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MICROALGAL BIOTECHNOLOGY: ETHICS AND INTELLECTUAL PROPERTY RIGHTS

(MİKROALGAL BİYOTEKNOLOJİ: ETİK VE FİKRİ MÜKLİYET HAKLARI)

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ABSTRACT

Microalgal biotechnology is a novel developing area which is persistent in most of the technological divisions. With the spread in microalgal biotechnology, there has been a peak in the number of products and services which has led to a new understanding covering the Intellectual Property Rights (IPRs). IPRs are the legal rights of the developer to hold and protect the defined product or service. With the recent developments in microalgal biotechnology, a new understanding should be adopted in terms of covering the opportunities, threads, legal rights and ethical issues to benefit from more realistic, secure and sustainable production technologies and reliable products. Thus this study aims to display the relation of microalgal biotechnology with IPRs.

Keywords: Microalgae, Intellectual property rights, Patents, Biodesign, Biotechnology, Sustainability

ÖZ

Mikroalgal biyoteknoloji hızla gelişen özgün bir alandır ve teknolojinin pek çok alanında adından söz ettirmektedir. Mikroalgal biyoteknolojinin yaygınlaşmasıyla beraber pazarda yerini alan ürün ve hizmetlerin yanı sıra mikroalgal üretimlerde fikri mülkiyet haklarından da bahsedilmeye başlanmıştır. Mikroalgal biyoteknolojinin gelişmesi için yeni firsatlar var olsa da; olası zorluklar ve etik konuları ile alakalı araştırmaların yaygınlaştırılması ve yasal düzenlemelere tabii tutulmasıyla daha güvenli ve sürdürülebilir üretim yöntemleri ile güvenilir ürünlerin ortaya çıkacağı düşünülmektedir. Bu nedenle hazırlanan bu çalışmada mikroalgal biyoteknolojinin fikri mülkiyet hakları ile ilişkisi incelenmiş ve değerlendirilmiştir.

Anahtar Kelimeler: Mikroalg, Fikri mülkiyet hakları, Patent, Biyodizayn, Biyoteknoloji, Sürdürülebilirlik

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1. INTRODUCTION

Microalgal biotechnology is gaining advanced knowledge to build a microalgae based bioeconomy with the strong adaptability to human welfare [1]. The diversity of microalgal species and the essentials in microalgal metabolism as well as metabolites [2] which are open for innovations and creativity are the main driving forces on the road to innovative approaches of microalgal biotechnology [3–5]. One of the advantages of microalgae is its sustainable nature which is fundamental for cost-effective development and a microalgaebased bio-economy. The marine and freshwater sources and aquatic richness of the microalgae holds great potential on the production of innovative substances and formulations as a gift of nature.

The core science of microalgae is currently adaptable for biofuels, nutraceuticals, pharmaceuticals, cosmetics and cosmeceuticals, environmental studies and even architecture and also art works constructed with microalgae [6, 7]. There are still challenges in microalgal biotechnology but achievements also have been done to affect global markets [8, 9]. The entrepreneurs and academicians aim to be successful while developing a service or product from microalgae in which they should be aware of the risks of failure, role models, local and global competitors and the legal issues related to their products. However current challenge of microalgal products is the achievement of a sustainable commercial production with higher amounts of return on investment ratios. At this point the Intellectual Property Rights (IPRs) become a major source to imagine and visualize the roadmap of successful biotechnological approaches where biosafety, biosecurity and biodesign are emerging socio-economic issues [10, 11].

In algal biotechnology patents and trade secrets are commonly used IP rights in biofuel and pharmaceutical industry. Providing the security of the developed technologies and products will benefit and return as a positive investment for SMEs and also encourages global corporates to set aside their R&D budgets and invest on microalgae based research and product development for marketing which is also a key movement that strengthens the collaboration of university and industry. Besides the green features of microalgae are also a positive impact on the advertisement of microalgal products which affects the public acceptance of the relevant product of a certain industry.

Thus the aim of present study is to display the importance of microalgal bioproducts considering IPRs on technology and product based approaches. Another point is to stress the ethical considerations on product development.

2. MICROALGAL BIOTECHNOLOGY FOR LIFE SCIENCES

Microalgae are photosynthetic microorganisms living in freshwater or marine environments [12]. They are responsible from more than half of the global oxygen production and carbon fixation [13]. The eco-physiological importance of microalgae is not limited with only natural balancing but also microalgal bioproducts are gaining importance due to tremendous features beneficial for living systems as well. The development of microalgal biotechnology for community use is not a new concept, however the sophisticated production strategies are accepted at late 1950s when a global demand for food and feed supplements has peaked [14]. During the 1950s, the bulk production of microlgae for several industries has started in order to cope with hunger, energy consumption, to supplement healthy food chain and adopt new technologies for future developments. Even in space missions, algae are considered as a sustainable oxygen and food source for the crew [15]. The development of algal biotechnology has moved forward with bilateral understanding of the taxonomy and promising biological compounds. Today, there are more than 100.000 species which are classified with the utilization of taxonomic tools [3], 16, 17]. Among them more than 200 species are important for biotechnology and some species are commercially available. Within this ocean more than 15.000 novel natural compounds are determined also and most of them are marketed or at their late development stages [16].

3. MAJOR INDUSTRIES FOR MICROALGAL BIOTECHNOLOGY

The continuous research on microalgae has concluded one final thing that microalgae have potential to support food sources, environmental balance and biofuel consumption. Considering the current status of the technology roadmap [18], microalgae have been evaluated as a fuel source rather than other novel applications [19]. However microalgae have potential more than being a fuel source but it holds a hidden know-how of the nature in its genome sequences [20]; actually microalgae provide alternative and natural compounds for pharmaceuticals [21], nutraceuticals [4], aquaculture [22] and cosmetics [23] as well.

A comprehensive understanding of the microalgal biotechnology starts from the strain selection to final product formulation and marketing. In this aspect, each research has its unique importance to draw a whole frame for commercial applications [24, 25]. Actually the ultimate goal is to leap up commercial scale rather than only feeding the core science and fundamentals which is also emerging for further large scale productions. Large scale microalgae production market has a value more than \$700 Million and grows steadily [26]. This market value display something important that microalgae have the capability to compete with existing technologies in economical point of view [27]. It is also estimated to develop further futuristic applications derived from microalgae which is a clue for the adoption of the technology for diversifying areas.

The microagal biotechnology development is highly affected from the geographical regions where the industry is facilitated [28]. Today the major share of aquatic biotechnology where microalgae is dominated belongs to the Asian countries such as Philippines, Malaysia, China, Japan, India, Taiwan and Republic of Korea (South Korea). This has a couple of reasons; one is that algae is the major food supplement in Asian culture thus most of the algae/microalgae is processed within internal market or nearby countries. The other is that; these countries have wide off-shore areas suitable for microalgae cultivation [29]. The geographical region is suitable for outdoor cultivation where natural light is utilized [30]. More importantly algae cultivation is like a tradition. With the global recognition of microalgae as a novel substance for industries mentioned in Figure 1, the marketing of microalgae and microalgae derived fine chemicals are expanded to external markets where US is the leading one. The spread in the microalgal biotechnology with a global vision has some sort of disadvantages as well. One of the most important thing is that with the rapid distribution of microalgae based compounds there will be a new undefined area in biotechnology, which may require certain classifications. Another point is related with the increasing number in the facilities a new job area will be opened however in here employment ethics will be a subject to discuss. Furthermore, in order to gain profit from microalgae, the balance of the environment may be disturbed, thus societies will face a major environmental protection risks, leading to cover environmental ethics.

In current market structure, microalgae is utilized as a source for dietary supplements such as single cell protein (SCP), omega-3 fatty acids; fine chemicals as astaxanthin, phycocyanin, β -carotene, lutein as colorful pigments for food, feed, pharmaceuticals and cosmetics [23],

[31–34]. One of the recent products from microalgae is bioactive peptides for human consumption which are considered to replace animal-derived protein supplements in formulations [35]. The market values of these products are 40 Million \$ of dietary supplements; 300 Million \$ of omega 3 (from fish); 1.2 billion \$ of carotenoid market which microalgae derived products can penetrate easily.

Figure 1 presents the current status of microalgal biotechnology in terms of major subdivisions of technology. With this knowledge and the know-how from literature studies, it is estimated that microalgae will be a "super-organisms" for any branch of biotechnology where human welfare and environmental health is of importance.



*The color classification of the major microalgae industry is done according to the scientific reports from databases such as *Scopus*, *ScienceDirect* and *Web of Science*

Figure 1. The development stages of microalgal biotechnology

3. INTELLECTUAL PROPERTY RIGHTS (IPRs)

Biotechnology is an open area for new inventions, technologies and products which may require protection in the frame of determined laws (WIPO, 2016). The ideas and designs can be protected with intellectual property rights (IPRs). IPRs encourage the inventors to create an independent study environment with a special focus to the related technology. With IP rights the forecasting of future trends can be established in order to navigate existing production or it gives inspiration to develop a new model for related field.

IP rights can be utilized in any area from core science to literature or artworks, however the IP rights related to algal biotechnology covers Patents or Trade Secrets. Both classifications are vital for algal biotechnology development. In order to have a claim to patent, there must be an invention step which give its value with an innovative approach according to the regulations of World Intellectual Property Organization, WIPO. Thus it should solve a problem in its related technology or utilization area. A patent gives the rights for the inventor to develop the product at marketing stage and creates an area in the market as being the only permitted holder for the developed product. The patents are preferred by the research institutes of universities before publishing the scientific date. The coverage duration of a patent is 20 years, this means that the patent owner holds the right for only 20 years and after the termination of the duration, the patent can be utilized by any other researchers. Thus rather than patents, most of the biotechnology companies prefers trade secrets. Trade secrets are required when a cutting edge scientific development is established. Trade secrets cover the manufacturing, industrial or commercial secrets. Trade secrets may contain a method of sales, production, manufacturing, channels reaching to the market and end-users. Thus the decision to hold a patent or keeping it as a trade secret is related to the corporate policy.



Figure 2. Patent Roadmap for microalgal product/technology development

The microalgae related products are good examples of trade secrets and patents. However due to a limited number of the algal biotechnology facilities, most of the IP rights are deal with patents. The patentable sources will be either production technology, machine or a final product or a method to pbtain a product. Thus in technology part, It can be divided into two section; (i) bioprocess and (ii) bio-products. In bioprocess part the machines, production technology and industrial designs can be utilized. Microalgae production requires light derived from either natural sources like sunlight or artificial illumination systems in order to provide photo flux for photosynthesis. Thus illumination systems can be patented. Also closed cultivation systems named as "photobioreactors" are gaining importance in order to cultivate algae in a more controlled environment. Photobioreactors can be designed in various shapes, volumes, external units (sensors to detect temperature, pH, dissolved oxygen and carbondioxide) required for cultivation and can be equipped with additional mixer systems and illumination chambers. Thus parts of a photobioreactor or the whole system itself can be patented. Not only upstream tools but also downstream equipments for biomass harvesting, cell disruption, extraction and formulation. Another point for patent pending is recombinant expression systems, recombinant proteins and other genetic engineering approach-related products (European IPR Helpdesk, 2014).

The main question in patenting a product or a design is that "*What* and *Why* to patent it?". In the patent file, the description of a product/design is vital and the claims will be the identity of the patent requested product which covers the features that inventor wants to protect. The

invention is important for related-technology development; however it is crucial to be aware of what to write.

4. CASE STUDY: MICROALGAL BIOFUELS

Microalgal biofuels are considered as a promising fuel source for a sustainable future in terms of energy safety [2] and with some aspects; energy security [36]. The microalgal biofuels are considered as a sustainable source which do not compete with first and second generations of biofuels thus it has no relevancy with food vs. fuel debate [37, 38]. However at it is current state the economic analysis displays that microalgal biofuels may not be that efficient for biofuel development. Here we face with some sort of challenge around ethics, politics, technology, and economy [9, 39, 40]. A comprehensive review is required to highlight the opportunities and strength of microalgal biofuels. Recent studies advise on genetic modifications as a promising tool for the development of algal biofuels [41–43]. With genetic engineering the yield efficiency is considered to be increased and may elevate to a level to compete with fossil fuel sources [20]. But in any case, as it is with existing production technology, genetic engineering techniques give birth to several questions and concerns. The certain questioning about genetically altered microalgae for commercial use is the biosafety issues [44].This problems are related with facility design, environmental balance (risks for natural aqua-systems), invasion risks, human error and regulatory leakages.

Figure 3 displays that if genetically modified microalgae is created than the risks and challenges will be divided into 2 segments; one is defined in outer scout regarding technology, economy and public acceptance. The inner scout defines the ones related to biotechnology of the algae which is created with desired traits. With this regard another concern is raising with the increasing tendency to pharmaceuticals derived from microalgae. In this case there are couple of questions to address which are listed below;

- □ Will microalgal biofuels provide sufficient energy?
- □ What is the chain value of algal biofuels in food ecosystem?
- □ What is required for industrial biofuel productions?
- □ Who are my global competitors?
- □ What am I serving with this investment?
- □ Research or product?

Currently among microalgal biofuels; biodiesel is the most promising one, at least commercial attempts are done. However microalgae have the potential to produce bioethanol, biohydrogen or biogas [45–47]. The most challenging part is keeping them in a sustainable production frame, which is not quite easy for biohydrogen case; oxygen sensitivity is still a major bottleneck even at lab scale applications [48]. Thus from state of the art to scale-up there seems to be quite a lot requirement on photobioreactor [49], scale-up strategy [25], strain improvement [50] and framing these issues with in an ethical boundary [51, 52]. Thus one can consider that producing biofuel or producing value added chemicals for pharmaceutical, cosmeceuical or nutraceutical industries with higher return of investment ratios. Considering the biofuel production case; one of the intelligent approach will be using biorefinery approach to benefit from microalgae [8, 53]. Thus R&D developments regarding algal biofuels should be done in the scope of;

- Understanding the algal metabolism,
- Improving the product quality,

- Exploring new strains as potential producers,
- Genetic engineering for desired product,
- Joint Research with existing companies,
- Investment on algal biofuel education, to improve the dissemination of algal biofuel production. Within this scope a strategic partnership will be a life-saving attemp to reconsider algal biofuel production.



Figure 3. The challenges regarding genetically modified microalgae "Superalgae"

Genetic modifications can be utilized to produce high value molecules for pharmaceutical importance, recombinant proteins, bioplastics and biofuels [20, 54, 55]; It can be also utilized to generate a super algae to produce any product that we desire to have, in theory. Genetic modification of algae have some advantages as increased productivity and decreased downstream process costs (in some cases products as fatty acids and pigments and recombinant proteins can be engineered to secreted out of the cell to extracellular environment). Because microalgae is eukaryotic, post-translational modifications of protein-based compounds are better than prokaryoric expression systems [56]. Another advantage is that, there are several species of microalgae; among them *Chlamydomonas reinhardtii* is considered as a model for eukaryotic systems [57] and *Phaeodactylum tricornutum* for diatoms [58]. The table 1 defines main challenges and opportunities regarding algal biofuels.

One of the main concerns in ethical issues not only includes current status of the environment, population and country-politics but also affects the future, that's why the decisions done according to the current situations should reflect the forecasting and best/worst case scenarios for future's societies. There should be millions of questions in terms of developing algal biofuels to cover why it is so important and according to the answers a roadmap should be adopted.

Fundamental	Challenges	
Technology	Regulatory	Opportunities
Low productivity	Legal issues	Do not compete with food
Product quality	□ IP protection	crops
and purity	GMO protocols	Utilization of non-arable land
Cost	and policies	Bioremediation and
Inadequate	National and	wastewater treatment
venture	global	Vertical scale up opportunity
Lost belief to	regulations	Adaptable to conventional
algal biofuels	(EFSA, EPA,	bioprocesses
Public demand	FDA etc.)	Natural products with high
Global	Publishing	bioactivities
competitors	policy	Model for genome research
Immature	Conflict of	Ease in genetic modifications
production	interests	□ Innovative
□ Scale up	Fluctuations in	Sustainable and renewable
Lack of	the fuel prices	Open to exploring new potential spacing
commercial		\square Existence of excitable species
		Existence of available species for beteretrophic production
wein-defined		Tor neterotropmic production
traditional		Adaptation to existing
production		technology tools
strategies		

Table 1. Fundamental challenges and opportunities on microalgal biofuel applications

5. CONCLUSION

Microalgae are considered to be a promising novel source for pharmaceutical, nutraceutical, cosmetics and biofuel industries. The nature of microalgae utilize sunlight and inorganic carbon sources as well as waste water streams, thus it is considered to be a sustainable source to protect environmental balance as well. However there are some ethical issues which are also important for the development of microalgal biotechnolgy to keep the production, development and demand imbalance. Considering production and distribution ethics, IPRs are vital for understanding the legal rights of the developer or producer. From a macroscopic point of view, in order to adopt microalgae for global market there must be a broader vision to cover both technical, ethical and regulatory challenges and discuss their relations with microalgal biotechnology.

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