KEI briefing note 2022:2
U.S. federal government FAR 52.227-1 authorizations (for non voluntary use of patents) disclosed in 166 SEC exhibits

October 12, 2022

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- The public is not generally aware of the extent to which the U.S. government grants private companies the right to use current and future patented inventions, and this lack of awareness extends to U.S. government officials and Members of the U.S. Congress.
- This briefing note reports on 166 U.S. contracts disclosed to the U.S Securities and Exchange Commission (SEC) that contain broad compulsory licenses to use patented inventions without the consent of patent holders when the use is “by or for” the U.S. government, under 28 U.S. Code § 1498.
- An earlier July 19, 2022 KEI briefing note focused on COVID 19 contracts obtained through FOIA litigation found that 59 of 62 contracts examined included an authorization to use patents without consent of patent holders, for a wide range of COVID 19 countermeasures. These nonvoluntary authorizations occurred at the same time the U.S. government was opposing a waiver of TRIPS rules on patents for therapeutics and diagnostic devices, and seeking restrictive rules for TRIPS rules on non voluntary use of patents for COVID 19 vaccines. (KEI Briefing Note 2022:1, Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents).

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1 Prepared by James Love with assistance from Lokesh Vyas.
This briefing note identifies 166 contracts disclosed to the U.S. Securities and Exchange Commission (SEC) that permit companies to use patented inventions without the consent of patent holders. The compulsory licenses were granted for a diverse set of purposes, and many by different federal government agencies.

Due to the SEC standards for disclosure, which address the interests of investors and not the general public, most U.S. government contracts that contain an authorization for nonvoluntary use of patents are not disclosed in SEC filings, and are only available through litigation or U.S. Freedom of Information Act (FOIA) requests, subject to extensive redactions.

Only 3 of the 166 contracts disclosed in SEC filings were among the 62 COVID 19 contracts described in KEI Briefing Note 2022:1.

The actual number of U.S. contracts that include an authorization and consent for non voluntary use of patents is such higher.

The U.S. authorizations involve a reference in a contract to a federal acquisition regulation, FAR 52.227-1, titled “authorization and consent,” and typically apply to all U.S. granted patents, without identifying specific patents or notifying patent holders.

The authority to grant a FAR 52.227-1 authorization and consent is highly decentralized, managed by federal contracting officers.

The use of FAR 52.227-1 authorization and consent in contracts should be more transparent, to avoid giving the public an incomplete and distorted understanding of the role of patent exclusivity.

The U.S. government use authorizations are implemented through a statutory elimination of the availability of injunctions to remedy infringement. Exceptions to enforce the exclusive rights of a patent holder through an injunction are allowed under Article 44 of the TRIPS Agreement, and while widely used by the U.S. government, is not generally appreciated as a possible mechanism for non voluntary use of patents by other WTO members. Limitations on the availability of injunctions provide a particularly uncomplicated mechanism for compulsory licensing of patented inventions, as is described in further detail in KEI Briefing Note 2022:3, Selected differences between Articles 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions.

Introduction

The United States has an usually straightforward and extensively used system for granting exceptions to the exclusive rights of a patented invention, when use is “by or for” the federal government. The U.S. approach provides the federal government with an automatic right to use any U.S. granted patent, subject to compensation to the patent holder, but without the possibility of an injunction. This right can be extended to non federal actors, such as a company providing a good or a service, through a simple authorization and consent. The authorization and consent can be implicit or explicit, and in writing or even oral. In practice, the federal government has four related regulations (FAR 52.227-1, 52,227-2, 52.227-3 and 52.227-4) that are often used to simplify the process. A brief sentence simply noting that a contract includes, by reference, FAR 52.227-1 can be used by an agency to grant the exception to the exclusive rights of a patent. The U.S. system allows such authorizations to be made by civil servants known as contracting officers. The authorizations are limited to the scope of the goods or services provided under the contract, but also are very broad, typically covering all U.S. current or future patents, without requirements to identify specific patents, or negotiate or even notify patent holders.
The frequency at which the U.S. federal government provides such authorization and consent clauses in contracts is not widely appreciated. In July, 2022, KEI published a report that identified 59 COVID 19 related contracts that contained an authorization and consent to use U.S. patents without the consent of the patent holder, and this list was not exhaustive. *(2022:1 KEI Briefing Note: Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents.)*

On September 17, 2022, KEI searched the U.S. Securities and Exchange (SEC) database of corporate disclosure and identified 166 contracts that included an authorization and consent clause. A table with links to those contracts and selected metadata is attached below.

**Statutory and Regulatory Framework**

The U.S. law, statute [28 U.S. Code § 1498](https://www.law.cornell.edu/uscode/text/28/chapter-15/patent-and-copyright-cases/section-1498), titled Patent and copyright cases, provides broad government use exceptions to patents, copyrights, designs and *sui generis* protections relating to plant varieties and semiconductor chips. As regards patented inventions, the U.S. government can use or authorize a third party to use any patent issued by the U.S. government, for a use “by or for” the government. Specifically, 28 USC § 1498(a) provides that:

> "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture."

The U.S. government can allow a third party to use patents through an explicit or implicit authorization, which can be written or even oral. An important mechanism for such authorizations is found in the U.S. government Federal Acquisitions Regulations (FAR). In particular are four sections in the FAR that are most relevant. The first concerns the authorization to use patents, the second cooperation in providing information relevant to infringement claims, the third and fourth relate to obligations by the contractor to reimburse (indemnify) the government for any costs or compensation to patent holders.

[FAR 52.227-1](https://www.federalregister.gov/documents/2018/02/23/2018-03504/federal-acquisitions-regulations-2018) is titled Authorization and Consent. This regulation includes options and is revised from time to time, and contracts that reference or use the regulation may cite both the regulation and the month and year of the revision, and a reference to either the standard clause or Alternatives I or II. The authorization is quite broad, and in the most common cases covers all U.S. patents. The standard language begins with this sentence.

> "The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent - “

In these cases, the government does not have to identify specific patents or proactively notify patent holders, and there is no requirement for negotiations with patent holders on reasonable commercial terms. These authorizations can and do cover a wide range of
activities, as illustrated below for contracts that companies have disclosed as exhibits in their U.S. Securities and Exchange (SEC) filings.

**FAR 52.227-2**, titled “Notice and Assistance Regarding Patent and Copyright Infringement,” requires the contractor to provide the U.S. government with “all evidence and information” pertaining to a “claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this contract.”

**FAR 52.227-3**, titled “Patent Indemnity,” requires the contractor to compensate the government (to indemnify) for any “liability, including costs, for infringement of any United States patent” relating to the performance under the contract. There are conditions on when the indemnity shall apply (the contractor has to have timely notice and opportunity to participate in defense of any claim), and exceptions, such as a change in the contract or when a claim is “unreasonably settled without the consent of the Contractor.”

**FAR 52.227-4**, titled “Patent Indemnity-Construction Contracts” addresses the indemnify obligations when the contract involves construction.

51 of the 166 contracts included either a 52.227-3 or 52.227-4 patent indemnity clause.

**Contracts disclosed in SEC filings with 52.227-1 authorization and consent**

The United States Securities and Exchange Commission requires certain companies that sell securities in the United States to make a number of disclosures. The SEC mandated disclosures cover a wide range of topics, as illustrated by the [SEC Disclosure Guidance](#). One consequence of these obligations is the disclosure of contracts that may have a material impact on the value of a company to investors.

On September 16, 2022, KEI searched the SEC database for contracts that included a reference to the FAR 52.227-1, the authorization and consent for use without consent of U.S. granted patents. This search, which is likely incomplete, provided links to 166 contracts, involving 114 different firms.

KEI has reviewed each of the 166 contracts, and provides as an attachment a list of the contracts, including metadata on the agency providing the authorization and consent, the firms involved, the purpose of the contract, and whether the contracts included, in addition to the 52.227-1 reference, a reference to 52.227-2, 52.227-3 or 52.2274.

Among the 166 contracts, 88, or slightly more than half, were issued by the U.S. Department of Defense (DOD) or one of its subsidiary agencies or departments. While several of the DOD contracts involved weapons or similar military products or services, a significant number involved biomedical procurement or research and development activities. Examples of the DOD biomedical procurement or R&D contracts are described in Table 1.
Table 1: Examples of DOD biomedical authorization and consent contracts

- SARS-CoV-2 mRNA-1273 Vaccine
- Novavax nanoparticle vaccine against COVID-19
- Broad Spectrum Countermeasures for Viral and Bacterial Sepsis,
- Hemorrhagic Fever Virus Therapeutic.
- Marburg virus countermeasures.
- Overcoming Resistance by the Application of Boron to Ribosomal Inhibitors
- H1N1 Countermeasure Development.
- Broad Spectrum Antibacterial Therapeutics from Marine Natural products
- αGal Adjuvant Technology for Biodefense Agents
- manufacture of Three Adenovirus Vectors Encoding Plasmodium falciparum Sporozoite/Liver Stage Antigens with Stability Program
- Improved Venezuelan Equine Encephalitis Virus Vaccines
- Advanced Development of Entolimod (CBLB502) To Mitigate and Treat the Acute Effects of Ionizing Radiation
- Sufentanil NanoTab Development
- Obtain FDA clearance for the PoNS™ 4.0 device
- NeuroHabilitation Corporation’s (NHC) Portable Neuromodulation Stimulator (PoNS™) aid to therapy for chronic balance deficits resulting from a mild to moderate traumatic brain injury (TBI).

The next largest group of SEC disclosed contracts with a 52.227-1 authorization and consent is the U.S. Department of Health and Human Services (HHS). This included 60 contracts, of which 33 were granted by the Biomedical Advanced Research and Development Authority (BARDA), and others by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the Office of Public Health Emergency Medical Countermeasures (OPHEMC).

Nine contracts involve the U.S. Department of Energy, and other contracts involve the Department of Homeland Security, the National Aeronautics and Space Administration (NASA), the Social Security Administration and the United States Office of Personnel Management (OPM).

The contracts disclosed in SEC filings are but a small fraction of the contracts issued by the U.S. government that include a 52.227-1 authorization and consent clause.

Not all entities obtaining such an authorization are subject to SEC disclosure obligations, and among those that are, the publishing of a contract is only required when material to the value of the firm to investors.

To illustrate the lack of transparency of 52.227-1 authorizations, consider the July 19, 2022, KEI report (KEI Briefing Note 2022:1) on “Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents." The KEI report was based upon data from contracts obtained from the U.S. government under Freedom of Information Act (FOIA) requests. Among 62 COVID 19 related contracts issued by the U.S.
government for which it could be determined if the government used this authority, 59 included an express authorization and consent to use U.S. granted patents without consent from patent holders. Among those 59 contracts, only three are included in the list of 166 contracts found in the SEC database. In other words, 56 of the 59 contracts obtained under FOIA were not disclosed in SEC filings.

In general, the SEC requires disclosure of information that is considered material to an investor’s investment decision. The larger the firm, the less likely the firm will disclose a federal contract as an exhibit. This can be illustrated when comparing the COVID 19 contracts obtained under FOIA, and the contracts disclosed to the SEC.

The few contracts in the SEC EDGAR database that involve large firms are contracts between the large firm and a smaller firm, as a subcontractor or collaborator, where the smaller firm makes the disclosure of the contract.

**Officials who grant a U.S. authorization and consent for use of patents without consent of patent holders**

The COVID 19 and the SEC contracts illustrate how the U.S. authorization and consent process works. Unlike many other countries, an authorization for a government use exception to the exclusive rights of a patent does not require a decision by the patent office or high level officials such as a Minister. The highly decentralized system used by the U.S. government typically relies on decisions by a contracting office (CO), who holds a warrant to exercise the authority to bind the federal government to a contract. (Discussion of the DOD approach [here](#))

**Consistency with WTO TRIPS provisions**

There are three Articles in the TRIPS agreement that have relevance to the U.S. approach to use of patents “by or for” the federal government without the permission from patent holders.

TRIPS Article 30, titled Exceptions to Rights Conferred, permits WTO members to provide “limited exceptions to the exclusive rights conferred by a patent” subject to a requirement that “such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” Some trade officials in the U.S. consider the U.S. liberal use of 52.227-1 authorizations during the COVID 19 pandemic to be consistent with Article 30 of the TRIPS.

Article 31 of the TRIPS, titled “Other Use Without Authorization of the Right Holder” sets out several rules that must be met to allow non-voluntary use of patents. The requirement for prior negotiation with rights holders is waived in the case of “public non-commercial use,” as well as for “a national emergency or other circumstances of extreme urgency.”

However, Article 31 also includes a number of other provisions which could be considered restrictive, depending upon future WTO jurisprudence.
Article 44 of the TRIPS, on injunctions, is perhaps that place where the U.S. government approach is most clearly consistent, including in particularly, the highly permissive last sentence in paragraph 2, which states that injunctions can be eliminated when a WTO member provide the possibility of declaratory judgments and adequate compensation, two conditions that are available in the U.S. law. In other words, the U.S. approach to government use is not to grant a compulsory license, but to limit the remedies for non-voluntary use to compensation. The “reasonable” compensation standard in U.S. law is certainly to be considered to meet the “adequate” standard in the Article 44.2 of the TRIPS, particularly given the discretion afforded to WTO members by Article 1 of the TRIPS, which provides that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” Using the flexibility in Article 44, a WTO member can effectively create liability rules, which provide the freedom to use patented inventions, subject to an obligation to provide compensation or remuneration to the patent holders.

A discussion of the differences between Article 30, 31 and 44 in TRIPS is available in KEI Briefing Note 2022:3 Selected differences between Article 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions. Table 2 summarizes some of the important differences between the three legal mechanisms.

Table 2: Selected differences between Article 30, 31 and 44 for non voluntary use of patented inventions

<table>
<thead>
<tr>
<th>exceptions to rights conferred</th>
<th>article 31, other use without authorization of the right holder</th>
<th>article 44 (injunctions denied or not available under national law)</th>
</tr>
</thead>
<tbody>
<tr>
<td>exceptions do not unreasonably conflict with a normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>authorization of such use shall be considered on its individual merits</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time</td>
<td>no</td>
<td>yes, except for national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.</td>
</tr>
</tbody>
</table>

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| Use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; | No | Yes, except when remedy to anticompetitive practice or regulated under Article 31bis or the June 17, 2022 agreement on TRIPS | No |
| Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances; | No | Yes | No |
| Compensation/remuneration required? | Not required, but is taken into account in considering the reasonableness of the exception. | Required | Required |

**Recommendation to improve transparency**

The extent that the U.S. government provides broad authorizations to use patented inventions without consent from patent holders is unknown, and judging from the diverse commentary on compulsory licensing, not widely appreciated. The data from KEI briefing Note 2022:1 benefited from the use of the U.S. government freedom of information laws, which can be a cumbersome and time consuming endeavor, and often involve substantial redactions. The SEC filings used in this briefing note are generally less redacted than contracts obtained for COVID 19 countermeasures, but the number of contracts available to the public is limited due to the SEC’s own more narrow standards and limited authority for requiring disclosure. For example, there are few disclosures from large firms and none from companies not regulated by the SEC.

Compulsory licenses or government use authorizations for patents in non-US jurisdictions are typically transparent. Judicial decisions to withhold injunctions in favor of royalty payments are also transparent.

When patented inventions are subject to government rights due to federal funding of inventions, patent applicants are required to make a public disclosure that is published with
the patent. [35 U.S.C. 202(c)(6).] Federal agencies that propose granting exclusive rights to a US owned patent not subject to a CRADA are required to first provide the public with an opportunity to comment on the license. [35 USC 209(e)].

Internationally, the U.S. government has supported requirements in the TRIPS agreement (Article 31bis and the June 17, 2022 WTO decision on TRIPS) that require governments to notify the WTO TRIPS Council when granting compulsory licenses.

In contrast to the practice in many countries, the U.S. compulsory licensing for government use is largely a stealth program. With the exception of a handful of contracts disclosed in FOIA requests, litigation between parties and in SEC filings, the U.S. system of non-voluntary use of patented inventions is generally secret, giving the public an incomplete and distorted understanding of the role of patent exclusivity.

Given the public interest in more transparency of the patent system, agencies that issue a FAR 52.227-1 or similar authorization should be required to publish on their web page a list of the contracts that include such a provision.

**Attachment: Table 3: List of contracts disclosed in SEC filings that include U.S. federal government authorization and consent to use patented inventions without consent from the patent holder.**

This table is based upon data from the tab SEC 52.227-1 in the Google Sheet available [here](#).