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PATENT

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E I hanol@hanollawip.com
T I 82-2- 942-1100
F I 82- 2-942-2600
www.hanollawip.com

6th Floor, 135, Beobwon-ro, Songpa-gu,
Seoul 05836, Korea

Min SON, Ph.D.
Patent attorney
minson@hanollawip.com

Byeong Seok CHOI
Attorney at law
hanol@hanollawip.com

Mixed awarding of patent damages for "lost profits and reasonable royalty" is now available beyond the patentee's capability (December 10, 2020)

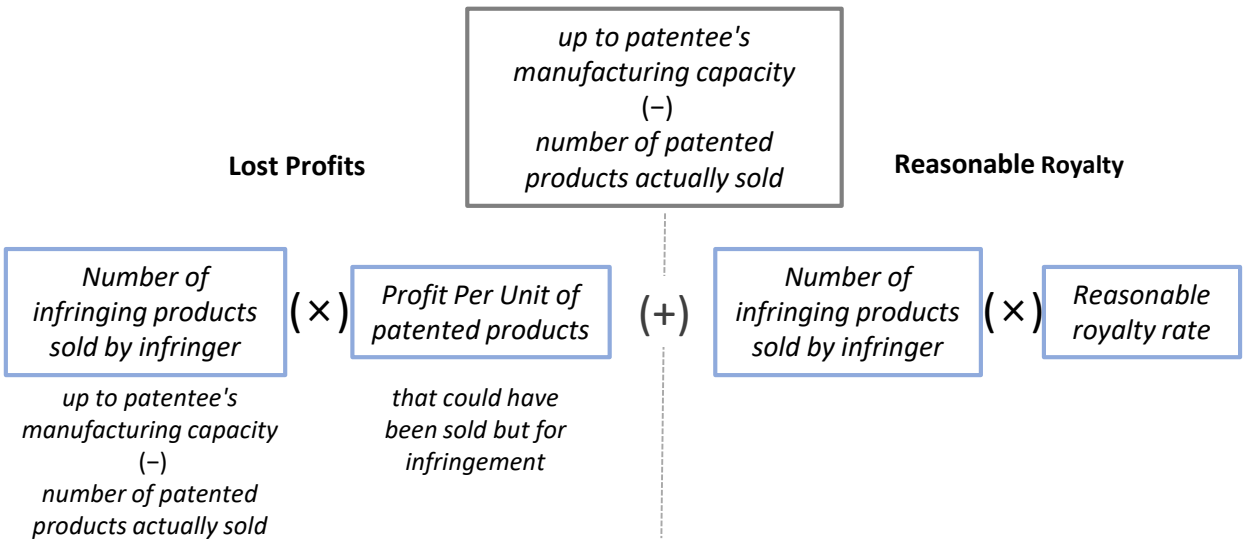
Recently, there were two significant legislative changes to patent damages in Korea. **Treble** damages for willful patent infringement were introduced in 2019, while **Mixed** awarding of damages for "lost profits and reasonable royalty" became effective from December 10, 2020. Article 128 of the Korean Patent Act (KPA) governs the awarding of damages in patent infringement litigation.

Under this provision, the patentee may freely choose any one of i) lost profits and mixed damages (Art. 128(2)), ii) profits earned by the infringer (Art. 128(4)), and iii) a reasonable royalty (Art. 128(5)). If the court finds that it is extremely difficult to prove damages, the court may award damages at its discretion (Art. 128(7)).

Lost Profits

Lost profits are the most basic and traditional form of damages awarded in civil courts. The patentee bears the burden of proof here, and he/she may request that the court order the infringer to submit relevant materials necessary to assess the number of infringing products (Art. 132). Where the infringer argues that materials are trade secrets, the court may order an *in camera* proceeding, and if the infringer refuses submission without a justifiable reason, the court may determine that the assertion by the patentee regarding the materials is true.

In calculating lost profits, the **upper limit** of the patentee's lost profits is set as the quantity of products that the patentee could have manufactured less the quantity of products he/she actually sold.



Mixed Awarding of Damages

The newly adopted "Mixed awarding of damages" now allows patentees to recover damages beyond their manufacturing capacity. Damages are calculated as the sum of lost profits by the patentee up to his/her manufacturing capacity (Art. 128(2)(i)) and reasonable royalty damages for the infringing products sold beyond the patentee's manufacturing capacity (Art. 128(2)(ii)).

Before the new law, because the lost profit damages were capped by the manufacturing capacity of the patentee, there has been continuous criticism that the KPA did not protect patentees' rights sufficiently against infringement by large companies, particularly in cases where the patentee had a relatively small production capacity, such as small and medium enterprises and start-ups.

Profits Earned by the Infringer

In Korea, the profits earned by the infringer are presumed to be equal to the patentee's damages (legal presumption) (Art. 128(4)). This presumption does not apply when the patentee has suffered no loss despite the infringement. If the accused infringer proves that the patentee's actual loss is for some reason less than the infringer's profit, such presumption will be rebutted.

The infringer's profits include all profits earned through the infringer's unauthorized practice of the patented invention. The burden of proof lies with the patentee.

Reasonable Royalty

Article 128, para. 5 provides that the patentee may claim a reasonable royalty as damages at the minimum. Damages are calculated by multiplying the sales of the infringing products by a reasonable royalty rate. If the actual damages exceed the reasonable royalties, the patentee may claim the excess (Art. 128(6)).

In calculating reasonable royalties, the Korean courts have considered many factors such as i) the value of the patented invention, ii) terms of agreements entered into between the patentee and the accused infringer or third parties, iii) royalty rates in the relevant technical field, iv) remaining patent term, v) the infringer's profit, *etc*.

The statistics show that average royalty rates awarded by the Korean courts range from 2% to 5% of the infringer's sales, or may be 1/3 of the infringer's profits.[1)]

Discretion of the Court

If it is found that a loss has been incurred due to the infringement but it is extremely difficult to prove the amount of damages, the court may award damages at its discretion based on the entire purport of the pleadings and evidence submitted. According to the statistics from 2010 to 2013, the ratio of damages awarded by the courts at their discretion is significantly higher than via other methods.

[1)] *Kim, K.S., "Patent infringement litigations and the status and tasks for determining damages: focusing on the district court holdings of the recent five years from 2009 to 2013", Ind. Prop., 46, p. 381 (2015)*

Methodology	Ratio (%)
Lost profits	13.5
Infringer's profits	28.8
Reasonable royalty	9.6
Discretion of the court	48.1

(Cho, Y. J., "Considerations on damages for patent infringement", Postal Information Service, 116, pp. 17–35 (2019))

Significance of New Changes

In the past, there was prevalent market sentiment that it is more profitable to take advantage of the IP assets of another and later pay damages after failing defense in the patent litigation, since the damages acknowledged by the Korean courts were quite tolerable.

The median value of damages in patent infringement lawsuits in Korea was only about USD 53,000, far less than in the U.S., where it was about USD 6 million as of 2016.[2)] Consequently, damages did not have any significant deterrent effect to patent infringers. However, this may change in the future.

Patentees now have a greater likelihood of obtaining increased damages for patent infringement by combining damages corresponding to lost profits with a reasonably royalty. When the award of mixed damages is combined with treble damages, the system may lead to a synergistic effect.

Currently, the introduction of a discovery process ("K-discovery") similar to that used in the U.S. is also under discussion. All of these changes are expected to strengthen innovation-led business in Korea.

[2)] *Kwon, B. Y., "Patent infringement damages: statistics for 20 years", Judge Training Advance Course, Judicial Research & Training Institute, pp. 733–780 (2017)*

Drug pricing policy was revised from "Same medicine, same price" principle to "Tiered pricing system"

At the end of March 2019, the government announced a plan to restructure the generic drug pricing system with the main goal of switching from the existing "same medicine, same price" principle to a "tiered drug pricing system". Eventually, the drug pricing rule was revised and implemented on July 1, 2020.

Under the revised drug pricing framework, it is expected that later generic entry will be discouraged and competition for patent challenges will intensify, especially for blockbuster drugs.

Updated "Tiered drug pricing system" allows differential generic drug prices

Under this system, the price of generic drugs is determined differentially based on the *qualitative* requirements:

(i) whether or not a bioequivalence or clinical study sponsored by the approval holder has been performed; and
(ii) whether or not an API registered in a drug master file (DMF) has been used.

In addition, the drug price is determined differentially according to *the order of market entry* (*i.e.*, order of registration on the insurance-reimbursement list).

Up to the 20th listed drug for the same medicine, the price cutting criteria are applied as follows:

1) if both of requirements (i) and (ii) are met, the drug price is calculated at 53.55% of the originator's drug price (original drug price);
2) if only one requirement is met, the drug price is calculated at 45.52% of the original drug price; and
3) if neither requirement is met, the drug price is calculated at 38.69% of the original drug price.

However, from the 21st listed drug as such, the drug price is set at 85% of the lowest price among the previously listed prices, *i.e.*, 85% of the lower drug price between the lowest price for the same medicine and the price determined according to criterion 3) above, regardless of whether or not the quality requirements are actually met.

Therefore, from the 21st entry, the drug price will decrease stepwise by 15% according to the order of registration; for example, the 21st drug will be priced at 85% of the lowest price among the previously listed 20 products, and the 22nd drug will be priced at 85% of the 21st drug price.

Later generic entry to be discouraged under current pricing system

- *Generic drug price after the 20th entry has fallen markedly*

Recently, a generic product was listed to have a drug price which had dropped significantly compared to the highest price of the same medicine. This was because the tiered drug pricing rule was applied continuously.

20 mg Exoxium tablet (esomeprazole), which was registered on the reimbursement list as of this February, was priced at KRW 339 (Korean currency), which corresponds to 85% of the lowest price of KRW 399, since there were already 124 esomeprazole products previously listed. This price is 55.6% lower than the highest price of KRW 764.

Just a month ago, another esomeprazole generic product was also listed to have the lowest price, KRW 399 according to the tiered drug pricing rule. As a result, the lower price cutting criteria was applied to 20 mg Exoxium tablet.

- *Generic listings for insurance coverage have decreased noticeably*

According to recent data from the Health Insurance Review and Assessment Service, the number of generic products added to the reimbursement list has decreased significantly.

From June to August 2020, immediately before the implementation of the revised drug pricing system, more than 2,000 drug products were registered on the insurance-reimbursement list.

However, in January and February 2021, only 28 and 32 products were newly registered on the reimbursement list, respectively.

Patent challenges to intensify for obtaining better generic prices

- *Competition for earlier approvals is becoming fierce*

Since the sales revenue of generics will decrease from the 21st entry for a given medicine, generic companies are more fiercely competing to obtain generic approvals earlier than others.

- *Patent challenge may be an essential option for better generic prices*

Assuming that more than 20 companies succeed in challenging an originator's drug patent at almost the same time, the highest generic price available up to the 20th entry is likely to be limited to only the products of these companies. As a result, later-entry generics may have to drop out of drug price competition.

Therefore, patent challenge may be an essential option for securing drug prices. This is noticeable for blockbuster drugs.

Previously, patent challenges were usually pursued so as to obtain first generic exclusivity; however, after the restructuring of the drug pricing system, patent challenges have become even more important for price competition.

- *Boehringer Ingelheim's blockbuster Jardiance is an exemplary case under the new system*

For example, overheated patent challenges may be observed in the case of Boehringer Ingelheim's blockbuster diabetes drug, Jardiance (empagliflozin).

After 12 companies, including Chong Kun Dang, failed in the invalidation trial filed in 2015 for the patent directed to a crystal form covering Jardiance (expiring in 2026, hereinafter "the 2026 patent"), Chong Kun Dang alone challenged the 2026 patent again by filing an action for negative scope declaration in January 2018.

As a result, Chong Kun Dang first succeeded in patent evasion in May 2019, and thereafter, there was a rush for patent challenges by about 50 generic companies between June 2019 and August 2020.

The companies who have succeeded in evading the 2026 patent will be allowed to release their products after another patent's expiration in October 2025. However, other companies who have not challenged are highly likely to fall behind in the entry of the corresponding generic market because they will be allowed to release their products only after 2026.

Interestingly, patent challenges by these companies took place after the government's tiered drug pricing policy was announced at the end of March 2019, and these companies have not met the requirements for the first generic exclusivity. In this light, these challenges may be interpreted as having been for the purpose of keeping up with drug price competition in the future.

KIPO has revised Examination Guidelines to clarify standards for CRISPR-Cas system in plant inventions

Technologies relating to the Fourth Industrial Revolution are maturing into patents. In December 2020, KIPO published new Examination Guidelines for the these new technologies. The CRISPR-Cas technology revolutionized genome engineering and has had an enormous impact on plant bio-science. The new guidelines updated the standards for determining the inventive step of plant-related inventions using the CRISPR-Cas system.

Assessing inventive step of plant-related inventions

Korean practice applies the following principles when assessing the inventive step of plant-related inventions:

1) Novel plant itself or part thereof

The inventiveness is mainly determined based on the "characteristics" of the novel plant. An inventive step is recognized if the characteristics have an "unexpected and advantageous effect" compared to the traits of known plants of the species to which the novel plant belongs.

2) Method for plant breeding or reproduction

The inventiveness is mainly determined based on (i) "combination of starting materials", (ii) the characteristics of the "means for inducing a mutation" or the "means for reproduction", and (iii) the "characteristics of the plant" bred or produced by the method.

Updated guidelines

The updated guidelines clarify the criteria for inventiveness applicable to plant inventions using CRISPR-Cas technology as follows.

In the case of a new plant obtainable by implementing similar traits in different plant species, exemplary consideration factors in assessing the inventive step are:

(1) disclosures of prior art documents related to known plants;
(2) ease of trying to express the traits in different species, in view of common technical knowledge at the time the application was filed;
(3) constitutional difference to overcome technical barriers in expressing the traits in different species; and
(4) unpredictable effects resulting from expressing the traits in different species.

In this regard, the guidelines provide rationales for acknowledging the inventive step as follows:

"[I]n the case of a simple implementation of similar traits in different species, the inventive step is not generally recognized since a person of ordinary skill can easily derive such implementation by using known means for breeding or transformation; however, the inventive step is acknowledged if experimental data is presented, which shows that there are *different or remarkable effects* resulting from applying the traits to different species."

In order to assist in the assessment of the inventive step of plant-related inventions, exemplary cases were provided in the updated guidelines. Key examples are summarized in the following tables:

- **Case 1**

[Claimed Invention]

A method for preparing a mutant maize plant (*Zea mays*) without the introduction of a foreign gene during gene editing, the method comprising:

(a) introducing a genetic material for inducing gene editing into **a pollen tube of a maize plant**;
(b) inducing fertilization in the pistil of the maize plant using the pollen tube having the genetic material introduced; and
(c) cultivating the fertilized plant to obtain a gene editing-induced mutant plant,
whereby the genetic material for introducing gene editing expresses transiently, and the method does not require selection of the gene editing-induced plant and tissue culture for generation of whole-plants.

[Prior Art]

It is disclosed that gene editing without the introduction of a foreign gene is induced by introducing a gene expression vector comprising guide RNA (U6-gRNA) and 35S-Cas9 **into the protoplast of *Arabidopsis thaliana***, which was prepared from its plant leaves, and performing transient gene expression.

[Assessment]

An inventive step is not generally acknowledged if there is only the difference in the type of a cell into which the gene expression vector for gene editing is introduced, compared to the prior art.

However, the claimed method can induce gene editing in a plant through a simple mating by introducing a genetic material for gene editing into a germ cell of the plant, whereby it does not require selection of the gene editing-induced plant and tissue culture for generation of whole-plants, **in contrast to** the prior art inducing gene editing in **a somatic cell**. These are considered as distinctive and unpredictable effects which are neither disclosed nor suggested in the prior art; therefore, the inventive step is acknowledged.

Case 2

[Claimed Invention]

A method for preparing a tomato (*Solanum lycopersicum*) plant with reduced ethylene production, the method comprising inhibiting the expression of RIN1 protein-encoding gene by transforming a tomato plant cell with a recombinant vector, which comprises

(a) an expression cassette 1 comprising a polynucleotide encoding CRISPR associated protein 9 (Cas9) protein which consists of the nucleotide sequence of SEQ ID NO: 1; and
(b) an expression cassette 2 comprising a **target sequence** of an RIN1 protein-encoding gene which consists of the nucleotide sequence of **SEQ ID NO: 3**.

[Prior Art 1]

It is disclosed that ethylene production was inhibited in a tomato plant transformed with a recombinant vector comprising an expression cassette comprising Cas9 gene and an expression cassette comprising sgRNA for mutation of RIN1 gene.

[Prior Art 2]

A cloning vector having a 100% homology to SEQ ID NO: 1 is disclosed.

[Prior Art 3]

A **whole sequence** of RIN1 gene comprising **SEQ ID NO: 3** is disclosed.

[Assessment]

The inventive step of a guide RNA sequence for the target gene is generally not recognized when the whole genome sequence for the target gene was disclosed.

However, the specification provides *experimental data* showing that gene editing was successfully induced with 10 gene targeting sequences consisting of nucleotide sequences of SEQ ID NOS: 2 to 11, but reduced ethylene production was **confirmed only** in the case of **SEQ ID NO: 3**. In consideration of such data, it is acknowledged that the claimed invention has *remarkable effects* of achieving optimization of the gene editing site and improvement of editing efficiency by using the specific guide RNA target sequence (SEQ ID NO: 3); therefore, the inventive step is recognized.

Comments

As described above, in order to obtain a patent for a plant-related invention using the CRISPR-Cas system, it is important to *demonstrate a remarkable effect* which cannot be predicted from the prior art, *e.g.*, a novel characteristic of a plant compared to the prior art, a distinctive effect due to the type of a cell to which CRISPR-Cas is applied, or a quantitatively remarkable effect.

In Korea, it is usually possible to submit **post-filing data** to prove an inventive step, and oftentimes, this is found to be a very powerful tool. It is expected that clarified standards will be able to efficiently assist in the formation of plant patenting strategies under current Korean patent practice.

COVID-related inventions are now eligible for accelerated examination (June 23, 2021)

According to a recently issued press release from KIPO, IP filings in Korea have notably increased in 2020 despite the upheavals of the COVID-19 pandemic. In particular, the rise in filings has been exceptionally apparent in COVID-related technologies and so-called "non-contact" industries.

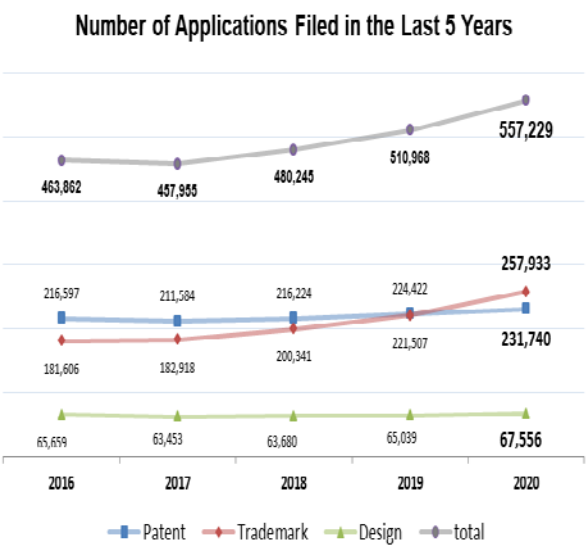
In response to the pandemic, the government has recently amended the Korean Patent Act so that accelerated examination can be allowed when it is deemed necessary in the prevention of, response to, or recovery from a disaster such as COVID-19.

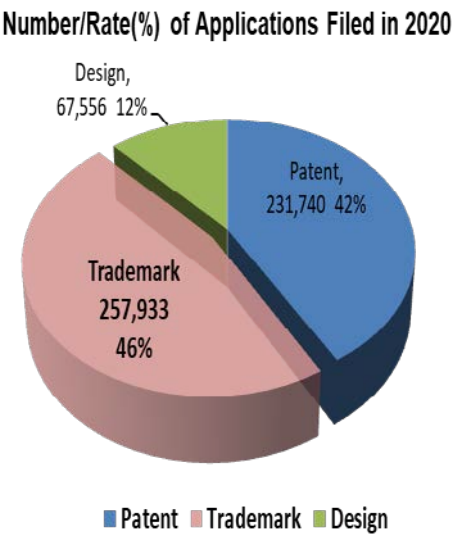
In 2020, IP filings increased, especially in COVID-related technologies and non-contact industries

KIPO reported that a total of 557,229 applications including patents, designs, and trademarks had been filed, marking a 9.1% increase from the previous year. There were 257,933 trademark applications (16.4% increase); 231,740 patent/utility model applications (3.3% increase); and 67,556 design applications (3.9% increase).

- *Patents/utility models*

Applications related to e-commerce technology (10,407 cases, 8.4% increase)





ranked first in year-on-year growth rate, reflecting the upswing of Korea's online e-commerce market with 8.5% y-o-y increase in October 2020. Further, there were relatively high increasing trends in medical technology (9,983 cases, 8.1% increase), pharmaceuticals (4,380 cases, 4.8% increase), and biotechnology (4,566 cases, 2.7% increase), reflecting growing concerns around medical health and hygiene due to COVID-19.

- *Trademarks*

There was sharp increase of 16.4% in trademarks. The number of trademark applications exceeded that of patent applications for the first time in 36 years, which implies that the spread of social recognition of brand values has been reflected. Dramatic increases in trademark applications appeared particularly in the classes of medical devices (8,391 cases, 42.7% increase year-on-year) and pharmaceutical products (14,530 cases, 31.3% increase). The increases in the classes of broadcasting and communication industries (7,998 cases, 37.3% increase) and electronic and AV devices (26,865, 18.0% increase) were also remarkable.

- *Designs*

Packaging design applications (5,840 cases) made up the greatest proportion of filings. Further, design applications in household healthcare and hygiene products (3,903 cases) marked an exceptional increase of 125.9% compared to the previous year.

These increasing trends are considered as demonstrating the spread of digital economic society triggered by increasing non-contact services and growing concerns with respect to the medical and hygienic fields.

Government allows accelerated examination for COVID-related applications

Despite the difficult economic circumstances resulting from the COVID-19 pandemic, IP applications saw their highest numbers in history. The rate of increase in applications was particularly high in COVID-related and non-contact technologies.

Recently, the Korean Patent Act has been amended so that accelerated examination can be allowed when it is deemed necessary in preventing, responding to, or recovering from a disaster. Therefore, COVID-related applications may benefit from accelerated examination.

This amendment will be effective from June 23, 2021; however, it will also apply to applications filed before the amendment enters into force. It is expected that such government measures will contribute to and support improvements in national or global health and safety.

Requirements for obtaining criminal remedies for patent infringement are now relaxed (October 20, 2020)

On October 20, 2020, the Korean Patent Act (KPA) was amended to allow criminal punishment of a patent infringer even if there was no criminal complaint.

Previously, criminal prosecution was not possible without a complaint

In addition to civil remedies, criminal remedies are also available for patent infringement in Korea. Fines of up to KRW 100 million (approximately USD 90,000) and/or imprisonment of up to 7 years may apply as criminal punishment.

According to the previous law, in order to initiate a criminal investigation and indictment for patent infringement, it was required to file a criminal complaint before the investigating authority (the police or prosecutor's office) within six months from the date on which the identity of the offender became known. Such requirements have been a bar to seeking criminal remedies for patent infringement.

Now, a complaint is no longer required, and the six-month time limit is not applicable

Under revised Article 225, para. (2), *ex officio* investigation is available even without a formal complaint, but the offender cannot be punished against the explicit will of the complainant. Further, the six-month time limit is not applicable. Therefore, the investigating authority can more actively initiate and conduct criminal investigations of patent infringement. Patent holders can consider pursuing criminal remedies more actively and easily.

This revision applies to offenses committed on or after October 20, 2020. It is expected that this revised provision will support patent protection more effectively in Korea.

Contributed by Byeong Seok CHOI, Seok Hwan JANG, Jeong Hyun KIM, Young Han KIM, Hyoung Pyo LEE, Eun Young LYU, Seon Yang PARK, Min SON *Edited by* Ryan KARSTEN, Sonnie KIM