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Hogan Lovells: ITC Section 337 monthly highlights

29 September 2017

Recent developments and practice tips from the ITC bench

The firm announced on August 28, 2017, that former U.S. International Trade Commission (ITC, or the Commission) Administrative Law Judge Theodore R. Essex has joined the firm's Intellectual Property Litigation practice in Washington, D.C. This news was extensively reported by The American Lawyer, Law360, IPPro Patents, World Intellectual Property Review, and Bloomberg/BNA, among others. One of the most well-known and respected judges at the ITC, Judge Essex was appointed to the ITC bench in October 2007, and has been at the forefront of intellectual property law issues for ten years, having handled scores of Section 337 proceedings involving the world's most valuable and renowned companies.

Judge Essex now joins our ITC Section 337 Highlights with a practice tip for writing, proofreading and arguing: strive for clarity. In patent law in particular, the English language suffers greatly. Any time fine minds can take 14 pages to conclude that "about means approximately," we will find English in a precarious condition. Due to the way claims are constructed, and patents written, clarity will always be a victim to some degree or another, but strive to minimize the damage. George Orwell produced a good set of rules to guide us:

- Never use a metaphor, simile, or other figure of speech which you are used to seeing in print.
- Never use a long word where a short one will do.
- If it is possible to cut a word out, always cut it out.
- Never use the passive where you can use the active.
- Never use a foreign phrase, a scientific word, or a jargon word if you can think of an everyday English equivalent.
- Break any of these rules sooner than say anything outright barbarous.

Amarin Pharma files Section 337: Complaint seeking jurisdiction over false labeling claim under Section 43(a) of the Lanham Act

On August 30, 2017, Complainants Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively Amarin) filed a Complaint in *Certain Synthetically Produced Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form*, ITC Docket No. 3247. The Complaint requests that the Commission institute an investigation into the unlawful importation for sale in the United States by Respondents of synthetically produced omega-3 products that Amarin claims are falsely labeled and/or advertised as "dietary supplements" in violation of both

Section 43(a) of the Lanham Act 15 U.S.C. §1125(a), and the standards set forth in the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 321 *et seq*.

The Complaint includes as Exhibit 30, Amarin Brief on Jurisdiction, relying on the recent Supreme Court decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228, 2234 (2014) (*POM Wonderful*), which holds that Section 43(a) of the Lanham Act "creates a cause of action for unfair import competition through misleading advertising or labeling", and the Commission's recent decision to institute *Certain Potassium Chloride Powder Products*, Inv. No. 337-TA-1013 (*Potassium Chloride*), where the Complainants alleged that the Respondents were selling a potassium chloride product – an unapproved "new drug" – with labeling that suggested the product was actually a U.S. Food and Drug Administration (FDA) approved drug. Amarin's Brief also distinguishes the Commission decision not to institute *Hydroxyprogesterone Caproate And Products Containing The Same*, ITC Docket No. 2991 (*HPC*).

Amarin contends that the *HPC* decision occurred prior to the Supreme Court's *POM Wonderful* decision and after a district court had refused to review the FDA's decision not to enforce the FDCA against compounding pharmacies that were selling unapproved versions of K-V Pharma's FDA-approved drugs that were accused of infringement in *HPC*. Amarin argues, in contrast, in the instant investigation, Amarin is asking the Commission to determine simply whether the labeling of a product that was never reviewed by the FDA is false and misleading. Unlike *HPC*, the FDA has not refused to enforce the FDCA against the importers of the synthetically produced omega-3 products accused in the instant investigation. It will be interesting to see if the Commission institutes the instant investigation to determine whether the labeling of the accused synthetically produced omega-3 products as "dietary supplements" is false and misleading.

New recombinant factor IX 1066 investigation instituted by the Commission

On August 8, 2017, the Commission voted to institute *Certain Recombinant Factor IX Products*, Inv. No. 337-TA-1066, based on a Complaint filed by Bioverativ Inc., Bioverativ Therapeutics Inc. and Bioverativ U.S. LLC (collectively Bioverativ). The Complaint alleges that CSL Behring LLC of King of Prussia, Pennsylvania, CSL Behring GmbH of Germany, and CSL Behring Recombinant Facility AG of Switzerland (collectively, CSL) unlawfully import into the U.S., sell for importation, and/or sell within the U.S. after importation certain recombinant Factor IX products that infringe one or more claims of U.S. Patent Nos. 9,670,475 (the '475 patent), 9,623,091 (the '091 patent), and 9,629,903 (the '903 patent). All three patents claim methods of treatment of hemophilia B using doses containing chimeric polypeptides. The chimeric polypeptides contain a factor IX piece (responsible for clotting) and a binding partner piece (which is either Fc or albumin, two commonly found proteins in the body).

Specifically, the '475 patent relates to methods of controlling a bleeding episode in a human subject by administering multiple doses of about 25 IU/kg to about 50 IU/kg of a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.*, Fc or albumin) at a dosing interval of about 7 days between two doses in order to maintain the plasma Factor IX activity of the subject above 1 IU/dL during the dosing interval. The '091 patent relates to methods of treating hemophilia B in a human subject by intravenously administering multiple doses of about 50 IU/kg to about 100 IU/kg of chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.*, Fc or albumin) at a dosing interval of about 10 days to about 14 days between two doses in order to maintain the plasma Factor IX activity of the subject above 1 IU/dL and reduce

the frequency of spontaneous bleeding. Lastly, the '903 patent relates to methods of treating hemophilia B in a human subject by intravenously administering multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.*, Fc or albumin) at a dosing interval of about 10 days to about 14 days between two doses in order to maintain a trough level of plasma Factor IX activity of at least 3 IU/dL after six days and reduce the frequency of spontaneous bleeding.

In the Complaint, Bioverativ refers to CSL's Idelvion product as an infringing product. Regarding domestic industry, Bioverativ states that its Alprolix product practices at least one claim of each asserted patent. Bioverativ further states that it, its contract manufacturer Biogen Inc. (Biogen), and third-party logistics providers employ U.S.-based personnel and resources in the manufacture, packaging, sale, and post-sale support of Alprolix. Bioverativ also filed a parallel complaint against CSL in the U.S. District Court for the District of Delaware alleging infringement of the asserted patents. With respect to potential remedy, Bioverativ requests that the Commission issue a limited exclusion order and cease and desist order directed at CSL and related entities. This investigation is exemplary of a recent trend of biopharma cases being filed in the ITC.

ALJ Lord issues ID granting respondents' motion to terminate 1052 investigation for complainant's lack of standing

On March 21, 2017, Complainant Intellectual Ventures II LLC (IV) filed a Complaint asserting infringement of four asserted patents in *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, And Products And Vehicles Containing Same*, Inv. No. 337-TA-1052. On June 20, 2017, Respondents filed a motion to terminate the instant investigation on the grounds that IV lacks standing to sue. On August 11, 2017, Administrative Law Judge Dee Lord issued a Corrected Initial Determination (ID) Granting Respondents' Motion To Terminate The Investigation Due To Complainant's Lack Of Standing.

The ID finds that an assignment in 2012 plainly and unambiguously purported to transfer ownership between Encap Technologies to IV's predecessor. However, the ID also finds that it was not possible for Encap Technologies to convey any rights in the asserted patents at this time because Encap Technologies had been merged with Encap Holding four years before the purported conveyance. The result is that after 2008, Encap Technologies had no separate existence and was legally unable to convey any ownership rights in the asserted patents. The ID held that because IV has not corrected the error that led to the break in chain of ownership of the asserted patents prior to filing the Complaint, IV lacks standing and cannot bring its claim before the ITC.

The Commission extended the date for determining whether to review the ID until September 29, 2017. In the meantime, IV filed a motion to withdraw its Complaint and vacate the ID. OUII notes that Complainant has not identified any instance where a party successfully moved to withdraw a complaint after an ID terminating an investigation in its entirety has issued. OUII does not oppose IV's motion for termination based on withdrawal but submits that if the Commission grants Complainants' motion to withdraw the Complaint, then there will no longer be an ongoing investigation, and Complainant's request to vacate the ID will be moot. Respondents assert that the Commission should terminate the Investigation in its entirety by determining not to review the ID, but the Commission should not vacate the ID. This issue is pending as of the time of publication.

Commission affirms violation in *Certain Automated Teller Machines*, Inv. 337-TA-989

On August 3, 2017, the International Trade Commission affirmed, after reviewing the Initial Determination (ID) of Judge David P. Shaw in *Certain Automated Teller Machines*, Inv. No. 337-TA-989, with respect to a domestic industry issue, that Respondent Diebold Inc.'s and Diebold Self-Service Systems' (Diebold) automated teller machines, ATM modules, components and products infringe several claims of U.S. Patent No. 8,523,235 (the '235 patent). The Complaint was brought by Nautilus Hyosung Inc. (Seoul, Republic of Korea) and Nautilus Hyosung America Inc. (Irving, TX) (collectively Nautilus) solely against Diebold as Respondent. Nautilus also asserted three other patents, which were withdrawn during the course of the investigation.

Specifically, the Commission affirmed the ID's findings that Diebold's accused products directly and contributorily infringe claims 1-3, 6, 8 and 9 of the '235 patent, that Nautilus established a domestic industry that practices the '235 patent, and that those claims are not invalid for indefiniteness, anticipation or obviousness. The '235 patent is directed to a "cash and cheque automatic depositing apparatus" that is "capable of performing banking transactions," where the claimed ATM is "capable of automatically depositing a bundle of cashes and cheques at once." The accused products are Diebold's "one-throat, mixed-media depositing ATMs" that "can receive and process both cash and checks in a single, mixed bundle, inserted at once." The Commission determined to review one aspect of the ID, with respect to the application of the doctrine of equivalents to the domestic industry products. The Commission determined that a limited exclusion order and cease-and-desist order should issue against Diebold, "prohibiting the unlicensed entry of automated teller machines, ATM modules, components thereof, and products containing the same" manufactured by or imported by Diebold or its affiliates. No bond is required during the Presidential review period.

Commission elects to review ID's finding of patent invalidity in *Certain Radio Frequency Identification (RFID) Products*, Inv. 337-TA-979

Administrative Law Judge MaryJoan McNamara issued an Initial Determination (ID) in *Certain Radio Frequency Identification (RFID) Products*, Inv. No. 337-TA-979 on June 22, 2017, finding no violation of Section 337, 19 U.S.C. §1337. Complainant Neology, Inc. (Neology) brought a Complaint against Respondents Kapsch TrafficCom IVHS, Inc. and affiliated entities, and Star Systems International Ltd. and an affiliated entity. The ID found that asserted claims 13, 14, and 25 of U.S. Patent No. 8,325,044, and claims 1, 2, and 4 of U.S. Patent No. 8,587,436 were not infringed, and that all of those claims were invalid for lack of written description under 35 U.S.C. §112, for anticipation under §102, and for obviousness under §103. The two patents asserted by Neology are directed to electronic tolling systems using RFID technology. RFID tags, which can be used for a variety of purposes including animal or object identification, inventory systems, public transportation, or electronic tolling, can be active (having their own power source) or passive (obtaining power from the reader's transmission signals). The asserted patents are directed to passive tags, and the asserted patents purported to solve situations where the readers were reading many tags at once and there was significant risk of interference, or "collision."

On August 16, 2017, the Commission issued a Notice to review the ID, in part, seeking further party written submissions on the issues selected for review. The issues under review are: (1) whether the lack of written description under §112 and the finding that the asserted patents are not entitled to an earlier priority date rise and fall together; (2) how cryptographic keys, credit and debit exchange

keys, encryption keys, and exchange encrypted keys are used in the application disclosure, how they relate to security keys, and whether they provide written description support for the claimed "security key"; and (3) whether the Respondents argued before the ALJ that the asserted claims were anticipated by prior art RFID readers, tags, and toll systems that practiced a standard called the Gen2 Standard/6C Protocol. The parties filed their initial written submissions on September 5, and replies on September 13, 2017.

ID finds violation with respect to one of three asserted patents in *Certain Semiconductor Devices, Semiconductor Device Packages, And Products Containing Same*, Inv. 337-TA-1010

On June 30, 2037, Administrative Law Judge Dee Lord issued an Initial Determination (ID) finding that a violation of Section 337, 19 U.S.C. §1337, has occurred in *Certain Semiconductor Devices, Semiconductor Device Packages, and Products Containing Same,* Inv. No. 337-TA-1010 Complainants Tessera, Inc. and Invensas Corporation filed a Complaint for violation of Section 337 based on infringement of three patents, U.S. Patent Nos. 6,849,946 (the '946 patent), 6,133,136 (the '136 patent), and 6,856,007 ("the '007 patent"), against Respondents Broadcom Limited and wholly owned subsidiary Broadcom Corp., as well as Arista Networks, ARRIS International PLC, ASUSTek Computer Inc., Comcast Cable Communications, LLC and Comcast Cable Communications Management, LLC, HTC Corp., *NETGEAR*, Inc., and Technicolor S.A. The three patents relate to various aspects of semiconductor technology. One patent describes a method for making substantially planarized semiconductor topographies; the second describes an improved copper interconnect structure; and the third describes a semiconductor chip carrier having a large thermal conductor that provides enhanced thermal conductivity to the circuit board, and electromagnetic shielding to the chip. The accused products are Wi-Fi microchips used in mobile devices, routers, modems and gateways, as well as DOCSIS chips used in set-top boxes and other consumer electronics equipment. The accused products also included Ethernet switches, chips that provide Bluetooth and GPS functionality, controllers and PHY chips.

The ID finds that a violation of Section 337 occurred with respect to one of the three asserted patents, the '946 patent as follows: the asserted claims of the '946 patent are infringed and not invalid; the asserted claims of the '136 patent are infringed and not invalid; certain asserted claims of the '007 patent are infringed but are invalid; and a domestic industry exists with respect to the '946 patent, but not the '136 and '007 patents. On July 27, 2017, the parties filed petitions for review by the Commission.

Federal Circuit affirms Commission final determination of no violation of patent directed to reusable coffee pods based on lack of written description in *Adrian Riviera et al. v. ITC* (2016-1841)

On May 23, 2017, the Federal Circuit issued an Opinion affirming a decision by the International Trade Commission that there was no violation in *Certain Beverage Brewing Capsules, Components Thereof, And Products Containing The Same,* Inv. No. 337-TA-929, because the claims were invalid as lacking written description. Adrian Rivera and ARM Enterprises (collectively, Rivera) filed a Complaint on August 4, 2014 alleging that Solofill, LLC (Solofill) and others infringed U.S. Patent No. 8,720,320 (the '320 patent) directed to single serving coffee pods and brewing systems. The asserted claims required a brewing chamber, and a container comprising

a receptacle and cover, disposed within the brewing chamber and adapted to hold brewing material. In the Initial Determination (ID), the ALJ found no violation because Solofil only imported the cartridges, while the claims required a combination of the cartridges and a brewer system. The ALJ also held that Solofill was not liable for induced or contributory infringement because it did not have pre-suit knowledge of the '320 patent. In its Opinion reviewing the ID, the Commission went further and found no violation occurred because, among other reasons, the asserted patent was invalid for lack of written description. In particular, the Commission found that the patent application as originally filed described and claimed a "pod adaptor assembly" and a "brewing chamber for a beverage pod," while the issued claims more broadly recited a "container … adapted to hold brewing material." The Commission found that the patent application's narrow disclosure of the pod adaptors and pod brewing chambers did not reasonably convey to a person of ordinary skill in the art that the inventor was in possession of the more broadly claimed "container" to hold the brewing material, and thus the patent was invalid for lack of written description.

On appeal to the Federal Circuit, Rivera argued that the Commission failed to apply a broad definition of "pod" contained in the specification, and that if such definition were applied it would have provided proper written description support for the claims. To support this argument, Rivera pointed to a disclosure of an "integrated filter cartridge" as an example of a generic disclosure of a pod in the patent. However, the Federal Circuit rejected this argument and agreed with the Commission and Solofill that there was a lack of written description because the specification was entirely focused on a particular pod and pod adaptor assembly, and did not contain a disclosure of a container that was a pod. The Federal Circuit noted that a distinction between "pods" and "cartridges" permeates the entire patent, and that the relationship between pod adaptor assembly, receptacle, and pod carries through every embodiment, such that there was no hint or discussion of a cartridge or pod adaptor assembly or receptacle that also serves as a pod.

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