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Article

Patents – Patentability with respect to inventive step and proof of right

By IPR Team

Introduction

In the case of *Stempeutics Research Pvt. Ltd. v. The Assistant Controller of Patents & Designs*¹, the Intellectual Property Appellate Board ('IPAB') adjudicated patentability with respect to inventive step under Sections 2(1)(ja) and 3(e) of the Patents Act, 1970 ('Act'). The IPAB also addressed the issue of submission of proof of right under Section 7(2) of the Act.

Facts and issues

Stempeutics Research Pvt. Ltd ('Appellant') is a life science company that develops and commercialises novel drugs based on adult stem cells. It filed an appeal against a refusal order under Section 15 of the Act, dated January 9, 2017, whereby the Assistant Controller of Patents & Designs ('Respondent') refused to grant the patent in respect of Indian Application No. 2932/CHE/2009 ('Patent Application') comprising claims 1 to 12, on the grounds of lack of inventive step (claims 1-12), Section 3(e) of the Act (claims 11-12), and for non-filing of the proof of right within the time limit prescribed under Rule 10 of the Indian Patent Rules, 2003.

Case timeline

The Appellant filed a patent application for an invention titled, "METHODS OF PREPARING MESENCHYMAL STEM CELLS, COMPOSITIONS AND KIT THEREOF" on November 27, 2009. Thereafter, the Respondent issued the First Examination Report (FER) on

November 28, 2013 pointing out that the complete specification was beyond the scope of the provisional specification, that the originally filed claims 1-15 fell within the scope of Section 3(j) of the Act, and the Appellant had not complied with the requirements under Section 7(2) of the Act. The FER also stated that the question of novelty and inventive step would be considered after compliance with the above objections.

The Appellant filed a reply to the FER on February 06, 2014. On September 10, 2014 the Respondent issued the hearing notice wherein, apart from maintaining objections under Sections 3(j) and 7(2) of the Act, new objections were raised under Sections 2(1)(i) and 3(e) of the Act, Section 6 of the Biodiversity Act, 2002, Form-I and Section 10(4) of the Act, and that the claims lacked clarity and support in the complete specification. Thereafter, an oral hearing was conducted, followed by the Appellant's written submission wherein the Appellant filed an amended set of claims. *Vide* impugned order dated January 09, 2017 the amended claims were rejected by the Respondent, causing the Appellant to approach the IPAB in appeal.

Patent application

The Appellant asserted that the patent application relates to stem cells, specifically Mesenchymal Stem Cells ('MSC'), which is a specific type of stem cell that can grow into specialised cells such as blood cells and bone cells, amongst others. It was further asserted that

¹ OA/03/2017/PT/CHN, decided on 07-08-2020.

at the time of filing the Patent Application, prior art in the field of MSC consisted only of products with MSC from a single donor and corresponding preparation methods. Further, the prior art was *teaching away* from combining MSC from different donors owing to the higher risk of rejection and associated complications due to compatibility issues between the donor and recipient.

The Appellant submitted that it had provided compositions comprising of *pooled MSC* i.e., MSC from more than one donor. The final product consisted of pooled MSC with human serum albumin ('HAS'), dimethyl sulfoxide ('DMSO'), and multiple electrolytes injections, type 1, USP ('**claim 11**'); and a composition termed, Working Cell Bank comprised of pooled MSCs, fetal bovine serum (FBS), and DMSO ('**claim 12**').

It was argued that the Appellant's pooled MSC was prepared by obtaining MSC from a single donor, which was cultured to prepare a *master cell bank* composition; multiple master cell banks with single donor MSC were prepared, and thereafter combined to form a pooled MSC. This pooled MSC was cultured to obtain the Working Cell Bank composition and the final product i.e., claims 11 and 12, respectively, of the Patent Application. Claims 1-10 of the Patent Application elucidated the method to prepare the compositions, whilst claims 11 and 12 listed the compositions of the pooled MSC.

As per the Appellant's submissions, claims 11 and 12 had been successfully translated to the practical treatment of medical conditions in the form of STEMPEUCEL, a pooled MSC stem cell drug envisaged by the Patent Application, and that it satisfied the safety requirement and functional purpose. Owing to the danger of injecting external donor cells and the possibility of the recipient's body attacking the donor cells as foreign particles and rejecting them, the Appellant

submitted that they had conducted compatibility tests along with immunosuppressant drugs to reduce the strength of the recipient's immune system to accept the donor cells.

Decision and analysis

Proof of Right

A total of eight (8) inventors helped create the Patent Application, all of whom were employees of the Appellant. The initial five (5) inventors were named in the provisional application filed on November 27, 2009, and the corresponding proof of right was filed within the six (6) month period under Rule 10 of the Indian Patents Rules, 2003. One of the five inventors left the Appellant, who in turn filed an affidavit to confirm the same. The remaining three (3) inventors were later added to the complete application and proof of right was timely filed.

The Respondent's objection was that the inventor who left had not signed the declaration form within the time limit as prescribed under Rule 10 of the Patent Rules, 2003. Despite having submitted the affidavit, the Appellant nonetheless obtained a declaration form from the inventor but the Respondent raised an objection yet again, stating that it was not filed within the time limit under Rule 10.

In *NTT DoCoMo Inc. v. The Controller of Patents and Designs*,² the IPAB recognized the importance of proof of right but went ahead and quashed the order of the Controller which rejected the patent application on the basis of non-compliance of Section 7(2) of the Act and allowed the Applicant to file necessary proof of right document.

In the present case, the IPAB noted that the delay was beyond the control of the Appellant whose conduct was *bona fide*, as the Appellant had even executed the form on the Respondent's

² Order No. 252 of 2013

request. The IPAB observed that the finding arrived by the Respondent was very harsh and incorrect, and the IPAB found this to be against the fundamental principles of law pertaining to master-servant relationship, and that the rights were deemed assigned to the Appellant (i.e. employer) by virtue of the inventor's employment relationship with the Appellant. The IPAB thus held that the refusal of the Patent Application despite the Appellant having fulfilled the proof of right requirement was untenable.

Ineligibility under Section 3(e) of the Act

As per Section 3(e) of the Act, a substance obtained by mere admixture resulting only in the aggregation of properties of the components is not an invention.

The IPAB referred to *Lallubhai Chakubhai Jariwala v. Chimanlal Chunilal and Co.*,³ wherein the Bombay High Court had held that in the case of a combination, if the inventor had tried to see which of the many things, that are common knowledge, produced a new and useful result and if he succeeded in proving that the result was arrived at by a particular combination, the combination will be eligible as a patentable subject matter.

According to the IPAB, applicability of Section 3(e) was only valid when the product was obtained by combining known ingredients, and hence the burden to showcase the synergistic effect becomes necessary. The IPAB emphasized that a product made from a novel ingredient could not fall under the purview of Section 3(e). It was held that by virtue of claims 11 and 12 of the Patent Application possessing a novel ingredient i.e. pooled MSC, Section 3(e) would not apply.

The IPAB also pertinently noted that most inventions are a combination of old elements.

The mere existence in the prior arts of each of the elements would not *ipso facto* mean that the invention would be barred under Section 3(e) of the Act. The IPAB held that Section 3(e) of the Act would apply only when a claimed product was obtained by combining known or already existing ingredients, and not when integers of the claimed product itself was unknown.

The IPAB observed that the pooled MSC was novel, inventive, and showed enhanced viability when combined with the specific combinations mentioned in the Appellant's claims. The Respondent's rejection under Section 3(e) was not per law, and the IPAB found the objection to be unsustainable.

Lack of inventive step under Section 2(1)(ja)

Through a series of experiments, the Appellant demonstrated the technical advantages of pooled MSC over single donor MSC including enhanced chondro-differentiation i.e., growth potential to generate cartilage cells, enhanced cytokine profile, enhanced immunosuppression, and a homogeneous MSC product with enhanced cell viability.

The Appellant presented results that showcased the synergistic interplay between all the ingredients in their specific concentrations which was absent when the MSC was combined with individual ingredients or ingredients with varying concentrations.

The Respondent rejected the Patent Application on the ground that optimisation of a parameter and ingredient concentration variation was routine experimentation and did not involve ingenuity, and was thus not inventive over the cited prior art.

However, the Appellant argued that the cited prior art provided products with single donor MSC and none of them suggested the pooling of MSC from multiple donors. The Appellant additionally

³ A.I.R. 1936 BOM 99

submitted that MSC products had not been widely employed to treat medical conditions, and MSC as a therapeutic was still a developing area. The Appellant emphasized that pooling MSC to prepare a product could not have been envisaged by a skilled person since even the concept of injecting a single donor product was unpredictable.

The Appellant asserted that none of the cited prior art documents, individually or in combination, taught or motivated pooling of MSC of multiple donors to arrive at a pooled MSC product. It was argued that the teachings of the prior art documents solely focussed on MSC from a single donor, followed by further processing of such single donor MSC without hinting or even remotely suggesting that pooling of MSC from multiple donors could even be an option.

The Appellant referred to the decision of Delhi High Court in *Bristol-Myers Squibb Holdings Ireland Unlimited Company & Ors. v. BDR Pharmaceuticals International Pvt. Ltd. & Anr.*,⁴ wherein it was held that, in case a prior art document showed a concept of teaching away from the inventive step, the said prior art document could not be used to demonstrate that the invention was obvious and thus not liable to be patented. The Appellant also relied on various principles for assessment of inventive step as laid down in the said order. The Appellant, in this regard, asserted that the general art and the disclosure in the cited prior art documents were clearly teaching away from the critical concept/feature of the Patent Application (claims 1-12) i.e. pooled MSC.

The IPAB observed that the concept and method of pooling MSC from multiple donors was unheard of and unforeseen in the cited prior art. The IPAB noted that when compositions themselves were not envisaged by the prior art,

arriving at the methods to prepare such unknown compositions was even more far-fetched for a person skilled in the art. The IPAB stressed that methods could not be randomly designed to pool MSC. Even a skilled person could not randomly introduce a method of pooling and expect the final product to work and give technically advanced solutions.

The IPAB also noted that on the contrary, such random introduction of mixing might cause the cells to die or give rise to negative interactions, as under normal circumstances, cells from one donor are not meant to interact with cells from another donor, let alone from three other donors. Hence, the IPAB acknowledged the inventive ingenuity in designing methods to pool the cells for the beneficial final product in the Patent Application. The IPAB held that the compositions and methods described in claims 1 to 12 of the Patent Application were non-obvious/inventive over the cited prior art documents.

The IPAB additionally pointed out that the Patent Application with similar claims was granted in 18 countries. In this context, the IPAB observed that some importance could be given when a similar patent was registered in many other countries after having overcome the objection of prior art, novelty, and obviousness. The IPAB admitted that while it may not have had any binding effect, the examiner could have taken this aspect into consideration at the time of examination and at the time of raising objections in the FER.

The IPAB stated as a general observation that, if cited prior arts by the IPO are different from the cited prior arts in USPTO and EPO, it may be justified that the IPO had done its examination as per law. However, where identical claims are granted in major jurisdictions but such

⁴ CS(COMM) 27/2020



patent claims are rejected in India, the same may be in contradiction to the statements and objects of the Patents Amendment Act, 2005, amounting to injustice, and against the principles of equity and fair play.

Conclusion

The IPAB set aside the impugned order and the appeal was allowed. The Respondent was directed to grant a patent and proceed as per the

rules. Besides its contribution to the medical world, the order succinctly clarified employer-employee relationship, particularly in respect to creation of intellectual property, and highlighted the role of prior art in allowing a claim.

[The article has been authored by the IPR team in Lakshmikumaran & Sridharan, New Delhi]



Ratio decidendi

Trademarks – Non-user rectification – Party not aggrieved if there is no similarity in marks

The Intellectual Property Appellate Board ('IPAB') has held that the two marks, 'Your Wings to Life' and 'Gives You Wings' are neither deceptively similar nor identical. Accordingly, the IPAB was of the view that the applicant, in the present case, was not the aggrieved party within the ambit of Section 47 of the Trademarks Act. It also noted that the Applicant's mark was not its main brand, but a sub-brand, and the goodwill and reputation alleged by the Applicant pertained only to the former. Dismissing the petition, the Appellate Board held that therefore, the grounds raised in the instant application were unnecessary and irrelevant. The applicant had filed the application for removal of the mark 'Your Wings to Life' alleging that the mark was registered without any *bona fide* intention to use and was not used also. [Red Bull Ag. v. Dr. Reddy's Laboratories Limited – Order dated 25-08-2020 in MP. No. 49/2015 in ORA/262/2015/TM/CHN, IPAB]

Patents – Divisional application when cannot be rejected

The IPAB has set aside the Order of the Controller of Patents rejecting the divisional application under Patents Act, 1970. The Board observed that the Controller erred in not appreciating that it was technically impracticable to make compound of formula (I) dependent on the main claim of the parent application, which was directed towards compound of formula (III). It observed that it was settled that when an independent sub-claim cannot be made dependent on the main claim, the subject matter of such claim would be distinct from the subject matter of the main claim. The IPAB observed that the compound of formula (I) as claimed in the subject divisional application could be prepared from compound of formula (III) claimed in the parent but not *vice versa*, and hence the compound of formula (I) could not be an intermediate of the compound of formula (III). Claim of falling within the scope of Section 3(d) of the Patents Act was also hence rejected. It also

noted that the compounds of formulae (I) were novel intermediates for the preparation of plant protection products and as such did not fall within the ambit of Section 3(d).

The IPAB also observed that Controller committed a grave procedural irregularity by reintroducing the objection on the validity of the divisional application during the official hearing, without prior notice. It held that the same was in contravention of the directions laid down by the IPAB in its various decisions holding that if the objections to be relied upon by the Controller are not communicated in the hearing notice, the same results in violation of principles of natural justice. Noting that the divisional application did not include any matter which was not disclosed in the parent application and that there was no overlap in the scope of the claims, it held that the divisional application fulfilled the requirements of Sections 16(2) and 16(3) of the Patents Act.

Further, observing that the Appellant had not derived any unfair advantage by filing a divisional application, the IPAB held that the Controller should not have refused the application on hyper technical grounds based on a premeditated intention. [*Bayer Aktiengesellschaft v. Controller of Patent & Designs* – Order dated 25-08-2020 in OA/6/2015/PT/MUM, IPAB]

Trademarks – Evidentiary value of unstamped licence agreement, concealment of material fact and prior user of mark for different goods in same classification

Relying upon proviso (a) to Section 35 of the Indian Stamp Act, 1899, the Delhi High Court has held that the non-stamping of an instrument is a curable defect and such instruments shall be admitted in evidence on payment of the duty with which the same is chargeable. The contention

that since the trademark license agreement was not stamped, it cannot be considered as evidence as per Section 35, was hence rejected. The Court for this purpose also relied upon the Bombay High Court's decision in the case of *Gautam Landscapes Pvt. Ltd.* where it was held that un-stamping or insufficient stamping of the document containing the arbitration clause would not affect the grant of an interim relief under Section 9 of the Arbitration and Conciliation Act and that the party cannot be put to a disadvantage merely because of insufficiency of the stamp on the agreement. It observed that in the present case also the suit was at the stage of grant of interim relief or the vacation thereof and not at the final stage after parties have led their evidences and duly exhibited admissible documents.

The High Court modified the *ex-parte* ad interim injunction granted in favour of the plaintiff after it observed that the plaintiff concealed material fact of defendant's director's proprietorship of mark 'Sujata' in respect of water filters, water purifiers and RO Systems from the Court at the time of grant of interim injunction. It also observed that even though plaintiff was the prior user of the mark 'Sujata' but for the goods mixer, grinders, blenders, in respect of water filters, water purifiers and RO System, the director of defendant No.1 (licensor) was the prior registered owner of the mark and also the prior user and in fact the only user as plaintiff had not used the mark for water filters, water purifiers and RO system. It noted that though the goods of the plaintiff and defendant may fall in same broad classification of home appliances, they were different goods used for different purposes. [*Mittal Electronics v. Sujata Home Appliances (P) Ltd.* – Order dated 09-09-2020 in CS (COMM) 60/2020, Delhi High Court]

Patents – Prior art must be known to the public, and only claims of the prior art need to be considered when assessing objection of anticipation by prior claiming

The IPAB has allowed an appeal filed against an order rejecting the patent application on the ground that the same was anticipated by prior claim and was not patentable under Section 3(d) of the Patents Act, 1970. The claimed compound was 3-((3R, 4R)-4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl)-3-oxo-propionitrile and pharmaceutically acceptable salts thereof. Rejecting the contention that Document WO0142246 was a valid prior art for Section 3(d) as it was applicant's own application and 'known' to the applicant, the IPAB observed that the prior art must be known to the public and not the inventor/ applicant of the patent specification. While it held that the inventor's knowledge is immaterial in patentability analysis, it also noted that the said document was published after the priority date of the present application.

Observing that for Section 3(d) to be applicable the invention should be 'a mere discovery', there should be 'known substance' and the 'known substance should have a known efficacy', the IPAB held that the Controller did not identify any

substance with known efficacy, leave apart from identifying the known substance. It also noted that the Controller did not even identify, in the hearing notice, any prior art which disclosed the known substance. The IPAB noted that even if Section 3(d) is applied, the applicant had supplied data to show that the present invention resulted in enhanced therapeutic efficacy. On the question of anticipation/lack of novelty, the IPAB, relying on number of precedents, observed that a generic disclosure does not take away the novelty.

Further, allowing the appeal, the IPAB observed that the Controller had rejected the application on ground of Section 13(1)(b) [anticipation by prior claiming] but did not raise an objection under said section in the hearing notice, despite the earlier order of the IPAB. The Board was of the view that it is against the principles of natural justice that an application was rejected without even communicating an objection to the Appellant as required under Section 14 of the Patents Act. On merits, it held that only the claims of a prior art need to be considered when assessing the objection of anticipation by prior claiming and that the disclosure is not to be considered. [*Pfizer Products Inc. v. Controller of Patent & Designs – Order dated 21-08-2020 in OA/2/2016/PT/MUM, IPAB*]



News Nuggets

Domain name registration – Plea that no technology to ensure non-availability of specific domain names, not acceptable

The Delhi High Court has granted *ex-parte* ad-interim injunction in favour of the plaintiff having trademark 'Amul', in respect of various fraudulent websites using the said mark as suffix or prefix in the domain names and offering dealership, distributorship, jobs, etc. The contention of the counsel for the defendant (Registrar of websites) that he is not aware of any technology by virtue of which the defendant can ensure that the websites with name 'Amul' therein will not be made available for sale, was found *prima facie* not acceptable. The Court in the case *Gujarat Cooperative Milk Marketing Federation Ltd. v. Amul Franchise.in* observed that the defendant must be operating its filters to ensure that websites under obscene and/or words denoting illegality are not available for sale. The defendants were directed to suspend/block/delete the domain names as mentioned in the plaint within 36 hours of the receipt of the order.

Glow & Handsome – Bombay High Court restrains defendants who is yet to bring its product in market

In an alleged case of passing-off of mark 'Glow & Handsome', the Bombay High Court has restrained the defendant (M/s. Emami Ltd.), who had not brought its goods into the market under its proposed same trademark, from doing so. The Court noted that the plaintiff (M/s. Hindustan Unilever Ltd.) was a prior adopter and user of the mark and had already launched its product while the defendant was only at the stage of adopting a

process of launching its goods under the said trademark. Granting ad-interim injunction, the Court observed that the plaintiff had submitted its sales figures as well as advertisement and promotional expenses incurred for the said trademark. The Court was also of the view that the plaintiff had sufficiently advertised its brand 'Glow & Handsome' which replaced the earlier well-known mark 'Fair & Lovely'. It held that at this threshold stage it is reasonable to see that there is concrete likelihood of confusion and deception in the public if identical marks are allowed to hold the field for popular and much sold commodities. The High Court in *Hindustan Unilever Ltd. v. Emami Ltd.* however made it clear that the Order will not come in way of the defendant claiming, in its own suit in Calcutta High Court, a restraint order against plaintiff for use of the mark. It may be noted that recently IPAB in its two separate orders in the case *Hindustan Unilever Limited v. Registrar of Trademarks*, allowing the appeals, has held that the marks 'Glow & Handsome' and 'Glow & Lovely' are inherently distinctive in nature.

Patents – Order must be passed by same officer who heard the matter

The IPAB has set aside the order of the Deputy Controller who had never heard the said matter. Holding the order to be illegal, bad and contrary to law, the IPAB observed that proper procedure was not followed and that the order must be passed by the same officer who had heard the matter. The IPAB held that in case, under some reasons, the officer is not able to pass the order, the matter must be released by passing the speaking order and thereafter it must be re-allotted to another

officer who has to conduct fresh hearing. The oral hearing in the concerned matter was done in July 2013 and another Deputy Controller *vide* order issued in October 2014 had rejected the patent application. Setting aside the impugned order, the IPAB in its order in the case *Optimer Pharmaceuticals, Inc. v. Controller* remanded the matter for fresh hearing by the Controller other than the two Controllers involved earlier.

Colour-based product packaging mark can be inherently distinctive

The United States Court of Appeals for the Federal Circuit has set aside the order of the Trademark Trial and Appeal Board ('TTAB'), wherein the TTAB had held that the colour may serve as a trademark only upon showing of secondary meaning, i.e., the colour marks alone cannot be inherently distinctive. The Court observed that the Board erred by concluding that a colour-based trade dress mark can never be inherently distinctive without differentiating between product design and product packaging marks. It held that a distinct colour-based product packaging mark can indicate the source of the goods to a consumer, and therefore, can be inherently distinctive. The Court of Appeals for the Federal Circuit in the case *In RE: Forney Industries, Inc.*, noted that the US Supreme Court in the case *Qualitex v. Jacobson* implied that a showing of acquired distinctiveness may be required before a trade dress mark based on colour alone can be protectable, but it did not expressly hold so. Board's conclusion that the product packaging marks that employ colour cannot be inherently distinctive in the absence of an association with a well-defined peripheral shape or border, was also found to be erroneous.

Embedding in website of works from other websites, when not requires copyright holder's authorisation

The Advocate General in the Court of Justice of the European Union ('CJEU') has opined that the embedding in a webpage of works from other websites, where those works are made freely available to the public with the authorisation of the copyright holder, by means of clickable links using the framing technique does not require the copyright holder's authorisation, since he or she is deemed to have given it when the work was initially made available. He was also of the view that the same applies even where that embedding by way of framing circumvents technological protection measures against framing adopted or imposed by the copyright holder. The Advocate General however in this case *VG Bild-Kunst v Stiftung Preußischer Kulturbesitz* [Opinion dated 10-09-2020] opined that the embedding of such works by means of automatic links (inline linking, the works being displayed automatically on the webpage viewed as soon as it is opened, without any further action on the part of the user), requires the authorisation of the holder of the rights in the works. It was however observed that some automatic links may fall within exception to authorisation.

Patents – IPAB suggests timelines for opposition proceedings

Observing that the objective to bring the amendment in the Patents Act in 2015, i.e., to simplify the procedure and to make system efficient in order to protect the exclusive rights to the genuine inventor, has been defeated, the IPAB recently in its Order dated 21-08-2020 has stated that the practice of filing of

benami opposition by the benami opponent and crooked imposter has to be stopped. The Appellate Board in the case of *Pfizer Products Inc. v. Controller* also suggested that the opposition proceedings under Section 25(2) of the Patents Act should be decided within maximum period of 12 to 15 months after filing of the opposition and the appeal filed under Section 117 before IPAB against such final order should also be decided within the period of 12 months in order to save the reasonable term of patent.

Nokia is a well-known mark – IPAB allows appeal against order of rejection

Relying on documentary evidence and supporting documents submitted along with the representation, the IPAB has held that the mark 'NOKIA' is entitled to be included in the list of well-known marks in India by virtue of Section 11(8) of the Trademarks Act. Allowing the appeal against the Order rejecting the application, the Board observed that the Registrar neither served a notice upon the appellant nor provided any opportunity and disallowed the representation for inclusion of the mark in the list of well-known marks in

India. It noted that the Appellant were not provided with an opportunity of being heard and that the order was based on conjectures, surmises and presumptions which were contrary to the record.

Patents – Divisional application with different combination of components, permissible

The IPAB has held that the application would merit divisional status when two applications claim different combinations of components, that is, the parent case claims composition 1: A + B + C whereas, the divisional application claims composition 2: A + B + D, [wherein components "C" (silicon oxide) and "D" (selected from the group consisting of water soluble polymers and surfactants) are different release controllers for the parent and divisional applications, respectively]. The IPAB in the case of *Nippon Soda Co. Ltd. v. Controller General of Patents* held that the divisional application may be filed for a different combination of components, such as, composition 1: A + B (parent application) and composition 2: A + C (divisional application).

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