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Intellectual Property in Facial Plastic and Reconstructive Surgery: The Importance and Process of Obtaining Intellectual Property Rights

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Abstract

Understanding the purpose and process of obtaining intellectual property rights (IPR) is fundamental to health care innovation. Facial plastic and reconstructive surgeons are natural innovators; however, knowledge deficit in this space may hinder the ability to move ideas from the "bench to bedside." Here we provide an overview of IPR, outlining the steps necessary to obtain intellectual property protection in an academic setting while highlighting recent U.S. Food and Drug Administration (FDA) approvals pertaining to facial plastic and reconstructive surgery.

Keywords

- intellectual property
- facial plastic and reconstructive surgery
- innovation
- FDA
- medical devices

Facial plastic and reconstructive surgeons are constantly analyzing surgical techniques and subsequent outcomes in an effort to optimize patient form and function. In a similar manner, we are critically evaluating the current state of the art, its deficiencies, and how this may lead to unmet clinical needs. Consequently, facial plastic and reconstructive surgeons are valuable contributors to surgical and technological innovation within the field.[1,2]

Essential to the process of innovation is the appropriate protection of intellectual property (IP) with intellectual property rights (IPR).[3] Failure to do so often results in stagnation of the invention secondary to lack of incentive and/or funding, ultimately precluding patients from any potential benefit. Despite the fundamental importance of IPR, most clinicians have a poor understanding of this process, and in particular how academic publications and/or presentations may affect IP protection.[4,5]

Here we describe the importance of IPR in innovation, discussing the process of securing IPR within an academic setting, while also highlighting novel drugs, devices, and materials pertaining to facial plastic and reconstructive surgery (FPRS), which have been recently approved by the U.S. Food and Drug Administration (FDA).

What Is Intellectual Property?

IP can be defined as inventions or creations of the mind or property of the human intellect.[6] These can include devices, artistic and/or literary works, or symbols/designs that can be used for financial gain. IPR are the legal mechanisms that give the inventor exclusive rights to the creation for a given period of time. In this way, the system is meant to balance the interests of the inventors and the public at large while incentivizing innovation.[5–7]

IPR can be categorized under three major categories: industrial property rights, trademarks, and copyrights[7] (►**Table 1**). Industrial property rights broadly encompass the invention of technology, including drugs and devices. Legal rights within this category comprise patents and trade secrets. Trademarks are symbols or signs that differentiate goods, services, or locations. Copyrights pertain to the rights creators have over literary/artistic works. Examples may

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Table 1 Intellectual property rights (IPR)

IPR	Duration of protection[a]	Notes and conditions
Patent	20 y from the patent application filing date. Of note, the provisional patent filing date is not included in the term calculation	Requires disclosure of the idea. The idea/technology must be invented, not discovered. Patents may be combined with other IPR such as copyrights
Copyright	The lifetime of creator followed by an additional 70 y	Protects original artistic, musical, and literary works. The work must have achieved expression in a tangible medium to be eligible for protection
Trademark	In perpetuity if in continuous use	Protects symbols, words, names, or combinations of these that are intended to distinguish sellers' goods and/or services from competitors

[a]For U.S. law.

include rights over digital content, manuscripts, paintings, and technical drawings. Most relevant to this text are patents, which will be the focus of discussion moving forward.

The Process of Obtaining Intellectual Property Rights

Commercialization of an idea requires a significant investment of both time and capital. Obtaining IPR greatly increases the odds of securing funding, as certain grant and seed funds are not accessible without these rights in place. Similarly, licensing of patented ideas can result in secondary funding. This expanded access to capital in turn increases the probability of a patented invention reaching market, and ultimately helping patients.[3] Despite this, clinician inventors largely lack the knowledge of how to obtain IPR, and often this hinders their ability to do so through public disclosure.[3,4] In a study examining the IP awareness of members of the European Association of Endoscopic Surgery, 60% of surgeons took no precautions or steps to protect IP prior to public disclosure of an idea. As such, these surgeons significantly hindered the patentability of their inventions.

Patentability

The patentability of an invention revolves around three main tenets: the idea being novel, not obvious, and having an industrial application. Although, this is straightforward in theory, clinician inventors often struggle to keep their ideas novel given the pressure to produce publications in the academic setting.[3] Scientific publication of an invention, even within a conference abstract, amounts to public disclosure, no longer making the idea novel. However, this can be avoided if a patent application has been filed prior to the publication date of an abstract or manuscript. As such, a patent application can be prepared simultaneously with the planned submission of data, and not delay the publication process. In fact, simultaneous preparation of a manuscript may assist the attorney(s) preparing the patent application as it functions as a reference. Notably, grant proposals are not considered public disclosure. However, if the proposal is published after the grant is awarded, this would then constitute disclosure.

Outside of scientific publications, thesis dissertations, oral presentations, and even discussions of the idea/invention among colleagues employed by other institutions can affect patentability. Inventions/ideas can be discussed with members of the same institution without IPR, as the patent will ultimately be owned by the institution under the premise of an employee's invention. As delineated in the Patent Act of 1977, IP that is developed during the course of employees' normal duties is within the employer's scope of business, or IP that is developed with more than incidental use of employer resources is owned by the employer.[5,8] That being said, coworkers should be instructed not to disclose the matter of the discussion elsewhere, and when in doubt, confidentiality or nondisclosure agreements (NDAs) can be used. NDAs can also facilitate free discussion of the invention with members outside the institution, although it can be difficult to demonstrate breach of an NDA in a court of law. As such, it is not advisable to disclose the entirety of an invention in detail prior to submission of a patent application even with an NDA in place.[3]

Types of Patents

There are four main types of patents as defined by the U.S. Patent and Trademark Office (USPTO). Utility patents comprise 90% of those submitted and are commonly referred to as "patents of invention." They are issued for new technologies, processes, or other inventions and are what most think of when referring to a patent. They are issued for a period of 20 years after application filing. Design patents protect ornamental designs, with examples including the shape of a device, design of footwear, and the shape of a bottle. The documents submitted are made up of drawings with little text. Unlike utility patents, they are granted for a 15-year term. Plant patents protect newly invented or discovered plants produced by nonsexual means such as cuttings, hybrids, and mutants. This type of patent prevents others from asexually reproducing the plant and/or selling the plant for 20 years. Finally, reissue patents are used to correct an error(s) in previously issued utility patents. Notably they do not affect the period of protection, which remains as established by the initial utility patent; however, the scope of protection may change. Further discussion of patents in this text will be in reference to utility patents.[9]

Table 2 Example of a revenue-sharing model at an academic intuition generated from monetization of a patent

Annual net revenue[a]	Inventor(s)' personal share	Inventor's research (lab) share	Inventor's department share	School share	University share
First $300K	35%	15%	15%	30%	5%
Over $300K	35%	15%	15%	25%	10%

[a]Less a 15% administrative fee.

Knowledge/Technology Transfer

At most academic institutions, knowledge or technology transfer offices (TTO) manage the IP and IPR of the institution and its faculty.[10] As previously discussed, any invention conceived or developed by an employee within the spectrum of their work responsibilities or with more than incidental use of company resources is owned by the institution. Important to note is that this is regardless of the initial source of funding. However, if government grants were used to develop the invention, the IP must be first offered back to the agency that funded it prior to any sale of the patent under the *Bayh–Dole Act*.[11] The role of the TTO is to partner with inventers to evaluate their creations, obtain IPR if indicated, market them to industry to obtain additional funding, negotiate licensing agreements, and, most importantly, support and advise the inventors as to determining the best commercialization path. As such, the first point of contact when considering IP protection within an academic setting should be the institution's TTO. Any revenue created through this process is collected and distributed by the TTO. Each institution will have their own policies for revenue sharing that distribute funding between the inventor(s) and institution. An example of one such model is illustrated in ►**Table 2**. Important to note is that the TTO covers the initial and subsequent costs of IP management, which at times can be an impediment to clinicians pursuing IPR.[6,12] For reference, the cost to file and prosecute a U.S. Patent Application is estimated to be between $30,000 and $45,000.

A study examining patent transactions of 58 top academic universities found that 37% of patents granted between 2002 and 2010 were involved in some sort of monetization including licensing, reassignment to a different institution, and patent sale. However, a separate study found that less than 1% of all licenses yield more than $1 million in revenue.[6,11,13] Furthermore, between 1996 and 2015, U.S. institutions of higher education spun off on average 550 startup companies yearly. This amounts to 0.001% of the 400,000 annual startups that are reported by the Bureau of Labor Statistics.[13] When considering the concentration of innovators and intellect within academia, this is a surprisingly low percentage. Although the etiology of this is very much multifactorial in nature, potential contributors may include a lack of awareness by academicians as to the process of obtaining IPR described within this text.[11]

Patent Timeline

Once an idea/invention has been submitted to the TTO and deemed to be indicated for protection, the patent filing process commences. This begins with a provisional application filed with the USPTO. Provisional patents are significantly less expensive than their nonprovisional 20-year protection counterparts and can be filed for under $1,000. They allow for continued data gathering and market analysis for a period of 1 year while establishing an earlier filing date if the patent is ultimately granted. Within 1 year of this filing date, a nonprovisional Patent Cooperation Treaty (PCT) application must be submitted.

Once the PCT application is submitted, the claims are then reviewed and cross-referenced against other USPTO patents or prior art by a patent examiner. This process generally occurs 2 years or more after initial filing and typically results in rejection of at least some of the claims by the patent examiner. These rejections are then sent back to the TTO in a document entitled an Office Action. The TTO will then work with the inventor to respond to the Office Action, demonstrating how the invention is either distinct from the referenced prior art or amending the initial claims. This process can be repeated several times until the examiner allows the requested claims or makes the rejection "final." This often occurs after the second Office Action. If the decision is made final, there are various administrative avenues to pursue the initial claims, including appeal, which we will not discuss in detail. As has been demonstrated, this process can become lengthy and it can take many years before a final patent is granted. Throughout this process, the TTO will be actively marketing the invention for licensing and/or other monetization, with the licensee often assuming the remaining patent expenses.[6,14]

Recent FDA Approvals Pertaining to FPRS

Although we have discussed the potential pitfalls in obtaining IPR and subsequent commercialization, numerous inventions are successfully patented and reach market each year. The American Academy of Otolaryngology-Head and Neck Surgery (AAOHNS) Medical Devices and Drugs Committee has reviewed newly approved drugs and devices related to the specialty on a yearly basis since 2019.[15–17] Using the FDA's publicly available approval database, the committee identified a total of eight drugs and devices they deemed to be relevant, novel, and impactful to FPRS that received approval between 2019 and 2021 that we will discuss here (►**Table 3**). Of note, this is not intended to be a comprehensive review of newly developed technologies within FPRS, but rather an overview of IP that has successfully moved through the development and regulatory process to achieve FDA approval and clinical utility.

Table 3 Recently approved drugs and devices relevant to facial plastic and reconstructive surgery

Approval year	Drug/device	Indication
2019	Latera Nasal Implant	Support of the upper and lower lateral nasal cartilage
2020	Hemoblast Bellows	Adjunct hemostatic agent
	Oxymetazoline (Upneeq)	Acquired blepharoptosis
	StarPore Implants	Augmentation of bony contour in craniofacial defects
2021	Kerecis Reconstruct	Soft-tissue repair and/or reinforcement, soft-tissue reconstruction, and reinforcement in plastic or reconstructive surgery
	Meticuly Patient-Specific Titanium Mesh Implant	Custom titanium implant for use in selective trauma of the cranial and craniofacial skeleton
	Sofwave System	Noninvasive treatment to improve facial lines and wrinkles and to lift the eyebrows and lax submental tissues for patients $\geq$22 y
	Ellacor Dermal Micro-Coring System	Treatment of moderate to severe wrinkles in the mid and lower face for patients $\geq$22 y

Latera 2019

Latera (Stryker, Kalamazoo, MI) is an absorbable nasal implant system designed to support the upper and lower lateral cartilages.[18] Prospective and randomized control studies have demonstrated improvement in quality-of-life assessments relating to nasal obstruction following implantation.[19,20] Although it first received approval in 2016, it was included in the 2019 review as additional approval was obtained for a new implant size, modified implant geometry, extended shelf life, and modified sterilization process. Given the well-known nature of the device, we will not further review its design, utility, or indications within this text.

Oxymetazoline for Blepharoptosis 2020

Although oxymetazoline is well known to facial plastic surgeons as a nasal decongestant and vasoconstrictive agent, in 2020 it became the first FDA-approved treatment for acquired blepharoptosis, marketed as Upneeq (RVL Pharmaceuticals, Inc, Bridgewater, NJ).[21] As a direct α-1 and α-2 agonist, oxymetazoline works to activate Mueller's muscle, which is an upper eyelid elevator.[22] In pooled analysis of two double-blinded placebo-controlled phase 3 clinical trials, daily use of 0.1% oxymetazoline was found to significantly improve visual field defects as evaluated by the Leicester Peripheral Field Test, as well as demonstrating improved outcomes on the marginal reflex distance (MRD) test. MRD-1 measurements were found to increase by 0.96 ± 0.89 and 1.16 ± 0.87 mm at days 1 and 14 of use, respectively, as compared with increases of 0.50 ± 0.81 and 0.50 ± 0.80 mm with placebo at the same time points.[23] The treatment was tolerated well over 6 and 12 weeks with a reported adverse reaction rate between 1 and 5%. Reactions reported included dry eye, blurred vision, pain, punctate keratitis, conjunctival hyperemia, eye irritation, and headache.[24] Interestingly, no studies found evidence of tachyphylaxis over a 42-day period of daily use.[23] This is despite the well-understood nature of rhinitis medicamentosa.

Hemoblast 2020

The Hemoblast Bellows (Dilon Technologies, Inc, Newport News, VA) is an absorbable porcine collagen hemostatic agent. Administration is performed using a handheld device that is squeezed to release a powder consisting of porcine collagen with glucose, chondroitin sulfate (bovine), and thrombin (human pooled plasma). It is intended to be used as an adjunct to conventional hemostatic techniques when there is minimal, mild, or moderate bleeding.[25] The compound is designed to work by combining properties of tamponade with expedited clot formation. Direct intravascular application is contraindicated. In a multicentered randomized study examining the performance of the Hemostat Bellows against absorbable gelatin sponge and thrombin, there was improved hemostasis with use of the Hemostat Bellows. This was evaluated in 242 patients with cessation in bleeding in 71.1 and 93.1% of patients at 3 and 6 minutes, respectively, with the Hemostat Bellows as compared with 45.8 and 73.5% at the same time points with use of absorbable gelatin sponge and thrombin ($p = 0.001$).[16,26]

StarPore 2020

StarPore implants (Anatomics Pty Ltd, Melbourne, Australia) are porous high-density polyethylene anatomic implants made of star-shaped particles. This creates a stellate lattice structure meant to replicate the trabecular bone, allowing for tissue ingrowth. They are designed for restoration/augmentation of craniofacial bony contour. This technology received 510k approval, meaning that it was deemed to be substantially equivalent to previously approved technology. Referenced technology includes MEDPOR (Stryker). Similar to referenced technology, StarPore implants can be used in an "off-the-shelf" fashion with various sizes/shapes that can be modified intraoperatively. Alternatively, patient-specific implants are also available based on preoperative 3D scans or imaging. The implants have an expected safety profile similar to referenced technology, and as such can be subject to infection, extrusion, migration, and peripheral bony resorption.[27]

Kerecis Reconstruct 2021

Kerecis Reconstruct (Kerecis, Limited, Isafjordur, Iceland) is an acellular dermal matrix indicated for use for soft-tissue repair or reinforcement in plastic or reconstructive surgery.

This technology received 510k clearance with reference technology including Biodesign (Cook Biotech Inc, West Lafayette, IN). In contrast to reference technology, Kerecis Reconstruct is sourced from decellularized Atlantic cod skin as opposed to porcine intestinal submucosa. The proposed advantage of this is the reduced risk of disease transfer between Atlantic cod and humans in comparison to porcine/bovine sources. Furthermore, there are no known cultural or religious impediments to use. Although acellular, native proteins and lipids are maintained, which facilitate neovascularization and wound healing. Several randomized studies have demonstrated that piscine dermal matrices heal wounds faster than traditional dressings and human amnion/chorion membrane allografts and more effectively than collagen alginate alone in diabetic foot ulcers.[28–30]

Meticuly Patient-Specific Titanium Mesh Implant 2021

Meticuly Patient-Specific Titanium Mesh Implants (Meticuly Co, Ltd, Bangkok, Thailand) are custom titanium implants indicated for use in selective cranial vault and craniofacial trauma and reconstruction. The implants are 3D printed based on patient computed tomography imaging in titanium alloy. The device received 510k clearance in December 2021 with the reference technology being BioArchitects Patient-Specific Cranial/Craniofacial Plate (BioArchitects USA, LLC, New York, NY). The Meticuly system is intended to be used with other commercially available titanium screws with a diameter of 1.4 to 1.8 mm. The custom implant designs are surgeon approved prior to fabrication.[31] Potential applications include craniofacial and orbital trauma reconstruction and cranial vault reconstruction after tumor resection or craniotomy/craniectomy.[17]

Sofwave System 2021

The Sofwave System (Sofwave Medical Ltd, Philadelphia, PA) is a focused ultrasound stimulator system indicated to improve facial lines and wrinkles and to lift the eyebrow and address submental laxity. Sofwave first received 510k approval in 2019 for management of fine lines and wrinkles, but its indications were expanded in 2021 to include lifting of the brow and tightening of the neck. In both cases, the reference technology was the Ulthera System (Merz Pharmaceuticals, Burlington, ON, Canada), which was first approved in 2009.[32] These technologies use microfocused ultrasound to induce thermal coagulation of the reticular dermis, causing tissue remodeling and contraction.[33] In contrast to the reference technology, Sofwave has a more superficial depth of penetration of <3 mm. The additional approval received in 2021 was based on a multicentered study of 80 patients who received two full face and neck treatments with the device. The follow-up endpoint was 3 months after the last treatment. Outcomes included submental laxity as evaluated by measurement of the area between two fixed anatomic reference points and brow position. These were measured and compared using quantitative image analysis by two blinded independent reviewers. The authors found a mean lift of 0.78 mm for maximal eye brow height and 0.69 mm for average eyebrow height, with a mean submental lift of 38 mm^2 following treatment. The only adverse outcome reported was a single event of skin blistering, which resolved with topical emollient therapy.[34]

Ellacor Dermal Micro-Coring System 2021 and AI.ME System 2022

Ellacor (Cytrellis Biosystems, Inc, Woburn, MA) is a micro-coring device approved for the treatment of moderate to severe wrinkles of the mid to lower face in patients $\geq$22 years. Hollow stainless-steel needles affixed to a handheld device are used to create micro-cores in the treated area. The removal of tissue leads to a skin-tightening effect without scarring, as the microcores heal along lines of relaxed skin tension. Preclinical studies also demonstrate an increase in collagen content and epidermal and papillary dermis thickness.[35,36] Subsequent prospective clinical trials demonstrated skin tightening and increased skin thickness with a decrease in skin surface area of $9.4 \pm 4.3\%$.[37] The combined effect of increased skin thickness and skin tightening suggests skin rejuvenation following treatment. A hypothesized advantage over energy devices, such as radiofrequency ablation and fractional laser, is that there is no cellular necrosis from thermal injury with micro-coring. Patients are meant to undergo at least two, but no more than three, treatments 4 weeks apart. Importantly, although the technology is approved for Fitzpatrick I to VI, the clinical trials only included patients who were Fitzpatrick I to III. Patients with a history of hypertrophic scarring or keloid formation were also excluded. While the Ellacor System is a handheld device, a similar technology with a robotic arm punch assembly received 510k approval in December 2022.[38] AI.ME (Venus Concept, Inc, San Jose, CA) is a robotic micro-coring device that uses a disposable punch assembly of six hollow needles with a fixed maximum penetration depth of 3 mm. The robotic arm and imaging system component of the device are meant to increase precision of the treatment area and prevent inadvertent retreatment.

Conclusion

As natural problem solvers, facial plastic surgeons are vital contributors to innovation within their field. Fundamental to this process is the appropriate protection of IPR and avoidance of inadvertent disclosure before these rights have been obtained. Here we have reviewed the basic workflow to do so within an academic setting while also highlighting technologies that have successfully navigated this process in the recent past.

Conflict of Interest
None declared.

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