

An evaluation of national patents and utility models during the last decade in the field of orthopedics and traumatology in Turkey

Türkiye'de son on yıl içinde ortopedi ve travmatoloji alanında ulusal patent ve faydalı modellerin değerlendirilmesi

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SUMMARY






Objective: The aim of this study was to evaluate the number and status of national patents and utility models, which had been applied for, registered or has become invalid in the field of orthopedics and traumatology in Turkey between 2007 and 2017. In addition, we aimed to categorize these patents and identify the areas with the most inventions.

Method: A61B17, A61F2, and A61F5 patent categories, which were relevant to orthopedics and traumatology and were applied for between 2007 and 2017 were investigated. In total, 341 patents and utility models which had a registration number, were pending for approval and those who lost validity were included in the study and categorized according to their subjects.

Results: Of the 341 patents and utility models, 172 were registered and valid, 73 were pending for approval, and 96 were invalid due to unpaid fees. The leading fields in categorical classification were spinal surgery with 121 patents and trauma surgery with 102 patents. According to subcategorical classification, implants led the group with 207 patents, followed by auxiliary tools with 62 patents. About 1/3 of the registered patents had lost validity.

Conclusions: To the best of our knowledge, this is the first study that investigates the status of the patents in the field of orthopedic and traumatology in Turkey. Spinal and trauma-related patents were the leading categories. One-third of the patent applications were invalid due to unpaid fees. Our study can be used as a reference in future studies investigating the patents and utility models.

Keywords: Orthopedics; patent; traumatology; utility model; Turkey

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ÖZET

Amaç: Bu çalışmanın amacı 2007 ve 2017 yılları arasında Türkiye'de ortopedi ve travmatoloji alanında başvurulmuş, kayıt altına alınmış veya geçersiz hale gelen ulusal patent ve faydalı modellerin sayısını ve durumunu değerlendirmektir. Ayrıca, bu patentleri kategorize etmeyi ve bu alanlarda en fazla yapılan icatları tanımlamayı hedefledik.

Yöntem: Ortopedi ve travmatoloji ile ilgili olan A61B17, A61F2 ve A61F5 patent kategorileri, 2007 ve 2017 yılları arasında incelenmiştir. Toplamda, kayıt numarası olan 341 patent ve faydalı model onay için beklemede ve geçerliliğini yitirmiş olanlar dahil edilmiştir. Çalışma ve konularına göre kategorize edildi. Kayıtlı ve geçerli toplam 168 patent ve faydalı model vardı. Bunlardan 76'sı onay için beklemede idi ve ödenmemiş yıllık patent ücretleri nedeniyle 97'si geçersizdi. Kategorik sınıflamanın önde gelen alanları, 121 patent ve 102 patentli travma cerrahisi ile spinal cerrahi idi. Alt kategorik sınıflandırmaya göre, implantlar 207 patentli gruba liderlik etti, ardından 62 patentli yardımcı araçlar izledi. Kayıtlı patentlerin yaklaşık 1 / 3'ü geçerliliğini yitirmişti.

Sonuç: Bildiğimiz kadarıyla, bu çalışma Türkiye'de ortopedi ve travmatoloji alanındaki patentlerin durumunu araştıran ilk çalışmadır. Spinal ve travma ile ilgili patentler ilk sıradadır. Ödenmemiş yıllık patent ücretleri nedeniyle patent başvurusunun üçte biri geçersizdir. Çalışmamız, ortopedi ve travmatoloji ya da diğer alanlardaki patent ve faydalı modelleri araştıran gelecekteki çalışmalarda referans olarak kullanılabilir.

Anahtar sözcükler: Ortopedi ,travmatoloji,patent,faydalı model,Türkiye

INTRODUCTION

Copyright protection of patents has started with the Venetian Patent Statute enacted in 1474^{1,2}. The statute which intends to encourage invention for the public good and protect the honor of invention offered protection for 10 years^{1,3}. The second legislation regarding this topic was the Statute of Monopolies of 1623 which was an Act of the Parliament of England notable as the first statutory expression of English patent law. Other legislations for patent protection that followed were in 1790 in the US, in 1791 in France, in 1877 in Germany and in 1879 in Turkey.

A historical review of the legislation on patents show that the Turkish Patent Law is among the first recognized legislations^{4,5}. The Turkish Patent and Trademark Office (TPTO; formerly known as the Turkish Patent Institute) was founded to share the knowledge and materials related to patents and trademarks with the public in an attempt to realize technological advancement, create a competitive environment and foster the research-development facilities.⁶ Patents prevent the unauthorized reproduction, use or sales of an invention by a third party for a limited time period in a specific country. The document for the 'use of copyrights' is called^{6,7} the Patent Certificate (PC).

Utility model (UM) is a relatively new intellectual property right intended to protect the inventions

applicable in the industry^{6,8}. The UM certificate can be obtained in a shorter time and with less cost than the PC. UM license does not require the 'inventive step' criterion. The inventive step is a general patentability requirement present in most patent laws, according to which an invention should be sufficiently inventive –i.e., not apparent to the skilled person in the light of state of the art– in order to be patented. Since it does not contain an inventive step, the products and methods fit for a UM certificate are not granted protection. These products and methods must not have been declared in written or oral form, or used before in public. Industrial applicability means that the product or the way possesses more practical features rather than being entirely theoretical. The simplified application process of UM and the lack of investigation and evaluation phases work in favor of the^{6,9,10} applicant. The differences between patents and UMs are summarized in Table 1.

The literature does not contain any data about the number of patents and UMs in the field of orthopedics and traumatology or other areas of medicine. In this study, we aimed to evaluate the number and status of the national patents and UMs, which had been applied for, registered or has become invalid in the field of orthopedics and traumatology between 2007 and 2017 in Turkey. In addition, we aimed to categorize these patents and identify the areas with the most inventions.

Table 1: Key features of patents and utility models.

	Patents	Utility Models
Novelty	+	+
Invention step	+	-
Industrial applicability/usefulness	+	+
Methods and products of these methods	+	-
Chemical substances	+	-
Research	+	-
Review	+	-
Publication	+	+
Copyright protection	20/7 years	10 years

MATERIAL AND METHODS

Using a patent tracking software (Marksoft v.13.7.4.0; Marksoft Yazılım, Ankara, Turkey) and the database of the TPTO, patents and UMs from the A61B17, A61F2 and A61F5 patent categories (those that fall under the ‘Medical Instruments and Supplies’ heading listed in Section 3, Class 32.50 of the Statistical Classification of Economic Activities^{4,5} in the European Community [NACE codes Rev. 2]), which included the most relevant patents and UMs for the field of orthopedics and traumatology and applied for between 2007 and 2017, were investigated.

The A61B17 category covers surgical instruments, devices, and methods. The A61F2 category includes: filters implantable into blood vessels;

prostheses, in other words, artificial substitutes or replacements for various body parts; apparatus, devices or methods for physically correcting or altering the body of patients or disabled persons; and devices providing patency to, or preventing collapsing of, tubular structures of the body. The A61F5 category covers the orthopedic methods and tools for non-surgical treatment of the bones and joints.

The 585 patents and UMs retrieved were reviewed, and the 244 left outside the interest of orthopedics and traumatology were excluded. The remaining 341 which had a registration number, were pending for approval, and those who lost validity were included in the study. The patents and UMs were categorized according to their subjects and the material used in their production (Table 2).

Table 2. An overview of the patents and utility models and their classification based on categories and subcategories.

Overview									
Pending		Registered				Rendered invalid due to unpaid fees			
73		172				96			
Surgical categories									
Spine	Trauma	Orthosis	Deformity	General	Sports	Arthroplasty	Tumor	Pediatric orthopedics	Microsurgery
121	102	37	23	22	17	15	2	1	1
Subcategories									
Implants		Auxiliary tools		Prostheses		Fixators		Hand tools	
207		62		37		25		5	
								Biomaterials	
								5	

Statistical method

Frequency and percentage values were used in descriptive statistics to evaluate the patents and UMs based on the years and their categories.

Statistical analyses were performed using the SPSS v.22 (SPSS Inc., Chicago, IL, USA) software.

RESULTS

The A61B17 category held 204 patents and UMs. Thirty-six of them were pending for approval, 103 were registered, and 65 were rendered invalid due to unpaid fees. The field of trauma had the most patent and UMs ($n=86$, 42.2%), whereas microsurgery patents claimed the last place ($n=1$,

0.5%). The fields of orthoses, tumor surgery, and pediatric orthopedics had no registries (Table 3, Fig. 1). A review of the subcategories revealed that the implants had the highest number of patents and UMs ($n=132$, 64.7%), whereas the biomaterials had the fewest ($n=2$, 1.0%). The prostheses category had no registries (Table 4, Fig. 2).

Table 3: Number and percentage of the patents in the A61F2, A61B17, and A61F5 categories.

Surgical Category	Total		A61B17		A61F2		A61F5	
	n	%	n	%	n	%	n	%
Spine	121	35.5%	70	57.9%	49	40.5%	2	7.1%
Trauma	102	29.9%	86	84.3%	9	8.8%	7	25.0%
Orthosis	37	10.9%	0	0.0%	24	64.9%	13	46.4%
Deformity	23	6.7%	13	56.5%	5	21.7%	5	17.9%
General	22	6.5%	18	81.8%	4	18.2%	0	0.0%
Sports	17	5.0%	13	76.5%	4	23.5%	0	0.0%
Arthroplasty	15	4.4%	3	20.0%	12	80.0%	0	0.0%
Tumor	2	0.6%	0	0.0%	2	100.0%	0	0.0%
Pediatric orthopedics	1	0.3%	0	0.0%	0	0.0%	1	3.6%
Microsurgery	1	0.3%	1	100.0%	0	0.0%	0	0.0%

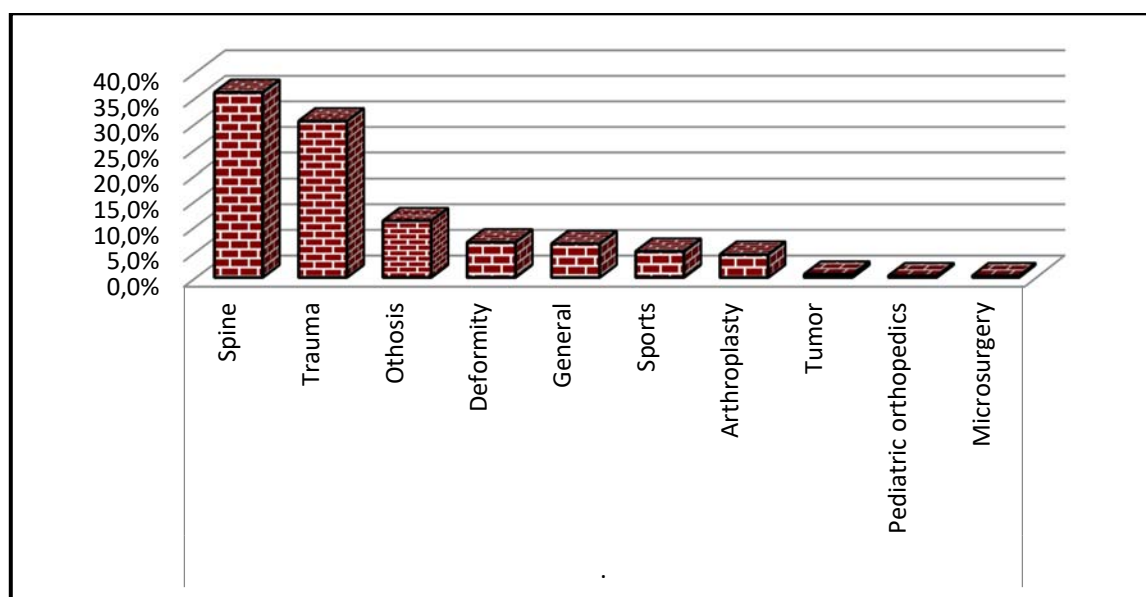


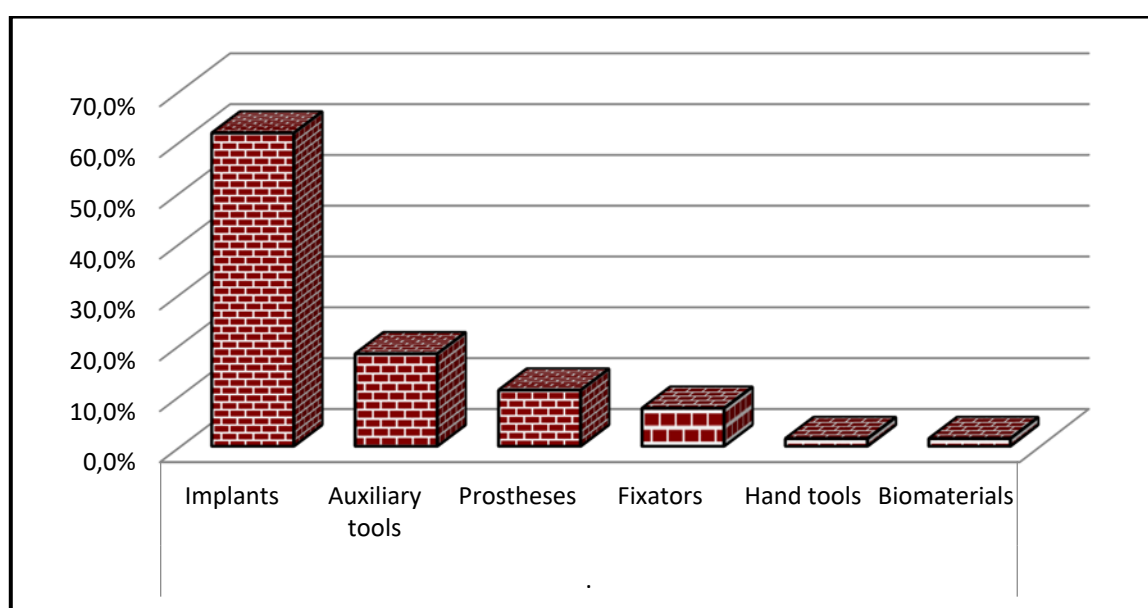
Figure 1: The highest number of patent applications was associated with spinal surgery, followed by trauma surgery.

The A61F2 category held 109 patents and UMs. Twenty-nine of them were pending for approval, 57 were registered, and 23 were rendered invalid due to unpaid fees. The field of spinal surgery had the most patents and UMs ($n=49$, 45.0%). The area of tumor surgery took the last place ($n=2$, 1.8%). The areas of pediatric orthopedics and

microsurgery had no registries (Table 3, Fig. 1). A review of the subcategories revealed that the implants had the highest number of patents and UMs ($n=66$, 60.6%), whereas the fixators had the fewest ($n=2$, 1.8%). Hand tools had no patent or UM registries (Table 4, Fig. 2).

Table 4: The number and percentage of the patents and utility models in subcategories.

Material	Total		A61B17		A61F2		A61F5	
	n	%	n	%	n	%	n	%
Implants	207	60.7%	132	64.7%	66	60.6%	9	32.1%
Auxiliary tools	62	18.2%	45	22.1%	14	12.8%	3	10.7%
Prostheses	37	10.9%	0	0.0%	24	22.0%	13	46.4%
Fixators	25	7.3%	20	9.8%	2	1.8%	3	10.7%
Hand tools	5	1.5%	5	2.5%	0	0.0%	0	0.0%
Biomaterials	5	1.5%	2	1.0%	3	2.8%	0	0.0%

**Figure 2:** Among the subcategories, the highest number of patent applications was for implants, followed by auxiliary tools.

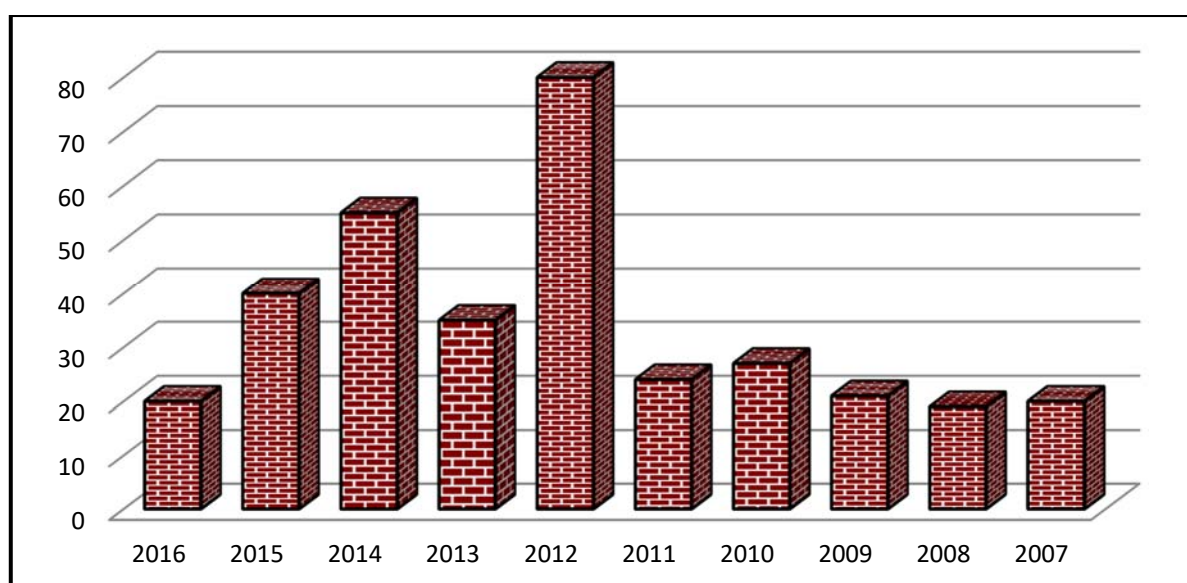
The A61F5 category held a total of 28 patents and UMs. Eight of them were pending for approval, 12 were registered, and 8 were rendered invalid. A categorical review showed that most patents and UMs (n=13, 46.4%) were related to trauma, whereas pediatric orthopedics patents and UMs had the least number of registries (n=1, 3.6%). No records were found regarding general surgery, sports surgery, arthroplasty, tumor surgery and microsurgery (Table 3, Fig. 1). In subcategorical review, the prostheses had the highest number of

patents, and UMs (n=13, 46.4%) and the auxiliary tools and the fixators had the lowest (n=3, 10.7%). Hand tools and biomaterials had no registries (Table 4, Fig. 2).

The year 2012 saw the highest number of patents and UMs (23.5%), followed by 2014 (16.1%) and 2015 (11.7%). The fewest number of patents and UMs (5.6%) were observed in 2008 (Table 5, Fig. 3).

Table 5. Distribution of patent and utility model applications based on the categories by years.

Year	Total		A61B17		A61F2		A61F5	
	n	%	n	%	n	%	n	%
2016	20	5.9%	12	5.9%	6	5.5%	2	7.1%
2015	40	11.7%	16	7.8%	19	17.4%	5	17.9%
2014	55	16.1%	37	18.1%	15	13.8%	3	10.7%
2013	35	10.3%	15	7.4%	16	14.7%	4	14.3%
2012	80	23.5%	56	27.5%	18	16.5%	6	21.4%
2011	24	7.0%	14	6.9%	9	8.3%	1	3.6%
2010	27	7.9%	16	7.8%	8	7.3%	3	10.7%
2009	21	6.2%	15	7.4%	5	4.6%	1	3.6%
2008	19	5.6%	11	5.4%	6	5.5%	2	7.1%
2007	20	5.9%	12	5.9%	7	6.4%	1	3.6%

**Figure 3:** The year 2012 was the year with the highest number of applications.

DISCUSSION

Patents are one of the headstones of contemporary society today ^{4,11}. Patents are granted to the inventor for a certain period of time and prevent the reproduction, use or the trade of the product by others without permission ^{5,12}. The right also grants the owners permission to transfer their rights to third parties or allows them to use their rights for a certain period of time ⁶.

The UM certificate brings along another kind of protection for inventions (Table 1). The ‘utility model’, dealt with in The Washington Treaty ^{7,13,22}

of 1911 for the first time, covers the industrially applicable invention, yet does not obligate for the ‘inventive step – non-obviousness’ criterion. Thus, protection of the inventions industrially applicable but without the inventive step is made possible. The UM certificate provides protection for 10 years.

Companies that applied to the TPTO for a trademark are classified according to the NACE codes. Section 3, Class 32.50 of the NACE codes covers medical instruments and supplies. In Turkey, 53 of the 20,976 applications in 2008 were in the field of Health Affairs ⁸ and Social Services

(%0.25). However, there is no categorical or contextual explanation in this annual report. Still, the ratio can be considered very low in comparison to the European Patent Office data from 2011, where the highest number of patent applications (24.8%) was for medical technologies^{9,14,15}.

According to the TPTO data, the number of UM registries in 1998 (n=144) increased by 4.4 times and reached 632 in 2003⁸. In 2007, the number of UM applications was 3,017 in total (2,973 domestic, 44 foreign). When compared to the previous year, the rate of increase in UM applications was 22% in 2004, 27% in 2005, 29% in 2006, and 23% in 2007⁸. As can be seen from above, there is a constant increase in the number of UM applications between 1998 and 2007. However, these data do not contain the categorical details.

To the best of our knowledge, this is the first study that investigates the patents and UMs in the field of orthopedics and traumatology in Turkey. There was no significant and a constant increase between 2007 and 2012, as it was between 1998 and 2007⁸, and the number of applications between 2012 and 2017 rose and fell irregularly. A review of the data showed that 49.3% of the applications were approved for registration. However, almost 30% of these registries had become invalid after registration due to unpaid legislative fees.

Spinal surgery took the lead in applications for patents and UMs by 35.5%, followed by trauma surgery with 29.9%. Among the subcategories, implants were the most patented devices with 60.7%, followed by auxiliary tools with 18.2%. The number of the patents and UMs for tumor surgery, pediatric orthopedics and microsurgery were the lowest.

The lack of similar research investigating the number of patents and UMs in the field of orthopedics and traumatology or other areas of medicine and thus our inability to make a comparison may be considered a limitation of our study. However, our research can be used as a reference in future studies investigating the patents and UMs in the field of orthopedics and traumatology. Further studies are required to monitor the progress regarding new patent and UMs to investigate productivity in the manufacturing of medical products.

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