adding the spacers makes the plasma immobilizing methods rather labour intensive and there by expensive. Thus, these methods are only used for the production of high-priced end products such as pharmaceuticals.

The new invention is a novel plasma-based immobilization method not requiring spacers and is thus less expensive and quicker compared to conventional methods. It moreover

provides immobilize enzymes with both high stability and activity. The method is presently suitable for enzymes of the following classes: esterase, lipase and oxygenase.

Development stage

Proof of concept has been made.

IP

A German (GE) patent is filed.

Market/Opportunity

As the new method for immobilize enzymes is less expensive compared to conventional plasma-based methods, it is suitable for the manufacturing of low-price end products such as foods, detergent, papers and diagnostic products. About 50 % of all enzymes sold to industrial manufacturers are used by the food industry, 35 % by the detergent industry and 14 % by the textile industry. The highest growth rate concerning the usage of enzymes for industrial manufacturing is seen in the paper and cellulose industry.

Another interesting area where enzymes are not only utilized during the manufacturing process but are also incorporated into end products is in in-vitro diagnostic industry. This includes biosensors for glucose measurement and immunoassays, etc. This is a market worth about €30M and is experiencing a growth rate of 5 %. The largest submarket is immunoassays comprising about 25 % of the entire in-vitro diagnostic market.

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BIODEGRADABLE SILICIC ACID CONDENSATES

Summary

The invention relates to the production and use of a novel biodegradable silicic acid condensate. Silicic acid is found in numerous tissues including bone, tendons, aorta, liver and kidney.

The novel usage of the silicic acid condensate is as a biomaterial placed inside the body with direct contact to biological tissues. The thereof resulting interaction will lead to degradation of the biomaterial into silicic acid, which is an essential molecule in the body's metabolism. Thus the degradation is not only not-harmful but also provides an essential nutrition. The novel material can, before it being degraded, act as a support or shield for certain application not yet identified.

Technology

The technology is not explained as a patent application is yet to be filed.

Development stage

Proof of concept has been made.

Market/Opportunity

The novel biomaterial may possess interesting properties for the use as a biomaterial, which are widely used in medical devices, tissue replacement, and surface coating applications. The biomaterial market was in 2008 worth $25.5 bn, with an expected annual growth of 15 % the coming five years. The major markets are the US and Europe, while the emerging markets in Asia, Eastern Europe and South America are experiencing the highest growth.

The most important success factors in the biomaterial market are improved patient benefits for an aging population, improved manufacturing techniques and new products at competitive prices.

IP

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METHOD FOR ANALYSING IMMUNOLOGICAL CHARACTERISTICS IN ORDER TO PERSONALIZE MEDICAL TREATMENT OF CERTAIN DISORDERS

Summary

The basis for the invention is a proven correlation between observable symptoms of autoimmune diseases and the existence of auto reactive T-lymphocytes (T cells) in the body. Thus, the presence of certain T-cells corresponds to specific symptoms of autoimmune diseases, such as MS, rheumatoid arthritis (RA), type-1 diabetes, Crohn's disease, ulcerative colitis, allergies, etc.

These observations led to the idea of developing an in vitro test, where T-cells act as a marker for certain autoimmune diseases. The application areas for such a test are extremely versatile, including;

1) Pharmaceutical industry and central registration authorities.

2) Therapy monitoring of patients with chronic autoimmune diseases.

Technology

The invention is a diagnosis method, which clearly stands out in its benefits in comparison to the current state of the art. Just a simple blood sample is needed which is something that spares the patient extra burden and the health care sector, including insurance companies, financial expenses.

The application areas for such a test are extremely versatile. In the pharmaceutical industry and central registration authorities a wide range of opportunities are possible. Medication and therapy tests could be done directly from the cell, therefore research and development could progress in a more purposeful way. The new technology also opens up possibilities to simulate different courses of diseases and observe the principle of operation of new treating methods in different stadiums of the disease, as well as it enables to screen if medications, in the first place not having been develop for treating autoimmune diseases, actually influence the immune system.

Interesting as a field of application is not only the research done by pharmaceutical companies, but also the actual therapy monitoring of patients who already are affected by chronic autoimmune diseases. Therewith it is possible to monitor the progress of a treatment and adjust the therapy if necessary.

Development stage

The invention is in the proof of concept stage.

The preparation and cultivation has to be started at least 8 hours after taking the blood sample. The cultivation takes 14 days and the evaluation another 3 days. The celerity of the evaluation and the durability of the sample are still improvable.

IP

A German patent has been filed.

Market/Opportunity

Parts of the potential target group are (I) hospitals and registered doctors who treat patients with autoimmune diseases, (II) pharmaceutical companies for screening of new medications and already existing ones for their influence on auto immune diseases as well as (III) registration authorities for evaluating new medication prior approval.

There are more than 80 clinical autoimmune diseases, and 300 million people suffering from symptoms. The innovation enables saving potential especially in the treatment of patient because the medication can be personalized and as the test is in vitro, it spares the patient extra burdens.

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GENETIC FACTORS IN AUTOIMMUNE DISEASES

Summary

The invention is a novel method for the diagnosis of autoimmune diseases, preferable multiple sclerosis (MS). MS is a disease in which the fatty myelin sheats around the axons of the brain and the spinal cord are damaged. This leads to so called demyelination, which affects the nerve cells' ability to communicate with each other. Symptoms rang from muscle spasms, coordination failure, chronic pain, visual problems, etc. The fact that the symptoms are very shifting and that the cause of the disease is still unknown, makes MS difficult to diagnose. This may lead to a delay in the treatment initiation which leads to unnecessary suffering. There are numerous treatment options available that prevents or reduce the symptoms, but at present no cure.

Technology

The invention is a diagnosis method for MS, which clearly stands out in its benefits in comparison with the current state of the art. Present MS-diagnosis is based upon conclusions about the history of the disease, invasive neurological tests and medical imaging. The neurological tests mainly include testing the cerebrospinal fluid for signs of an ongoing inflammation. This is a complicated and for the patient very unpleasant procedure, which moreover does not give an exact answer whether a detected inflammation is caused by MS or another disease such as meningitis.

The imaging technique used for identifying MS, is magnetic resonance imaging (MRI) that visualizes areas of demyelination. Gadolinium can be administered intravenously as a contrast to highlight active areas of demyelination associated with the current symptoms and exclude inactive demyelination areas. MRI is a very expensive technique and does more over not always provide pictures from which unambiguous answers whether the demyelination areas are associated with MS or not.

The new method enables a cost effective early detection of MS based on a newly discovered molecular marker. The cost effectiveness comes mainly from the fact that a single blood drop from the patient's finger is enough for the method to provide a reliable answer. The method moreover can provide information about the most suitable treatment option for an individual patient. This is not only of great relevance for the individual patient who thereby can receive the right treatment at an early point in time, but also provides an opportunity for pharmaceutical companies to improve the evaluation of their anti-MS drug candidates.

Stage of development

Proof of concept has been shown.

Market/Opportunity

MS is, after epilepsy, the second most common neurological disorder. The WHO has estimated that 2.5 million people worldwide suffer from the disease and that the number is increasing. The highest prevalence is found in countries in northern Europe and North America where it is about 0.15%.

The pharmaceutical market related to MS showed global revenues of over $6 in 2008 and it is expected to increase to $9bn during the second half of next decade. Today about 36 % of all MS patients are treated with MS drugs. The inteferone-based drugs are dominating, including, “Avonex“ from Biogen, “Betaseron“ from Berlex Laboratories and Bayer Schering Pharma as well as “Rebif“ from Serono and Pfizer. The only non-inteferon-based drug in large use is “Copaxone“ from Teva and Sanofi Aventis. The number of patients on MS-drugs is expected to rise to 56 % by 2014. The reason for this increase is the expected market authorization of orally administrated MS-drugs showing less side effects compared to today’s drugs having to be injected. The increase usage of MS-drugs, oral or not, will likely have a positive impact on the usage of new cost-efficient diagnosis methods, especially those that also can provide information about which treatment works best for an individual patient. The latter aspect will be considered of importance both for the doctors want to prescribe the correct drug and also for the pharmaceutical companies requiring new evaluation methods for their drug candidates.

IP

A German patent has been filed.

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Catalyst for asymmetric olefin metathesis

Summary

The homogeneously catalyzed olefin metathesis has in recent decades emerged into a major industry and is one of the most widely used transformations in modern chemical synthesis. The starting material for the transformation is designated as olefins alkenes (a very large group of carbon compounds). Their chemical backbone consists of a chain or ring of carbon atoms, wherein at least two of these atoms are connected by a double bond. In the olefin metathesis reaction, the carbon-carbon double bond of two molecules is cut apart and remaining fragments are then assembled together.

The problem until now with the mentioned transformation is its inability to synthesis asymmetric compounds (i.e. enantiomers) due to the absence of a suitable catalyst system for this purpose. This task is what the innovation enables.

Technology

So far in the field of Grubbs-catalyst used for olefin metathesis the following approaches have been utilized: the use of monodentate non-functional n-heterocyclic carbene ligands (NHC) with chiral centers in the imidazole ring or in the side chain, and the use of functionalized NHC, based on the 1,1 '- binaphthyl for formation of a chelate ligand. These approaches have so far failed to provide the desired performance in asymmetric catalysis. The essential disadvantage of the NHC is the distribution of the different enantiomer products, which does not meet expectations.

The invention relates to a metal complex and its use as catalyst in the synthesis of organic compounds, preferably in the olefin metathesis and asymmetric olefin metathesis respectively. In the latter, the innovative catalyst succeeds in providing the required distribution of the enantiomer products.

Development stage

The innovative catalyst exists at a proof of concept stage.

Market/Opportunity

The innovative catalyst enables the production of pure enantiomer products through an industrially very important synthesis reaction, known as olefin metathesis.

Olefin metathesis is used for the production of a wide range of products including medicines, polymers and fuels. The main industrial use of olefin metathesis is the so-called "Shell Higher Olefin Process (SHOP). It is a chemical process for the production of linear α-olefins (unsaturated carbon compounds), which was introduced in 1977 and today has a global annual capacity of about ten million tons.

The enormous economic importance of olefin metathesis is one of the explanations for three of its inventors/improvers to receive the Nobel Prize in Chemistry in 2005; Yves Chauvin of the Institut Français du Pétrole in Rueil-Malmaison (France), as he was the first to declare how the olefin metathesis works in detail, Richard Schrock of Massachusetts Institute of Technology in Cambridge (US), did in 1990 for the first time develop an efficient catalyst for olefin metathesis and Robert Grubbs of the California Institute of Technology (US), succeeded to produce an even better and above all more stable catalyst in 1992.

Thus, the invention is based on preliminary work of the Nobel Prize winners and provides a new process for the industrial synthesis of asymmetric molecules. Therefore and moreover due to the large usage of the olefin metathesis, the interest from chemical industry is expected to be large.

IP

A German patent is pending. International applications are still possible.

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Treatment of degenerative diseases with mutated peptides

Summary

The invention is a method for treating patients with neurodegenerative diseases associated with the accumulation of certain proteins inside the brain. Alzheimer's, Parkinson and Huntington disease can be counted to such diseases and can thus be treated by the novel method.

Technology

The new method enables the reduction of accumulated amyloids, which are insoluble fibrous protein aggregates. Accumulated amyloids lead to amyloidosis, a condition playing a major role in neurodegenerative diseases such as Alzheimer's.

The method involves the infusion of a short peptide, which is the abbreviated version of the accumulated amyliod proteins. The peptide binds to the accumulated amyliod protein and prevents further amyliod proteins to accumulate on the same spot, thus it reduces the entire accumulation and could thereby retard the progression of the disease and possible also cure it.

Stage of development

Pre-clinical studies in mouse has successfully been performed.

IP

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Market/Opportunity

Dementia, which is caused by Alzheimer's and other neurodegenerative diseases, belongs to one of the largest health-related challenges of the future due to an increasingly elderly population in the western world. There are around 1 million people in Germany alone over the age of 65 suffering from dementia. The number of new dementia cases is about 200 000 annually.

Worldwide about 28 million suffer from Alzheimer's and 4 million from Parkinson. The total market related to these two diseases exceeds $14bn with a growth rate of almost 20 %.

New innovative treatments with less side effects and/or higher efficacy will experience a tremendous market opportunity in the coming years.

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Stimulation electrode for cochlear implants

Summary

The invention is a novel cochlear stimulation electrode for improved insertion and more reliable intra-cochlear stimulation. A cochlear implant is a surgically implanted electronic device that provides a sense of sound to a person who is profoundly deaf or severely hard of hearing. A cochlear implant consists of a microphone picking up sounds, an external speech processor filtering the sound, transmitter placed on the outer ear transmitting sound signals to the receiver. The receiver is placed in an artificially-made cavity inside the bone behind the ear and converts the sound signals to electric impulses and transmits there to the stimulator. The stimulator is an array of electrodes placed inside the cochlea that stimulates the nerve fibers leading to auditory perception.

The stimulation electrodes currently in the market are usually difficult to both insert into and correctly place inside the cochlea. This leads to a suboptimal stimulation of the nerve fibers and in worst case damage to the basilar membrane, which leads to negatively affected auditory perception.

Technology

The new cochlear stimulating electrode differs substantially in length (insertion depths 10-31 mm), and shape, compared to conventional electrodes. The chosen spiral shape will ensure that at least every other turn or every second ring is in contact with the basilar membrane, which significantly contributes to the amplification of acoustic signals. At the same time, its shape and way of insertion, minimizes the risk of trauma to the basilar membrane and simplifies manual handling. Furthermore, at the electrode entrance a so called Filzcuff impregnated with broad band antibiotics can be wrapped around the electrodes, which reduces the risk of post-surgical infections.

Development stage

Prototype has been developed.

IP

A German patent is granted and a PCT application is field.

Market/Opportunity

It is estimated that 112 000 cochlear implants are sold worldwide each year, of which 41 000 in Europe. The sales price for a cochlear implant is between € 26 000 and 27 000. The largest manufacturer of cochlear implants is Cochlear Implants Ltd with a market share of about 60 % in 2004. Cochlear Implant could be a possible licensee for the invention by letting them manufacture and sell it.

According to the inventor, the price of the new stimulation electrode could initially be set at € 750 a piece and after about three years drop to € 350. If the rights to the patent was licensed with 4% licensing-fee, the possible licensing revenue could reach about € 40 000 during the first three years. Another opportunity would be to start a spin-off company and manufacture and sell the stimulating electrode to manufactures of cochlear implants.

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CARBABENEM DERIVATE AS ANTIBIOTIC AND BETA-LACTAMASE INHIBITOR.

Summary

The innovation consists of a number of patented drug candidates that can be used as antibiotics and/or beta-lactamase inhibitors. The importance of this area is increasing as many bacterial strains are developing resistance against treatments presently used, which lead to severe consequences. The patents rights are widely internationalized and with one exception already granted. The drug-candidates have successfully completed pre-clinical testing and can initiate phase I clinical trials, which is considered necessary to complete in order to license the rights for the drug-candidates to a pharmaceutical company. Comparable transactions of phase I validated drugs are worth up to seven-digit amounts.

Technology

In 2005, about three million Europeans were infected with germs resistant to known antibiotics - 50,000 of them died. Since then, the prevalence has increased. Patients are often infected with bacteria strains resistant to multiple antibiotics (multidrug resistance) and comprising increasingly advanced defense mechanisms. Beta-lactamases, enzymes produced by many bacteria such as S. aureus and E. coli, can be counted as such defense mechanisms. These enzymes have the ability to inactivate beta-lactam antibiotics, which include the world's most commonly used antibiotics; penicillin or cephalosporin. To prevent the threat of complete ineffectiveness of antibiotics, a combination of antibiotics and beta-lactamase inhibitors such as clavulanic acid has been used since some years. However, even this treatment is experience increased problems with resistance evolvement. In addition, clavulanic acid leads to severe digestive tract disorder and should not be administrated orally.

The patented drug-candidate belongs to a class of antibiotic compounds known as carbabenem that is effective against most penicillin and cephalosporin-resistant strains. In addition, carbabenem has already shown a high efficiency in vitro and can be administered orally. Another advantage is its simple and cost-effective synthesis, compared to other antibiotics.

Development stage

The drug candidates have already been tested in vitro and in animal models (mouse, dog) regarding their effectiveness and toxicity. Moreover, the efficacy of oral administration was successfully demonstrated in animal models. The pre-clinical phase may thus be regarded as successfully completed.

Market/Opportunity

The possible market for novel antibiotics is immense. However, bringing the drug candidates all the way to the market is an expensive and time consuming task. Thus, the preferred business model is to license the rights to the drug candidates to a pharmaceutical company having the capacity to execute all require trials and sell the drug. Most likely, the drug candidates must successfully complete phase I clinical trials in order for a pharmaceutical company to be interested in purchasing the rights.

Comparable transactions of phase I validated drug candidates to major pharmaceutical companies include a vaccine (3151x, Affiris AG) against Alzheimer's, which was licensed to GlaxoSmithKline for an up-front payment of € 22.5M and revenue-related licensing fees. Further recent transactions include: GlobeImmune $41 M (immune modulator), Nereus Pharmaceuticals $45 M (anti-tumor agent, even before phase I), Agensys purchase of Astella for $387 M (monoclonal antibody against tumors).

IP

The IP rights are granted in the following countries: Austria, Belgium, Switzerland, Germany, Spain, France, Germany, Ireland, Italy, Netherlands, Portugal and Sweden (EP1100800). In addition, the rights in Australia, Canada, China, USA, South Africa, Israel, Mexico and New Zealand are granted. The application in Japan is still pending.

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Amylopectin based biodegradable copolymer used for nucleic acid delivery

Summary

The invention relates to a biodegradable copolymer used for nucleic acid (DNA or RNA) delivery into cells. Such delivery is usually used for means of gene therapy which is medical procedure having received a lot of attention since its discovery in the 1980s. By gene therapy, genetic material is transferred into cells through the use of certain carries. Once inside the cell the gene therapeutic affects the expression of defect genes. The expectations on gene therapy as a treatment of cancer, HIV and above all genetic diseases are high.

Technology

Gene therapy differs from ordinary drug therapy by affecting defect genes instead of proteins encoded by defect genes. The mechanism by which a gene therapeutic being transferred into a cell acts on a defect gene differs. The most common ones are; replacing a defect gene through a functional one being the inserted gene therapeutic, silencing a defect gene or indirectly by integrating with a non-defect gene encoding proteins responsible for the expression of a defect gene (e.g. interferon).

The main problem with gene therapy today is the transfer of gene therapeutics into cells. This can be done by physical methods (e.g. shooting genes placed on gold particles into cells or treating the cell membrane with an electric current in order for it to be more permeable) or by chemical/biological method (usage of vectors). The latter procedure is the only viable form when it comes to pharmaceuticals as it does not require the patient to visit a doctor. A vector is a carrier material that either can be viral or non-viral. A viral vector is introduced into a cell by transduction and a non-viral vector through transfection.

The new vector belongs to the non-viral type and consists of biodegradable cationic copolymers. The research area related to using biodegradable vectors in gene therapy is not new, but this specific vector has properties, which makes it stand out compared to the present state of the art, including low toxicity, high gene transfer efficacy and low manufacturing costs.

Stage of development

Proof of concept has been shown.

Market/Opportunity

Gene therapy is still in a testing phase. The first clinical trials were initiated at the end of the 1980s. Until 2008, more than 1100 gene therapy clinical trials have been performed or are still in progress. 60 % of them concerned cancer treatment and about 80 % of them were performed in the US. The first gene therapeutic receiving market authorization was the anti-cancer drug Gendicine, developed by the Chinese company SiBiono GeneTech. It received its market authorization in China in 2003 and has since been used for the treatment of thousands of patients suffering from head and neck squamous cell carcinoma (HNSCC).

However, no gene therapeutics, including Gendicine, have received market approved in the US or in Europe. Still the US market for gene therapy is estimated to be worth $2.8bn in 2010 according to Frost & Sullivan. The revenue comes from the research and the ongoing clinical trials requiring quite substantial amounts of both gene products and vectors. Thus, even though gene therapy does not turn out to be such a success as is anticipated, there is still a market potential for a novel vector with superior properties.

IP

A European (EP) patent has been filed.

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Metastatic model in zebra fish

Summary

The invention is a method for the visualizing of tumours and cancer cells, or even biopsies obtained from a tumour in another organism, in a transparent zebra fish. The zebra fish does in this fashion act as a model organism for metastasis, which is the spread of a disease (usually and in this context related to cancer) from one organ or part of an organism to another non-adjacent organ or part.

Until now, the migration of cancer cells has only been possible to study in-vitro, in cell culture, as the visualization of the cells in more complex organisms has not been possible. However, the metastasis is likely to function in another way in more complex organisms compared to in single cells.

The zebra fish is a well known organism for the study of embryonic development as its embryonic stages are easily detectable and its genome has been sequenced. Zebra fish is probably along with baker's yeast (Saccharomyces cerevisiae) one of the most important model organisms for this type of life science research.

It has more over received a lot of attention as a model organism for the study of cancer and anti-cancer drugs. Mice have historically been the preferred model organism for this purpose as they are mammals and therefore rather alike humans. However, mice have much longer development cycle stages compared to zebra fish which makes the research more time consuming.

Technology

Not described as the new method is not patented.

Stage of development

Proof of concept has been shown.

Market/Opportunity

The field of cancer research if of course immense and provides a great market opportunity. The use of zebra fish models is also of importance in at least academia. The European Commission funded a consortium of fifteen European research institutions under the direction of the Tübingen Max Planck Institute for Developmental Biology under the Sixth Research Framework Programme with €12M for the further investigation of zebra fish. This project called ZF-MODELS was considered one of the flagships of the Sixth Research Framework Programme. Thus, it shows the importance of zebra fish as a model organism for life science related research.
If or when a new method for zebra fish research will be a successful market opportunity is presently difficult to answer.

IP

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